



# THE HEALTH LAWYER

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## FINAL CY 2016 STARK LAW CHANGES—WELCOMED REVISIONS TO STARK

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### Introduction

*ABA Health Law Section Members can download a free “Redline” of the Final PFS CY 2016 Physician Self-Referral Changes by Going to <http://ow.ly/UfjCY>.*

Section 1877 of the Social Security Act, the statutory provisions of the Physician Self-Referral Law<sup>2</sup> (“Stark Law” or “Stark”), generally prohibits a physician from making referrals for certain designated health services (“DHS”) payable by Medicare to an entity with which he or she (or an immediate family member) has a financial relationship (ownership or compensation), unless an exception applies.<sup>3</sup> Over time, as the Centers for Medicare & Medicaid Services (“CMS”) has implemented numerous Stark rulemakings, the regulatory provisions of the Stark Law have increasingly become challenging for healthcare providers and suppliers to balance with providing patient care services. This has led to an environment where healthcare providers face innumerable potential “technical” violations of the Stark Law rules, despite best efforts to ensure compliance.

On November 16, 2015, as part of the 2016 Physician Fee Schedule, CMS released final revisions to the Stark Law (the “Final Rule”)<sup>4</sup> — the first major evolution of the Stark Law’s regulations since 2009.<sup>5</sup> The Final Rule builds upon, and largely adopts, the similar July 8, 2015 proposed Stark rule (“Proposed Rule”).<sup>6</sup> The Final Rule changes were designed to accommodate healthcare delivery/payment system reform, reduce burdens, facilitate compliance, clarify certain applications of the Stark Law, and issue new Stark exceptions.<sup>7</sup>

CMS recognized the need for the Final Rule’s changes after its dialogue with industry stakeholders, review of relevant literature, and examination of the actual self-disclosures submitted to the Medicare Self-Referral Disclosure Protocol (“SRDP”).<sup>8</sup> CMS developed the Final Rule’s clarifications and new exceptions in part to reduce future self-disclosures under the SRDP. CMS realizes that many current self-disclosures are not: (i) actual technical violations of the Stark Law; or (ii) of a nature that poses risk to the Medicare program or patient abuse.<sup>9</sup> In fact, many self-disclosures that CMS received via the SRDP could be readily defensible to avoid self-disclosure.<sup>10</sup> Further, due to

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the significant number<sup>11</sup> of self-disclosures made under the SRDP,<sup>12</sup> and the general fear of the Stark Law in the healthcare community, it is speculated that CMS used the Final Rule to amend the Stark Law before industry-stakeholder pