# **Stark Law Overhaul:** An In-Depth Review of the 2020 Rulemaking

White Paper No. 5
New Wine in Old Bottles:
Providing Greater Flexibility Under Existing Exceptions

# New Wine in Old Bottles: **Providing Greater Flexibility Under Existing Exceptions**

In December 2020, the Centers for Medicare & Medicaid Services (CMS) finalized its long-awaited changes to the agency's regulations governing the federal physician self-referral law, commonly known as the Stark Law (Final Rule).[1] The Final Rule represents the most significant Stark Law rulemaking in more than a decade. The Health Care Group at Dentons US is presenting a series of seven webinars, each with a companion white paper, addressing the principal components of the Final Rule. This is the fifth of these white papers. It addresses changes made in the Final Rule to nine Stark Law exceptions. Eight of these exceptions focus on the exchange of remuneration in specific types of compensation arrangements. They include the exceptions for:

- Rental of office space (Space Rental Exception);[2]
- Rental of equipment (Equipment Rental Exception);[3]
- Fair market value compensation arrangements (FMV Exception);[4]
- Physician recruitment (Recruitment Exception);[5]
- Assistance to compensate a non-physician practitioner (NPP Exception);[6]
- Remuneration unrelated to the furnishing of DHS (Unrelated to DHS Exception);[7]
- Payments by a physician (Physician Payments Exception);[8] and
- Isolated financial transactions (Isolated Transactions Exception).[9]

1 The Stark Law is codified at 42 U.S.C. §§ 1395nn, 1396b(s), and 42 C.F.R. § 411.350 et seq. The Final Rule was published at 85 Fed. Reg. 77492 (Dec. 2, 2020).

2 42 U.S.C. § 1395nn(e)(1)(A); 42 C.F.R. § 411.357(a).

3 42 U.S.C. § 1395nn(e)(1)(B); 42 C.F.R. § 411.357(b).

4 42 C.F.R. § 411.357(l).

5 42 U.S.C. § 1395nn(e)(5); 42 C.F.R. § 411.357(e).

6 42 C.F.R. § 411.357(x).

7 42 U.S.C. § 1395nn(e)(4); 42 C.F.R. § 411.357(g).

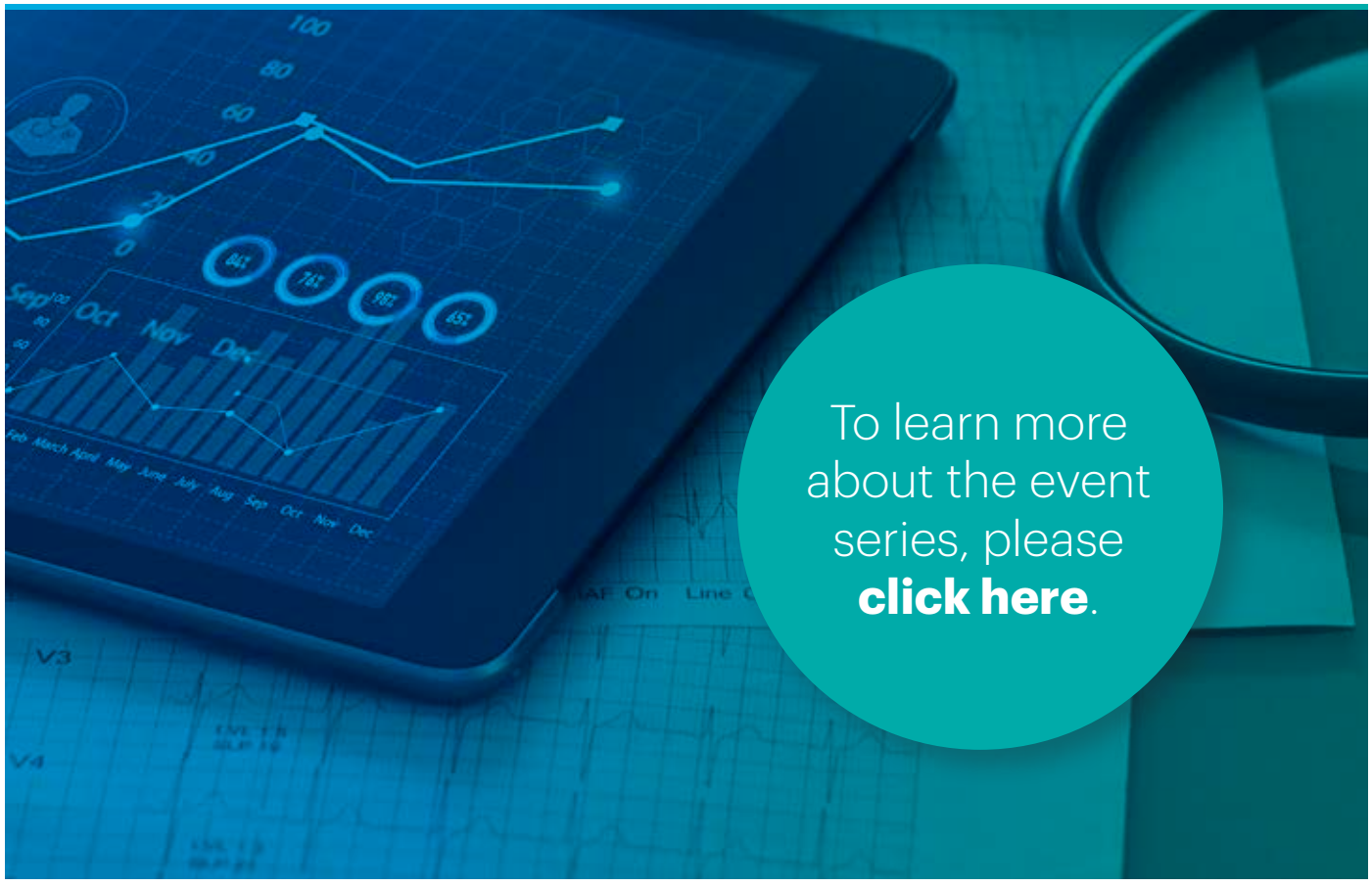
8 42 U.S.C. § 1395nn(e)(8); 42 C.F.R. § 411.357(i).

9 42 U.S.C. § 1395nn(e)(6); 42 C.F.R. § 411.357(f).

The ninth exception—for in-office ancillary services (In-Office Ancillary Services Exception)—is a so-called "all purpose" exception,[10] which means it protects certain designated health services (DHS) furnished in a physician's office, provided a number of conditions are satisfied, regardless of the form of the parties' underlying financial relationship.[11]

10 See e.g., 42 U.S.C. § 1395nn(b).

11 42 U.S.C. § 1395nn(b)(2); 42 C.F.R. § 411.355(b).



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# I. Direct Compensation Arrangement Exceptions

## A. Space and Equipment Rental Exceptions

It is common for physicians to lease office space and equipment from entities that furnish DHS (DHS Entities), and vice versa. Recognizing this, the Stark Law has both statutory and regulatory exceptions for the rental of office space and equipment. These are the Space Rental Exception and Equipment Rental Exception, respectively.

Among the key conditions applicable to both Exceptions are that the lease arrangement be set out in writing, signed by the parties and specify the premises or equipment covered by the lease. In addition, both Exceptions require that the arrangement have a term of at least one year and provide for compensation that is set in advance and consistent with fair market value. Finally, both Exceptions require that when the space or equipment is being used by the lessee, the space or equipment at issue be used *exclusively* by the lessee (Exclusive Use Requirement).

Although CMS did not make major changes in the Final Rule to the Space Rental or Equipment Rental Exceptions, the agency did clarify the Exclusive Use Requirement. By way of background, in 1998, the Health Care Financing Administration (HCFA), CMS's predecessor, stated that Congress intended the Exclusive Use Requirement to prevent "paper" or "sham" leases where payment passes from a lessee to a lessor, even though the lessee is not actually using the office space or equipment.[12] In 2004, CMS further explained that the purpose of the Exclusive Use Requirement is to ensure that the rented space or equipment cannot be shared with the lessor when it is being used or rented by the lessee. CMS was concerned that absent such restrictions, "unscrupulous physicians or physician groups might attempt to skirt the [Exclusive Use Requirement] by establishing holding companies to act as lessors."[13] To foreclose this possibility, CMS modified the Exclusive Use Requirement in both the Space and Equipment Rental Exceptions to stipulate that the rented office space or equipment may not "be shared with or used by the lessor or any person or entity related to the lessor" when the lessee is using the office space or equipment.[14]

Notwithstanding CMS's various clarifications and amendments, over time, questions regarding the scope of the Exclusive Use Requirement persisted. For example, could multiple lessees utilize the space contemporaneously or in close succession to one another? To address any lingering ambiguity, while still guarding against potentially abusive arrangements, CMS made further revisions to the Exclusive Use Requirement in the Final Rule. Specifically, both Exceptions now provide that "exclusive use" means:

> that the lessee (*and any other lessees of the same office space or equipment*) uses the office space or equipment to the exclusion of the lessor (or any person or entity related to the lessor). The lessor (or any person or entity related to the lessor) may not be an invitee of the lessee to use the office space or equipment.[15]

This amendment adds flexibility and certainty by making it clear that the lessee—as well as any other lessee of the same space or equipment—may use the office space or equipment at the same time as long as the *lessor* (and its affiliates) is excluded from the space (and the arrangement otherwise satisfies the

12 63 Fed. Reg. 1659, 1714 (Jan. 9, 1998).

13 69 Fed. Reg. 16054, 16086 (Mar. 26 2004).

14 *Id.* at 16138; 42 C.F.R. § 411.357(a)(3) and (b)(2).

15 42 C.F.R. § 411.357(a)(3) and (b)(2) (emphasis added).

remaining requirements of the Space or Equipment Rental Exceptions). With this added flexibility, lessees can explore collaborations that will make the utilization of resources (e.g., space and equipment), as well as the furnishing of care, more efficient.

## B. FMV Exception

Separate and apart from modifying the definition of "fair market value" (which is addressed in White Paper No. 4), CMS made significant changes to the FMV Exception in the Final Rule, including (i) expanding the bases upon which physicians and DHS Entities may utilize the Exception, (ii) addressing the application of the "holdover" doctrine to the Exception, and (iii) clarifying the Exception's writing requirement. To the extent physicians and DHS Entities are relying on the FMV Exception to protect active compensation arrangements, steps should be taken to ensure that the conditions of the Exception, as revised under the Final Rule, are met. Physicians and DHS Entities also should explore opportunities to take advantage of the expanded flexibility the Exception now offers, particularly with respect to office space lease arrangements.

### 1. Rental of Office Space

Historically, the FMV Exception, by its terms, could not be used to protect arrangements involving the rental of office space. The Exception protected any arrangement between an entity and a (i) physician, (ii) immediate family member (IFM), or (iii) physician group "for the provision of items or services (*other than the rental of office space*)."[16]

Over the years, CMS rejected numerous requests to remove the office space rental carve-out from the FMV Exception. In the Final Rule, however, CMS acknowledged that in reviewing self-referral disclosure protocol (SRDP) submissions, the agency became aware of a number of legitimate office lease arrangements that could not satisfy either the Space Rental Exception (because the term was less than one year) or the exception for timeshare arrangements (because the arrangement conveyed a possessory leasehold interest in the office space).[17] In light of these and other considerations, CMS revisited its position in the Final Rule and removed the office space rental carve-out from the FMV Exception. This change is important for a number of reasons.

- First, and perhaps most obviously, parties now have another exception available to protect arrangements involving the rental of office space. This, in and of itself, decreases the likelihood that a given space rental (or use) arrangement will result in violations of the Stark Law's referral and billing prohibitions.
- Second, unlike the Space Rental Exception, the FMV Exception does not have an Exclusive Use Requirement. (It should be noted, however, that CMS retained the requirement that the arrangement not violate the federal health care program anti-kickback statute, stating that it "provides a substitute safeguard for the [Exclusive Use Requirement] and serves to prevent program or patient abuse."[18]).
- Third, unlike the Space Rental Exception, the FMV Exception does not have a one-year term requirement. This will allow parties to enter into short term space arrangements that would not be permitted under the Space Rental Exception. (It is important to note, however, that although the office space rental arrangement may now have a term of only one month, for example, and "may be renewed any number of times" under the FMV Exception, "the parties may not enter into more than one arrangement for the same . . . office space . . . during the course of a year."[19])

### 2. Rental of Equipment

Historically, the FMV Exception did not, by its terms, include an equipment rental carve-out; thus, at least in theory, equipment rental arrangements could be protected under either the Equipment Rental Exception or the FMV Exception. Given the office space carve-out in the FMV Exception, however, some stakeholders remained apprehensive about whether the FMV Exception could, in fact, be used to protect equipment rental arrangements. To avoid any further doubt or

16 42 C.F.R. § 411.357(l) as set forth in 72 Fed. Reg. 51012, 51095 (Sept. 5, 2007) (emphasis added).

17 85 Fed. Reg. 77492, 77605 (Dec. 2, 2020).

18 *Id.* at 77568.

19 42 C.F.R. § 411.357(l)(2).

confusion with respect to this issue, CMS amended the FMV Exception to make it clear that it can be used to protect equipment rental arrangements.[20] Specifically, the Exception now protects any arrangement between a DHS Entity and a physician, IFM or physician group "for the provision of items or services or for the lease of office space or *equipment*."[21]

### 3. Holdover Arrangements

Historically, the Space Rental Exception, Equipment Rental Exception and exception for personal services arrangements (Personal Services Exception)[22] have included so-called "holdover" provisions, pursuant to which the arrangement in question will continue to comply with the exception at issue even after the arrangement "expires," as long as certain conditions are satisfied (e.g., as long as the "holdover lease arrangement is on the same terms and conditions as the immediately preceding arrangement"). Initially, such holdover arrangements were limited to periods of up to six months, but CMS ultimately amended the regulations to allow for indefinite holdovers.[23]

Commenters lobbied CMS to include a holdover provision in the FMV Exception, noting that although the Exception permits an arrangement to "be renewed any number of times if the terms of the arrangement and the compensation for the same items or services do not change," this arguably requires the preparation of a new round of written documentation in connection with each such renewal.[24]

Although CMS declined to include in the Final Rule an indefinite holdover provision in the FMV Exception, the agency did clarify that as long as the compensation and other terms of the arrangement do not change, renewals under the FMV Exception are not required to be in writing.[25] In effect then, the "renewals" provision in the FMV Exception effectively serves the same purpose (and function) as the "holdover" provisions in the Space Rental, Equipment Rental and Personal Services Exceptions.

### 4. Writing Requirement

Although the FMV Exception historically has required that the arrangement at issue be in writing, CMS amended the Exception in the Final Rule to require that the writing "specify" (i) the "items, services, office space, or equipment covered under the arrangement," (ii) the "compensation that will be provided under the arrangement" and (iii) the "timeframe for the arrangement."[26] Although these conditions are similar to those imposed under other, similar exceptions, it is important for physicians and DHS Entities to be aware that they now (explicitly) apply to the FMV Exception as well.

### 5. Required Referrals

Finally, as explained in White Paper No. 3, the Final Rule treats the Stark Law's so-called "Volume/Value Standard" as separate and distinct from all other Stark Law provisions and, as a result, eliminates the nexus between that standard and the so-called "Required Referrals Special Rule," which is memorialized at 42 C.F.R. § 411.354(d)(4). As also noted in White Paper No. 3, CMS did not abandon the Required Referrals Special Rule altogether, it simply incorporated it into certain Stark Law exceptions, including the FMV Exception. Under the updated Exception, then, the arrangement must satisfy the Required Referrals Special Rule if the arrangement provides for (i) "[r]emuneration to the physician that is conditioned on the physician's referrals to a particular provider, practitioner, or supplier," or (ii) "[r]emuneration paid to the group of physicians that is conditioned on one or more of the group's physicians' referrals to a particular provider, practitioner, or supplier."[27]

20 *Id.* § 411.357(l).

21 *Id.* (emphasis added).

22 *Id.* § 411.357(d).

23 80 Fed. Reg. 70885, 71319 (Nov. 16, 2015). We note that the Bipartisan Budget Act of 2018, Pub. L. 115-123 (Feb. 9, 2018), codified indefinite holdovers into the statutory exceptions for personal services and rentals of office space and equipment.

24 85 Fed. Reg. 77492, 77607-77608 (Dec. 2, 2020).

25 *Id.* at 77608.

26 42 C.F.R. § 411.357(l)(1)(i)-(iii).

27 42 C.F.R. § 411.357(l).

## C. Recruitment Exception

For decades, hospitals interested in recruiting physicians to relocate their medical practice to the geographic area served by the hospitals (Sponsoring Hospitals) have sometimes agreed to (i) pay for certain recruitment-related expenses (such as headhunter fees and moving expenses), and (ii) provide collection or income guarantees to cover shortfalls while the recruited physician (Recruited Physicians) ramps up their clinical practice. These expenses, guarantees and other remuneration create financial relationships between the Sponsoring Hospitals and the Recruited Physicians that implicate the Stark Law. Recognizing that physician recruitment is a common and beneficial practice in the health care industry, Congress and HCFA created the statutory and regulatory versions of the Recruitment Exception.

In 2004, CMS expanded the Recruitment Exception to address not only remuneration from a Sponsoring Hospital directly to a Recruited Physician (Two-Party Recruitments), but also remuneration from a Sponsoring Hospital to a Recruited Physician who joins a physician group practice (Host Practice) (Three-Party Recruitments). In 2007, CMS clarified that in a Three-Party Recruitment, the written recruitment agreement must be signed by all three parties—i.e., the Sponsoring Hospital, the Recruited Physician and the Host Practice.[28]

In the Proposed Rule, CMS reconsidered whether a Host Practice must sign the written recruitment agreement if the Host Practice itself receives no remuneration under the arrangement between the Sponsoring Hospital and Recruited Physician. The agency provided the following examples of such arrangements:

- The Recruited Physician joins a Host Practice but the Sponsoring Hospital pays the recruitment benefits to the Recruited Physician directly.
- The recruitment benefits are transferred from the Sponsoring Hospital to the Host Practice, but the Host Practice serves merely as an intermediary, passing all of the remuneration received from the Sponsoring Hospital to the Recruited Physician.
- The Recruited Physician joins the Host Practice after the period of the income guarantee but before the Recruited Physician's "community service" repayment obligation is completed.[29]

28 *Id.* § 411.357(e)(4)(i).

29 84 Fed. Reg. 55766, 55816 (Oct. 17, 2019).

In these types of arrangements, CMS concluded that a compensation arrangement does not exist between the Host Practice and the Sponsoring Hospital and, therefore, the Host Practice is not required to sign the written recruitment agreement.[30]

In the Final Rule, CMS adopted its proposal without modification, concluding that the modified signature requirement would reduce the burden of compliance with the Stark Law without posing a risk of program or patient abuse.[31] Thus, the relevant section of the Recruitment Exception now provides that the "writing" at issue must be signed by the Host Practice only if (i) "the remuneration is provided indirectly to the [Recruited Physician] through payments made to the [Host Practice]" and (ii) "the [Host Practice] does not pass directly through to the [Recruited Physician] all of the remuneration from the [Sponsoring Hospital]."[32] The easing of the signature requirement under these circumstances should modestly reduce the transaction costs of these arrangements, as well as the overall burden of compliance.

## D. NPP Exception

In 2015, CMS finalized the NPP Exception to the Stark Law. Provided certain conditions are satisfied, the NPP Exception permits hospitals, Federally Qualified Health Centers (FQHCs) or Rural Health Clinics (RHCs)—each a "Relevant DHS Entity"—to provide remuneration to physicians for purposes of their recruiting, employing and contracting with certain non-physician practitioners. These NPPs include physician assistants, nurse practitioners, clinical nurse specialists, certified nurse midwives, clinical social workers and clinical psychologists.

Among other things, the NPP Exception was intended to address projected shortages in the primary care workforce.[33] Consistent with this objective, prior to the Final Rule, the NPP Exception prohibited the provision of assistance by a Relevant DHS Entity to a physician if, at any point during the prior year, the NPP in question had either (i) "[p]racticed in the geographic area served by" the Relevant DHS Entity, or (ii) "[b]een employed or otherwise engaged to provide patient care services by a physician or a physician organization that has a medical practice site located in the geographic area served by the hospital, regardless of whether the non-physician practitioner furnished services at the medical practice site located in the geographic area served by the hospital."[34] (For purposes of discussion, we will refer to this as the "Prior Service Condition.") In the years following the promulgation of the NPP Exception, two questions arose concerning the Prior Service Condition:

- First, do services provided by an individual *before* they became an NPP (e.g., services provided as a registered nurse or some other health care professional not included in the Stark Law definition of an NPP) constitute "patient care services" for purposes of the Prior Service Condition?[35]
- Second, do services provided in the geographic area served by the Relevant DHS Entity by an individual *before* they became an NPP constitute "practicing" in such geographic service area for purposes of the Prior Service Condition?[36]

CMS addressed both of these questions in the Proposed Rule. Specifically, the agency proposed replacing references to "patient care services" in the Prior Service Condition with "NPP patient care services" and then defining the latter as "direct patient care services furnished by [an NPP] that address the medical needs of specific patients or any task performed by [an NPP] that promotes the care of patients of the physician or physician organization with which the [NPP] has a compensation arrangement."[37] CMS also proposed replacing the term "practiced" with "furnished NPP

30 *Id.*

31 85 Fed. Reg. 77492, 77600 (Dec. 2, 2020).

32 42 C.F.R. § 411.357(e)(4)(i).

33 80 Fed. Reg. 70886, 71301 (Nov. 16, 2015).

34 42 C.F.R. § 411.357(x)(1)(v).

35 84 Fed. Reg. 55766, 55826 (Oct. 17, 2019).

36 *Id.* at 55826-27.

37 *Id.* at 55846.

patient care services."[38] As a result of these changes, services provided by an individual who was not an NPP at the time the services were provided would not be considered NPP patient care services for purposes of the Prior Service Condition.[39] CMS adopted these proposed changes to the Prior Service Condition in the Final Rule.[40]

In the Proposed Rule, CMS also proposed adding an express requirement that the compensation arrangement between the Relevant DHS Entity and physician commence before the physician enters into the compensation arrangement with the NPP. CMS noted that allowing a Relevant DHS Entity to reimburse a physician for the costs associated with *current* employees, who were *already* serving patients in the Relevant DHS Entity's geographic service area, would not serve one of the principal goals of the NPP Exception—i.e., *increasing* access to needed care.[41] CMS also adopted this proposed change in the Final Rule.[42]

## E. Unrelated to DHS Exception

The statutory version of the so-called Unrelated to DHS Exception is mercifully concise: "Remuneration" that is provided "by a *hospital* to a *physician*" is protected under the Exception as long as "such remuneration does not relate to the provision of designated health services."[43] That's it. There's no Volume/Value Standard; there's no requirement that the compensation at issue be consistent with fair market value (FMV Standard); and there's no requirement that the arrangement be commercially reasonable even in the absence of referrals between the parties (Commercial Reasonableness Standard). Nor does the arrangement at issue have to be in writing or signed by the parties. Again: As long as the remuneration does not "relate" to the "provision" of "DHS," it's protected under terms of the statutory version of the Unrelated to DHS Exception.

Even before unpacking the key terms—"relate," "provision" and "DHS"—one thing is clear: Simply because a hospital is a DHS Entity, this cannot mean that *any* remuneration a hospital provides to a physician "relates to the provision of DHS." Were that the case, the Unrelated to DHS Exception would (literally) serve no purpose. So, what's in and what's out? Let's begin by unpacking the key terms.

We know what "DHS" are because (as discussed in White Paper No. 1) they are clearly defined in the Stark Law statute and regulations.[44] DHS include, for example, hospital inpatient and outpatient services. "Provision"—the "act or process of providing"[45]—also is pretty straightforward. "Relate" is a bit fuzzier, but for our purposes, suffice it to say most definitions equate relating and "connecting."[46] Thus X and Y are "related" if they are "connected" in some way (e.g., "logically" or "causally"[47]). So remuneration provided by a hospital to a physician will "relate" to the furnishing of DHS in the form of hospital inpatient services, for example, if the remuneration is somehow logically or causally connected to the furnishing of hospital inpatient services.

Although some arrangements involving hospitals providing remuneration to physicians might be difficult to categorize, others would seem (at least at first blush) to be pretty straightforward. At one end of the spectrum, for example, if a hospital employs a surgeon to perform inpatient hospital procedures, the payments the hospital makes to the physician in exchange for those services would seem to "relate" to the "provision of DHS." At the other end of the spectrum, if a hospital pays a physician to climb Mount Everest, that remuneration would not seem to "relate" to the "provision of DHS." Other arrangements, however,

38 *Id.* at 55827.

39 *Id.* at 55826.

40 85 Fed. Reg. 77492, 77621 (Dec. 2, 2020).

41 84 Fed. Reg. at 55827.

42 85 Fed. Reg. at 77621.

43 42 U.S.C. § 1395nn(e)(4)(emphasis added).

44 42 C.F.R. § 411.351 (definition of "designated health services").

45 *See* 85 Fed. Reg. at 77601 (defining "provision").

46 *See*, e.g., Relate, Merriam-Webster.com, https://www.merriam-webster.com/dictionary/relate (last visited May 5, 2021).

47 *Id.*

arguably present closer calls. For example:

- What if a physician owns a warehouse and a hospital rents space from the physician in the warehouse to store medical records? Do the rental payments from the hospital to the physician "relate" to the "provision" of "DHS"?
- What if a physician owns a medical office building (MOB) and a hospital rents one floor of the MOB from the physician for use by the hospital's employed primary care physicians (PCPs)? Assuming no DHS are being furnished in the office suite, do the rental payments from the hospital to the physician "relate" to the "provision" of "DHS"?
- What if a hospital is considering the implementation of a new electronic health records (EHR) system and hires a physician—whose practice group adopted that same system several years ago—to provide consulting services to the hospital? Would the payments from the hospital to the physician for consulting services "relate" to the "provision" of "DHS"?

Historically, CMS has been *extremely* wary of the Unrelated to DHS Exception. The concern, of course, is that the Exception, if interpreted broadly, could effectively render moot (or partially moot) a host of other Stark Law exceptions. Consider, for example, the MOB example above, pursuant to which a hospital rents one floor of a physician's MOB for use by hospital-employed PCPs. If this arrangement must be protected under the Space Rental Exception, then the lease payments from the hospital to the physician will have to be "set in advance," "consistent with fair market value," "not determined . . . in any manner that takes into account the volume or value of referrals or other business generated between the parties," and so on. But if the arrangement can be protected under the Unrelated to DHS Exception, *none* of these conditions will need to be satisfied.

Not surprisingly, then, when CMS in 2004 finalized its regulatory version of the Unrelated to DHS Exception, the agency interpreted the statutory Exception *very* narrowly.[48] First, the regulatory Exception provided that in order to be protected, the remuneration could not relate "directly or indirectly" to the furnishing of DHS.[49] Second, in an effort to drive home the point, the regulatory Exception provided that to qualify as "unrelated," the remuneration at issue must be "wholly unrelated" to the furnishing of DHS.[50] Finally, in addition to inserting these various qualifiers, the agency created (out of whole cloth) a test for determining whether remuneration does, in fact, "relate[ ] to the furnishing of DHS."[51] According to the regulatory Unrelated to DHS Exception, remuneration would be deemed "related" to the furnishing of DHS if any one of the following were true:

- The remuneration from the hospital to the physician takes the form of "an item, service, or cost that could be allocated in whole or in part to Medicare or Medicaid under cost reporting principles."[52]
- The remuneration from the hospital to the physician is "furnished, directly or indirectly, explicitly or implicitly, in a selective, targeted, preferential, or conditioned manner to medical staff or other persons in a position to make or influence referrals."[53]
- The remuneration from the hospital to the physician "[o]therwise takes into account the volume or value of referrals or other business generated by the referring physician."[54]

48 69 Fed. Reg. 16054, 16093 (Mar. 26, 2004) ("[W]e are interpreting the [Unrelated to DHS] exception to be narrow.").

49 42 C.F.R. § 411.357(g) as set forth in 69 Fed. Reg. at 16140.

50 *Id.*

51 *Id.*

52 42 C.F.R. § 411.357(g)(1) as set forth in 69 Fed. Reg. at 16140.

53 42 C.F.R. § 411.357(g)(2) as set forth in 69 Fed. Reg. at 16140.

54 42 C.F.R. § 411.357(g)(3) as set forth in 69 Fed. Reg. at 16140.

## 1. Proposed Rule

Between 2004 and 2019, the regulatory Unrelated to DHS Exception remained unchanged; and during that 15-year period, CMS was able to point to *just one* (obscure) arrangement that might possibly qualify for protection under the Unrelated to DHS Exception: rental payments by a teaching hospital to a physician for the use of the physician's residence by one of the hospital's visiting faculty members.[55] After years of grumbling by the industry, however, in 2019, CMS conceded that its interpretation of the statutory Unrelated to DHS Exception had, in fact, been "too restrictive."[56] According to the agency, while Congress intended the Unrelated to DHS Exception to apply to a "narrow" subset of compensation arrangements between hospitals and physicians, a "narrow" subset is not an "empty" subset.[57] But that's, in effect, what the Unrelated to DHS Exception had become: an exception that had been interpreted so narrowly that it essentially protected nothing.

To "give appropriate meaning" to the text and legislative history of the Unrelated to DHS Exception, CMS proposed starting from scratch.[58] Most notably, the agency proposed moving the focus from whether the remuneration provided for under the arrangement could be "allocated in whole or in part to Medicare or Medicaid under cost reporting principles" to whether the remuneration "is for an item or service that is not related to the provision of patient care services."[59]

Because CMS proposed defining "the provision of patient care services" broadly, however, it was not clear the extent to which the proposed amendments would, in fact, expand the universe of arrangements that could be protected under the Unrelated to DHS Exception. CMS emphasized, for example, that (in its view) there doesn't have to be a "direct one-to-one correlation" between a physician's services and the provision of DHS in order for payments for the service to be "related" to the "provision" of DHS.[60] According to CMS, for example:

- A hospital's payment for Emergency Department call coverage would "relate" to the furnishing of DHS "even if the physician is not as a matter of fact called to the hospital to provide patient care services, because the hospital is paying the physician to be available to provide patient care services at the hospital."[61]
- Further, "medical director services typically include, among other things, establishing clinical pathways and overseeing the provision of [DHS] in a hospital." Thus, "payments for such services" would be "related" to the furnishing of DHS.[62]
- In addition, "utilization review services are closely related to patient care services" and, as such, "remuneration" for such services is "related to the furnishing of [DHS]."[63]
- Moreover, "remuneration from a hospital for items provided by a physician" is "related" to the furnishing of DHS if the items are "medical equipment" or "medical devices" that are "used in the provision of patient care services," whether the patient care services are DHS or "directly correlated" with the provision of DHS (whatever that means).[64]
- CMS also believes that a hospital's "rental of office space where patient care services are provided"—including patient care services that are not "necessarily" DHS—is (nevertheless) remuneration "related" to the provision of DHS.[65]

55 84 Fed. Reg. 55766, 55819 (Oct. 17, 2019) ("[W]e continue to believe that, as first stated in the 1998 proposed rule, § 411.357(g) (including proposed § 411.357(g)) applies to rental payments made by a teaching hospital to a physician to rent his or her house in order to use the house as a residence for a visiting faculty member.").

56 *Id.* at 55818.

57 *Id.*

58 *Id.*

59 *Id.* at 55818, 55844.

60 *Id.* at 55818.

61 *Id.*

62 *Id.*

63 *Id.*

64 *Id.* at 55819.

65 *Id.*

What would be protected then? According to CMS—at least when it comes to remuneration provided by a hospital to a physician in exchange for *services* (as opposed to items)—the basic test would be this: If a service can be provided legally by a person who is not a "licensed medical professional" and "the service is of the type that is typically provided by such persons," then payment for such a service is "unrelated to the provision of [DHS]" and, as such, may be protected under the proposed revisions to the Unrelated to DHS Exception, provided the payment "is not determined in a manner that takes into account the volume or value of the physician's referrals."[66] For example, "administrative services of a physician pertaining solely to the business operations of a hospital" don't "relate" to "patient care services" (or therefore, the "provision" of DHS).[67]

> Thus, if a physician is a member of a governing board along with persons who are not licensed medical professionals, and the physician receives stipends or meals that are available to the other board members, it is our policy that this remuneration would not relate to the provision of [DHS] under [the proposed revisions to the Unrelated to DHS Exception], provided the physician's compensation for the administrative services is not determined in a manner that takes into account the volume or value of his or her referrals.[68]

As for "remuneration provided in exchange for any item, supply, device, equipment, or office space that is used in the diagnosis or treatment of patients, or any technology that is used to communicate with patients regarding patient care services," the proposed regulation would "presume" those to be "related" to the "provision of designated health services" and, as such, not qualified for protection under the Unrelated to DHS Exception.[69]

In sum, then, if adopted, the proposed changes to the Unrelated to DHS Exception would have moved the focus of the inquiry from whether the remuneration at issue could be "allocated" to Medicare under "cost reporting principles" (which is awkward, difficult to implement, and narrow) to whether the remuneration is for an "item or service" that is related to the provision of "patient care services" (which is less awkward, less difficult to implement, but perhaps only *slightly* less narrow).

## 2. Final Rule

But whether the proposed version of the Unrelated to DHS Exception would have protected materially more arrangements than the 2004 version of the Unrelated to DHS Exception turns out to be academic, because in the Final Rule, CMS kicked the can down the road. After stating that commenters "generally supported our efforts to restore utility to the statutory exception," CMS noted that a "few commenters" expressed concern that the "expansion" of the Unrelated to DHS Exception, "especially without substantial guidance and examples of its application, would risk program or patient abuse," and that others had asked the agency to (i) clarify the meaning of "patient care services" and (ii) "codif[y] specific remuneration that would be deemed not to relate to the provision of [DHS]."[70] And then, instead of responding to these (or any other) comments on the Proposed Rule, CMS, essentially, gave up, offering just the following two sentence explanation:

> Given the concerns raised by commenters, we are not finalizing our proposed revision to [the Unrelated to DHS Exception] at this time. We are continuing to evaluate the best way to restore utility to the statutory exception, and we may finalize revisions to the [Exception] in [a] future rulemaking.[71]

66 *Id.*

67 *Id.* at 55818.

68 *Id.* at 55818-19.

69 *Id.* at 55819.

70 85 Fed. Reg. 77492, 77603 (Dec. 2, 2020).

71 *Id.*

It is not entirely clear what spooked CMS. The agency already had provided "substantial guidance and examples of [the Exception's] application" in the Proposed Rule; and it would not have been a heavy lift to either (i) clarify the meaning of "patient care services" (which already is defined in the Stark Law regulations[72]) or (ii) decide—one way or the other—whether to include in the Exception specific examples of protected remuneration. Whatever the reason, the agency's decision to punt is unfortunate. CMS's proposal was better than the status quo and meaningfully (if imperfectly) addressed what the agency stated in the Proposed Rule, and reiterated in the Final Rule: The Unrelated to DHS Exception "is too restrictive," "has an extremely limited application" and needs to be overhauled in order to "give appropriate meaning to the statutory exception."[73]

## F. Physician Payments Exception

Like the Unrelated to DHS Exception, and for largely the same reasons, the statutory Physician Payments Exception has never been much liked by CMS. By its terms, the Exception is both broad and straightforward, essentially protecting any amount that a physician pays to a DHS entity for "items or services" as long as the payment is "consistent with fair market value." More specifically, the statutory Exception protects "[p]ayments made by a physician" either (i) to "a laboratory in exchange for the provision of clinical laboratory services," or (ii) to any entity "as compensation for other items or services if the items or services are furnished at a price that is consistent with fair market value."[74]

Prior to issuing the Proposed Rule in 2019, CMS (and its predecessor, HCFA), had taken the position that the statutory Physician Payments Exception was so narrow as to be, effectively, null and void. The agency accomplished this in 2004 by prohibiting use of the Physician Payments Exception, which (again) is provided by *statute*, if the arrangement at issue concerned items or services that were covered by any other *regulatory* exception.[75] Thus, for example, if a physician wished to enter into an arrangement pursuant to which she would compensate a hospital for services, the parties could not use the Physician Payments Exception even if, pursuant to the plain terms of the statutory Exception, the "services [were] furnished at a price that is consistent with fair market value." Instead, the parties were forced to rely on the regulatory FMV Exception, which protected "[c]ompensation resulting from an arrangement between an entity and a physician . . . for the provision of items or services," but only if the arrangement met a dozen or so additional technical and substantive conditions.

### 1. Proposed Rule

In the Proposed Rule, CMS—persuaded by the arguments that the agency had "unreasonably narrowed the scope of the statutory exception"—proposed substantially expanding the protection offered by the Physician Payments Exception.[76] The agency first distinguished the Stark Law's statutory and regulatory compensation arrangements exceptions.[77] For purposes of this discussion, and generally speaking, "statutory" compensation exceptions include those exceptions set out in 42 U.S.C. § 1395nn(e)(1)-(8) *and* their regulatory counterparts set forth in 42 C.F.R. § 411.357(a)-(i). See Table 1.

72 42 C.F.R. § 411.351 (definition of "patient care services").

73 84 Fed. Reg. at 55818.

74 42 U.S.C. § 1395nn(e)(8).

75 42 C.F.R. § 411.357(i)(2) as set forth in 69 Fed. Reg. 16054, 16140 (Mar. 26, 2004).

76 84 Fed. Reg. at 55820.

77 *Id.*

**Table 1**

"Statutory" Compensation Exceptions

| | Exception | Statute (42 U.S.C.) | Regulation (42 C.F.R.) |
|---|---|---|---|
| 1 | Space Rental | § 1395nn(e)(1)(A) | § 411.357(a) |
| 2 | Equipment Rental | § 1395nn(e)(1)(B) | § 411.357(b) |
| 3 | Employment | § 1395nn(e)(2) | § 411.357(c) |
| 4 | Personal Services | § 1395nn(e)(3) | § 411.357(d) |
| 5 | Physician Recruitment | § 1395nn(e)(5) | § 411.357(e) |
| 6 | Isolated Transactions | § 1395nn(e)(6) | § 411.357(f) |
| 7 | Unrelated to DHS | § 1395nn(e)(4) | § 411.357(g) |
| 8 | Hospital-Group Arrangements | § 1395nn(e)(7) | § 411.357(h) |
| 9 | Physician Payments | § 1395nn(e)(8) | § 411.357(i) |

"Regulatory" exceptions, on the other hand, do *not* have a statutory basis/counterpart and, as such, are *exclusively* to be found 42 C.F.R. § 411.357(j)-(bb). See Table 2 below.

**Table 2**
"Regulatory" Compensation Exceptions

| Exception | Regulation 42 C.F.R. |
|---|---|
| Charitable Donations by Physician | § 411.357(j) |
| Non-Monetary Compensation | § 411.357(k) |
| Fair Market Value Compensation | § 411.357(l) |
| Medical Staff Incidental Benefits | § 411.357(m) |
| Risk-Sharing Arrangements | § 411.357(n) |
| Compliance Training | § 411.357(o) |
| Indirect Compensation Arrangements | § 411.357(p) |
| Referral Services | § 411.357(q) |
| Obstetrical Malpractice Insurance Subsidies | § 411.357(r) |
| Professional Courtesy | § 411.357(s) |
| Retention Payments in Underserved Areas | § 411.357(t) |
| Community-Wide Health Information Systems | § 411.357(u) |
| Electronic Prescribing Items/Services | § 411.357(v) |
| Electronic Health Records Items and Services | § 411.357(w) |
| Nonphysician Practitioner Assistance | § 411.357(x) |
| Timeshare Arrangements | § 411.357(y) |
| Limited Remuneration to a Physician | § 411.357(z) |
| Value-Based Arrangements | § 411.357(aa) |
| Cybersecurity Technology | § 411.357(bb) |

In the Proposed Rule, CMS stated that it continued to believe that the *statutory* Physician Payments Exception "was not meant to apply to compensation arrangements that are specifically excepted" by other *statutory* exceptions (i.e., exceptions 1-8 in Table 1), such as the Space Rental Exception.[78] Thus, under CMS's 2019 proposal, an arrangement pursuant to which a physician would pay a DHS Entity for office space could continue to be protected, if at all, only by the Space Rental Exception, which requires, among other things, that the rental charges over the term of the lease arrangement be set in advance and not determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties. In CMS's view, Congress would not "have imposed these particularized requirements" in the Space Rental Exception (or any other potentially applicable statutory exception in Table 1), but then "allowed parties to sidestep them by relying on" the Physician Payments Exception.[79]

On the other hand, the agency noted, "we no longer believe" the Stark Law's "*regulatory* exceptions should limit the scope" of the *statutory* Physician Payments Exception.[80] Accordingly, CMS proposed removing from the Exception "the reference to the regulatory exceptions."[81] Thus, under the Proposed Rule, if adopted, parties could "rely on the [Physician Payments Exception] to protect fair market value payments by a physician to an entity for items or services furnished by the entity," even if another *regulatory* exception would otherwise be applicable.[82] Table 3 compares the original and proposed regulatory versions of the Physician Payments Exception.

**Table 3**
Original and Proposed Physician Payments Exception

| Original | Proposed |
|---|---|
| (i) Payments by a physician. Payments made by a physician (or his or her immediate family member)—<br><br>(1) To a laboratory in exchange for the provision of clinical laboratory services; or<br><br>(2) To an entity as compensation for any other items or services that are furnished at a price that is consistent with fair market value, ***and that are not specifically excepted by another provision in § 411.355 through 411.357 (including, but not limited to, § 411.357(l).*** | (i) Payments by a physician. Payments made by a physician (or his or her immediate family member)—<br><br>(1) To a laboratory in exchange for the provision of clinical laboratory services; or<br><br>(2) To an entity as compensation for any other items or services—<br><br>i. That are furnished at a price that is consistent with fair market value; and<br><br>ii. ***To which the exceptions in paragraphs (a) through (h) of this section [i.e., exceptions 1-8 in Table 1] are not applicable.*** |

78 *Id.*

79 *Id.*

80 *Id.*

81 *Id.*

82 *Id.*

### 2. Final Rule

In the Final Rule, CMS adopted the modifications to the Physician Payments Exception the agency proposed in 2019.[83] On a go-forward basis, then, with just two exceptions (discussed below), protecting arrangements pursuant to which a physician is obtaining items or services from a DHS Entity requires a showing of nothing more than that the physician is paying FMV for the items or services. No technical requirements and no substantive requirements (other than a showing of FMV) need to be satisfied. Thus, for example, the arrangement does not need to be memorialized in a signed writing, the compensation does not need to be "set in advance," the arrangement does not need to be "commercially reasonable," etc. The two exceptions are arrangements pursuant to which a physician is leasing office space or equipment from a DHS Entity, in which case the parties must comply with the conditions of the Space and Equipment Rental Exceptions, respectively.[84]

## G. Isolated Transactions Exception

The statutory version of the Isolated Transactions Exception provides that an isolated financial transaction—"such as a one-time sale of property or practice"—will be protected if:

- The amount of the remuneration under the arrangement is (i) consistent with FMV and (ii) "not determined in a manner that takes into account (directly or indirectly) the volume or value of any referrals by the referring physician";
- The arrangement would be commercially reasonable even if no referrals were made by the referring physician to the DHS Entity; and
- The "transaction meets such other requirements as the Secretary may impose by regulation as needed to protect against program or patient abuse."[85]

Historically, the regulatory version of the Isolated Transactions Exception largely tracked its statutory counterpart, with a few additional safeguards and definitions. Specifically, in addition to meeting the statute's FMV, Volume/Value, and Commercial Reasonableness Standards, the regulatory Isolated Transactions Exception:

- Provides that there can be "no additional transactions between the parties for 6 months after the isolated transaction," except for (i) transactions that are protected under another Stark Law exception and (ii) "commercially reasonable post-closing adjustments that do not take into account (directly or indirectly) the volume or value of referrals or other business generated by" the referring physician.[86]
- Defines "transaction" to mean "an instance or process of two or more persons or entities doing business."[87]
- Defines an "isolated transaction" to mean one involving either (i) "a single payment between two or more persons or entities" or (ii) "a transaction that involves integrally related installment payments" provided that:

83 85 Fed. Reg. 77492, 77605 (Dec. 2, 2020).

84 *Id.* at 77604.

85 42 U.S.C. § 1395nn(e)(6).

86 42 C.F.R. § 411.357(f)(3) as set forth in 69 Fed. Reg. 16054, 16140 (Mar. 26, 2004).

87 42 C.F.R. § 411.351 as set forth in 69 Fed. Reg. at 16131 (definition of "transaction").

- The "total aggregate payment is fixed before the first payment is made and does not take into account, directly or indirectly, the volume or value of referrals or other business generated by the referring physician," and
- The "payments are immediately negotiable or are guaranteed by a third party, or secured by a negotiable promissory note, or subject to a similar mechanism to ensure payment even in the event of default by the purchaser or obligated party."[88]

## 1. Proposed Rule

In the preamble to the Proposed Rule, CMS stated that it had come to the agency's attention that some in the industry believed that the Isolated Transactions Exception could "protect service arrangements where a party makes a *single* payment for *multiple* services provided over an extended period of time."[89] According to CMS, some parties had been turning to the Isolated Transaction Exception "when they discover . . . that they failed to set forth the service arrangement in writing, and thus cannot rely on" the Personal Services or FMV Exceptions.[90] Going back to a hypothetical we used in White Paper No. 1, for example, assume the following:

- **January 15**. Hospital telephones Physician and asks, "Would you be interested in becoming the medical director of Hospital's Cardiology Department? One-year term, 10 hours per week, $250 per hour, as documented in a timesheet. We need someone by 2/1." Physician says, "Absolutely."
- **February 1**. Physician begins furnishing medical director services to Hospital. From February 1 through March 22, Physician works a total of 65 hours.
- **March 23**. Hospital prepares (and signs) a medical director agreement (MDA) that memorializes the parties' arrangement and mails it to Physician.
- **April 20**. Physician signs the MDA and sends it to Hospital, along with an invoice for the work Physician did from February 1 through March 22. The total amount due under the invoice is $16,250 (65 x $250).

Historically, assuming the parties had no "writings" other than the MDA itself, this arrangement would not have met the writing requirement of the Personal Services or FMV Exceptions from February 1, when the parties financial relationship began, through March 22, the day before the writing requirement was satisfied. According to CMS, under these circumstances, some parties were taking the position that although the period from February 1 through March 22 might not qualify for protection under the Personal Services or FMV Exceptions, Hospital's payment of Physician's April 1 invoice (for $16,250) covering that same period *could* be protected under the Isolated Transactions Exception on the grounds that:

- The arrangement and compensation satisfied the FMV, Volume/Value, and Commercial Reasonableness Standards;
- Hospital and Physician had "no additional transactions" (i.e., transactions other than the payment of $16,250 for services furnished from February 1 through March 22) except for those that were protected under another Stark Law exception; and
- Payment of the April 1 invoice qualified both (i) as a "transaction" (i.e., it was "an instance" of "two or more persons or entities doing business"), and (ii) an "isolated financial transaction" (i.e., it involved "a single payment between two or more persons or entities").

In the Proposed Rule, CMS disagreed, stating that the Isolated Transactions Exception is "*not* available to except payments for multiple services provided over an extended period of time, even if there is only a single payment for all the services."[91] Having already proposed (i) further liberalizing the Stark Law's writing and other technical requirements, and (ii) creating a new exception for the provision of limited remuneration to a physician—both discussed in White Paper No. 2—CMS stated it saw "no reason to unduly stretch the meaning and applicability of the exception for isolated transactions beyond what was intended by the Congress."[92]

88 *Id.*

89 84 Fed. Reg. 55766, 55808 (Oct. 17, 2019).

90 *Id.*

91 *Id.*

92 *Id.*

According to CMS, Congress made it clear that the types of transactions the Isolated Transactions Exception is meant to exempt are "a one-time sale of property" or "a one-time sale of a practice," each of which is a "unique, singular transaction."[93] In contrast, the agency noted:

> [I]f a physician provides multiple services to an entity over an extended period of time, remuneration in the form of an in-kind benefit has passed repeatedly from the physician to the entity receiving the service prior to the payment date. The provision of remuneration in the form of services commences a compensation arrangement at the time the services are provided, and the compensation arrangement must satisfy the requirements of an applicable exception *at that time* if the physician makes referrals for designated health services and the entity wishes to bill Medicare for such services.[94]

In sum, CMS concluded, the Insolated Transactions Exception "is not available to retroactively cure noncompliance with" the Stark Law.[95]

## 2. Final Rule

In the Final Rule, CMS adopted the policy position it articulated in the Proposed Rule, modifying the regulatory definition of "isolated financial transaction" to make it clear that it "does not include a single payment for multiple or repeated services (such as payment for services previously provided but not yet compensated)."[96] In response to pushback, CMS reiterated its position:

> Under our interpretation of the statutory scheme, ongoing service arrangements, where a physician provides multiple services to an entity over an extended period of time, must satisfy all the requirements of another applicable exception, such as the [Personal Services Exception] or the [FMV Exception]. We do not believe that the Congress would have required ongoing service arrangements to meet all the requirements of [the Personal Services Exception, for example,] including writing, signature, 1-year term, and set in advance requirements, and then permit parties to sidestep these requirements by making a single, retrospective payment for multiple services relying on the [Isolated Transaction Exception].[97]

Importantly, however, the agency conceded that "stakeholders may have been under the impression," due to the use of the word "process" in the definition of "transaction," that the Isolated Transactions Exception "was available to protect service arrangements involving multiple or repeated services provided over an extended period of time."[98] CMS also acknowledged that although an "isolated financial transaction" involves a single payment, "it does not explicitly state that a single payment cannot be made for repeated or multiple services."[99] Consistent with these concessions, the agency emphasized that its amendments to the Isolated Transactions Exception and definitions of "transaction" and "isolated financial transaction" only would apply "prospectively."[100]

93 *Id.*

94 *Id.*

95 *Id.*

96 85 Fed. Reg. 77492, 77579, 77659 (Dec. 2, 2020).

97 *Id.* at 77578.

98 *Id.* at 77579.

99 *Id.*

100 *Id.*

CMS then took up a second issue, which had not been raised in the Proposed Rule. According to the agency, in response to the Proposed Rule, many commenters expressed concern that the revised definition of "isolated financial transaction" might preclude the Isolated Transactions Exception from applying "to the settlement of a *bona fide* legal dispute, especially a dispute arising from an ongoing service arrangement."[101]

> Commenters noted that parties to a service arrangement may have a legitimate dispute concerning the amount of compensation due under a service arrangement . . . . In these circumstances, a physician may have reasonable belief that he or she is owed more money under the contract, while the entity may believe in good faith that the physician is entitled to less than what the physician claims. Under such circumstances, the parties may wish to settle the matter to avoid litigation. The commenters expressed concern that the settlement could be construed as a single payment for multiple services previously provided by the physician and, therefore, the [Isolated Transactions Exception] would be unavailable to protect the compensation arrangement arising from the settlement payment (or reduction in debt).[102]

Assume, for example, the following:

- Home Health Provider (HHA) contracts with Physician to provide medical director services starting January 1 on a part-time basis for one year for $200 per documented hour. The parties enter into a written, signed agreement that meets all the conditions of the FMV Exception.
- Over the course of the year, Physician submits monthly invoices, which include timesheets indicating the days she worked and the number of hours she worked on those days.
- Over course of the agreement, HHA pays Physician a total of $24,000 for 120 hours of service.
- Shortly after receiving her final payment from HHA, Physician writes a letter to HHA, stating that she actually worked a total of 130 hours and, as such, is due an additional $2,000 (i.e., 10 hours x $200).
- According to Physician, she was not paid for (i) three hours she worked in February, (ii) four hours she worked in August, and (iii) three hours she worked in November.
- Although HHA believes the better argument is that the 12 timesheets reflect a total of 120 hours worked, and not 130 hours, HHA agrees that the February, August and November timesheets are not models of clarity.

Can HHA and Physician enter into a settlement agreement regarding the disputed amount—e.g., can HHA pay Physician $1,000 in settlement of her $2,000 claim—and protect that arrangement under the Isolated Transactions Exception?

In the Final Rule, CMS indicated the answer is "yes." According to the agency, its policy "has always been" that the Isolated Transactions Exception "is applicable to a compensation arrangement arising from the settlement of a *bona fide* dispute, even if the dispute originates from a service arrangement where multiple services have been provided over an extended period of time."[103] To "clarify" this "longstanding policy," CMS amended the definition of "isolated financial transaction" in the Final Rule to specifically provide

101 *Id.* at 77577.

102 *Id.*

103 *Id.*

that it includes a "single instance of forgiveness of an amount owed in settlement of a *bona fide* dispute."[104] CMS also made a similar amendment in the text of the Isolated Transaction Exception itself, which now provides that "[a]n isolated financial transaction that is an instance of forgiveness of an amount owed in settlement of a *bona fide* dispute is not part of the compensation arrangement giving rise to the *bona fide* dispute."[105] CMS explained its reasoning as follows:

> [S]ettlement of a *bona fide* dispute arising from an arrangement is fundamentally different from making a payment, including a single payment, for items or services provided under the arrangement . . . [T]he cornerstone of a settlement of a *bona fide* dispute, as opposed to a payment for items or services, is that one or more of the parties forgoes a good faith claim to be paid more under the arrangement than the party actually receives. [106]

Although the authors welcome CMS's willingness to provide the industry this additional tool for addressing contractual irregularities, the demarcation between (i) a retroactive payment for items and services previously exchanged under a compensation arrangement, on the one hand, and (ii) a good faith dispute arising from that same arrangement, on the other hand, may prove difficult to navigate and continue to be source of uncertainty. It also will be interesting to see how well this application of the Isolated Transactions Exception interacts with the new special rule for payment discrepancies discussed in White Paper No. 2.

104 *Id.*

105 42 C.F.R. § 411.357(f)(4) as set forth in 85 Fed. Reg. at 77674.

106 85 Fed. Reg. at 77577.

# II. All-Purpose Exception - In-Office Ancillary Services Exception

The In-Office Ancillary Services Exception is a statutory exception[107] with a regulatory counterpart.[108] Pertinent to our discussion here, and subject to a host of additional conditions, the regulatory In-Office Ancillary Services Exception protects the furnishing of certain types of DHS as long as they are furnished personally by (i) a physician who is a member of the same "group practice" as the referring physician or (ii) an individual who is supervised by another physician in the "group practice."[109]

Two or more physicians will be deemed part of the same "group practice," in turn, only if the myriad conditions set forth in 42 C.F.R. § 411.352 are satisfied. Several of these conditions concern the manner in which the physicians in the prospective group practice are compensated. Prior to the Final Rule, for example, 42 C.F.R. § 411.352(g) (Section 352(g)) provided that "[n]o physician who is a member of the group practice directly or indirectly receives compensation based on the volume or value of his or her referrals," except as provided in 42 C.F.R. § 411.352(i) (Section 352(i)). Section 352(i), in turn, had three sections:

- *General*. Section 1 provided that "[a] physician in the group practice may be paid a share of overall profits of the group, provided that the share is not determined in any manner that is directly related to the volume or value of referrals of DHS by the physician. A physician in the group practice may be paid a productivity bonus based on services that he or she has personally performed, or services 'incident to' such personally performed services, or both, provided that the bonus is not determined in any manner that is directly related to the volume or value of referrals of DHS by the physician (except that the bonus may directly relate to the volume or value of DHS referrals by the physician if the referrals are for services 'incident to' the physician's personally performed services)."
- *Overall Profits*. Section 2 provided that "[o]verall profits means the group's entire profits derived from DHS payable by Medicare or Medicaid or the profits derived from DHS payable by Medicare or Medicaid of any component of the group practice that consists of at least five physicians. Overall profits should be divided in a reasonable and verifiable manner that is not directly related to the volume or value of the physician's referrals of DHS. The share of overall profits will be deemed not to relate directly to the volume or value of referrals if one of the following conditions is met":
    - "The group's profits are divided per capita (for example, per member of the group or per physician in the group)."
    - "Revenues derived from DHS are distributed based on the distribution of the group practice's revenues attributed to services that are not DHS payable by any Federal health care program or private payer."
    - "Revenues derived from DHS constitute less than 5 percent of the group practice's total revenues, and the allocated portion of those revenues to each physician in the group practice constitutes 5 percent or less of his or her total compensation from the group."
- *Productivity Bonuses*. Section 3 provided that a "productivity bonus 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. A productivity bonus will be deemed not to relate directly to the volume or value of referrals of DHS if one of the following conditions is met":
    - "The bonus is based on the physician's total patient encounters or relative value units (RVUs). (The methodology for establishing RVUs is set forth in § 414.22 of this chapter.)"

107 42 U.S.C. § 1395nn(b)(2).

108 42 C.F.R. § 411.355(b).

109 42 U.S.C. § 1395nn(b)(2)(A)(i); 42 C.F.R. § 411.355(b)(1).

- "The bonus is based on the allocation of the physician's compensation attributable to services that are not DHS payable by any Federal health care program or private payer."
- "Revenues derived from DHS are less than 5 percent of the group practice's total revenues, and the allocated portion of those revenues to each physician in the group practice constitutes 5 percent or less of his or her total compensation from the group practice."

## 1. Overall Profits

In the Proposed Rule, CMS proposed a series of organizational and more substantive changes to Section 352(i) as it relates to the distribution of "overall profits." We will address four of the more substantive changes.

### a. Split-Pooling

First, and perhaps most significantly, in the Proposed Rule, CMS addressed the question of "whether a group practice may share profits from one type of [DHS] with a subset of physicians in a group practice and the profits from another type of [DHS] with a different (possibly overlapping) subset of physicians in the group practice"[110]—sometimes referred to as "split pooling."[111] In the Final Rule, CMS said "no." According to the agency, for example, if a "physician practice provides both clinical laboratory services and diagnostic imaging services—both designated health services—to its patients," and the practice wants to qualify as a group practice, "it may not distribute the profits from clinical laboratory services to one subset of its physicians and distribute the profits from diagnostic imaging to a different subset of its physicians."[112] CMS revised the text of Section 352(i) in the Final Rule to make this clear.[113] In order to give practices that had relied on a contrary interpretation time to "adjust their compensation methodologies," CMS delayed the effective date of this amendment to Section 352(i) until January 1, 2022.[114]

CMS noted in the preamble to the Final Rule that a number of commenters opposed the agency's proposed prohibition on split-pooling.[115] According to the agency, these commenters asserted, for example, that:

- Split-pooling should be permitted because "service-by-service profit shares would allow physicians to receive profits shares more closely related to the services they referred, their specialty, the services they provide, or the expenses they have personally incurred";[116]
- "[A] service-by-service allocation methodology aligns compensation with the physicians who are furnishing professional services in conjunction with designated health services and incurring the related expenses";[117]
- Prohibiting split-pooling would permit "physicians who have no treatment involvement in the designated health services" to be "rewarded financially" nonetheless;[118] and
- Where, for example, a subset of physicians agrees to "assume all of the costs of expensive diagnostic testing equipment," split-pooling helps to ensure that "the physicians who bear the cost of the equipment also receive the profits arising from the use of the equipment."[119]

In sum, these commenters complained, the prohibition on split-pooling "may inadvertently penalize the 'practices' within a group that are more profitable due to efficiency and reward those that are less efficient."[120]

110 84 Fed. Reg. 55766, 55801 (Oct. 17, 2019).

111 85 Fed. Reg. at 77563.

112 84 Fed. Reg. at 55801.

113 85 Fed. Reg. at 77561.

114 *Id.*

115 *Id.* at 77563.

116 *Id.*

117 *Id.* at 77564.

118 *Id.*

119 *Id.*

120 *Id.*

In responding to these commenters, CMS made it clear there was nothing "inadvertent" about its decision with respect to this issue: (i) the statute "permits a group practice to pay a physician in the group practice a share of overall profits" of the group; (ii) for 20 years, the agency has interpreted "overall profits" to mean the "entire" profits of the "entire" group (or any component of the group that consists of at least five physicians) derived from DHS; and (iii) the Proposed and Final Rules "incorporate this long-held interpretation."[121] The agency then went on to warn/remind readers that to qualify as a "group practice," conditions beyond those set forth in Sections 352(g) and 352(i) must be met.

> These include that the practice is a unified business with centralized decision making by a body representative of the practice that maintains effective control over the practice's assets and liabilities (including, but not limited to, budgets, compensation, and salaries) and consolidated billing, accounting, and financial reporting. In addition, revenues from patient care services must be treated as receipts of the practice. Certain of the justifications for the commenters' assertions that we should permit a group practice to share the profits from [DHS] on a service-by-service basis call into question whether a physician practice that operates as described in the comments could satisfy the unified business test at § 411.352(f) or, potentially, whether the revenues from patient care services are treated as receipts of the practice, as required at § 411.352(d)(1).[122]

CMS made it clear that although split-pooling is not permitted, a group practice may establish components of at least five physicians "by including physicians with similar practice patterns, who practice in the same location, with similar years of experience, with similar tenure with the group practice, or who meet other criteria determined by the group practice."[123] In the agency's view, "a threshold of at least five physicians is likely to be broad enough to attenuate the ties between compensation and referrals of [DHS]."[124]

121 *Id.*

122 *Id.*

123 *Id* at 77565.

124 *Id.*

CMS also made it clear that a group practice may utilize "different distribution methodologies" to distribute shares of the overall profits from all the DHS of "each of its components of at least five physicians," provided the distribution to any physician is not directly related to the volume or value of the physician's referrals.[125] For example, the agency continued, assume that a group practice comprised of 15 physicians (i) "furnishes clinical laboratory services, diagnostic imaging services, and radiation oncology services," and (ii) "has divided its physicians into three components [A, B, and C] of five physicians" for purposes of distributing the overall profits from the DHS of the group practice.[126] Under these circumstances, pursuant to the Final Rule, "for each component, the group practice must aggregate the profits from all the [DHS] furnished by the group and referred by any of the five physicians in the component."[127] The group practice may then distribute "the overall profits from all the DHS" of:

- Component A using one methodology (for example, a per-capita distribution methodology);
- Component B using a different methodology (for example, a permissible personal productivity methodology); and
- Component C using a third methodology that does not directly relate to the volume or value of the component physicians' referrals (or the methodology used for component A or B).[128]

"However," CMS emphasizes, "a group practice must utilize the same methodology for distributing overall profits for every physician in the component" (e.g., the group practice must use the per-capita distribution methodology for each physician in component A).[129]

### b. Categories v. Payers

As noted above, prior to the Final Rule, Section 352(i) provided that the share of overall profits would be deemed not to relate directly to the volume or value of referrals if they were "distributed based on the distribution of the group practice's revenues attributed to services that are not DHS payable by any Federal health care program or private payer."[130] In the Proposed Rule, CMS changed the quoted language to read "distributed based on the distribution of the group's revenues attributed to services that are not designated health services and would not be considered designated health services if they were payable by Medicare."[131] According to the agency, this change—which CMS adopted in the Final Rule[132]—better captures CMS's policy that profits may be distributed based on the distribution of the group practice's revenues from services other than those in the "categories of services" that are DHS.[133] Once again, the agency delayed the effective date of this change until January 1, 2022.[134]

### c. Medicaid

The Proposed Rule also proposed removing the reference to Medicaid from the definition of "overall profits," noting that it "unnecessarily complicates" the regulation.[135] Most obviously, perhaps, the definition of DHS includes only those services payable in whole or in part by Medicare and, as such, "designated health services payable by . . . Medicaid"—the terminology used in Section 352(i)—would "not include any services."[136] As is the case with the changes relating to split-pooling, CMS delayed the elimination of the reference to Medicaid in Section 352(i) until January 1, 2022.[137]

125 *Id.*
126 *Id.*
127 *Id.*
128 *Id.*
129 *Id.*
130 *Id.* at 77562.
131 84 Fed. Reg. at 55802.
132 85 Fed. Reg. at 77562.
133 84 Fed. Reg. at 55802.
134 85 Fed. Reg. at 77562.
135 84 Fed. Reg. at 55801.
136 *Id.* at 55801-02.
137 85 Fed. Reg. at 77565.

### d. Five or More Physicians

CMS also proposed revisions to clarify the agency's interpretation of the "overall profits of a group" that can be distributed to physicians in the group. As noted above, "overall profits" historically has been defined to mean either (i) the group's entire profits derived from DHS, or (ii) the profits derived from DHS of any group practice component that consists of at least five physicians. Some stakeholders questioned, then, "whether the profits of a group practice that has only two, three, or four physicians may be distributed at all."[138] The answer is "yes," and to clarify this, CMS proposed revising the definition of "overall profits" to make it clear that "if there are fewer than five physicians in the group, 'overall profits' means the profits derived from all the [DHS] of the group."[139] CMS adopted this proposed change in the Final Rule.[140]

## 2. Productivity Bonuses

In the Proposed Rule, CMS also proposed a series of organizational and more substantive changes to Section 352(i) of the group practice definition as it relates to the payment of "productivity bonuses." We will address two of the more substantive changes.

### a. "Incident To" Services

As noted above, prior to the Final Rule, Section 352(i) provided that a "productivity bonus 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."[141] In the Proposed Rule, CMS considered revising this language to make it clear that, consistent with longstanding policy, a physician in the group may be paid a productivity bonus based on (i) services that she has personally performed, or (ii) services "incident to" such personally performed services.[142] This proposal was adopted in the Final Rule, and the relevant provision now provides that:

> [A] physician in the group may be paid a productivity bonus based on services that he or she has personally performed, or services "incident to" such personally performed services, that is indirectly related to the volume or value of the physician's referrals (except that the bonus may directly relate to the volume or value of referrals by the physician if the referrals are for services "incident to" the physician's personally performed services).[143]

### b. Worked Relative Value Units

As noted above, prior to the Final Rule, Section 352(i) provided that:

> A productivity bonus will be deemed not to relate directly to the volume or value of referrals of DHS . . . [if the] bonus is based on the physician's total patient encounters or relative value units (RVUs). (The methodology for establishing RVUs is set forth in § 414.22 of this chapter.)[144]

In the Proposed Rule, CMS proposed amending this language to read as follows:

> A productivity bonus will be deemed not to relate directly to the volume or value of referrals . . . [if the] productivity bonus is based on the physician's total patient encounters or the relative value units (RVUs) *personally performed by the physician*. (The methodology for establishing RVUs is set forth in § 414.22 of this chapter.)[145]

138 *Id.* at 77561.

139 84 Fed. Reg. at 55801.

140 85 Fed. Reg. at 77561.

141 42 C.F.R. § 411.352(i)(3).

142 84 Fed. Reg. at 55802.

143 42 C.F.R. § 411.352(i)(1) as set forth in 85 Fed. Reg. at 77682.

144 42 C.F.R. § 411.352(i)(3).

145 84 Fed. Reg. at 55841.

The agency also sought comment on whether the parenthetical reference to 42 C.F.R. § 414.22(a) should be removed such that "*any* personally-performed relative value units [w]ould be an acceptable basis for calculating a productivity bonus" (and not just those specifically covered under the cross-referenced regulation).[146]

In the Final Rule, CMS opted to (i) include the "personally performed by the physician" phrase, and (ii) remove the reference to 42 C.F.R. § 414.22(a), as a result of which the deeming provision at issue now reads as follows:

> A productivity bonus will be deemed not to relate directly to the volume or value of referrals … [if the] productivity bonus is based on the physician's total patient encounters or the relative value unit (RVUs) personally performed by the physician.[147]

146 *Id.* at 55802.

147 85 Fed. Reg. at 77682.

# III. Conclusion

As is the case with several of the Stark Law's foundational components and definitions (White Paper No. 1), technical requirements (White Paper No. 2), and key standards (White Paper Nos. 3 and 4), the changes CMS made in the Final Rule to several of the Stark Law's exceptions should, on balance, ease the overall compliance burden for physicians and DHS Entities. Narrowing the Exclusive Use Requirement in the case of the Space Rental Exception, permitting the FMV Exception to be used in the case of office lease arrangements, significantly expanding the scope of the Physician Payments Exception, and clarifying that the Isolated Transactions Exception may be used to protect the settlement of bona fide legal disputes are perhaps the most notable in this regard. Once again, however, the news is not all positive, as best exemplified by CMS's concession that the regulatory Unrelated to DHS Exception is "too restrictive" and fails to "give appropriate meaning" to its statutory counterpart, and then failure to address these shortcomings.

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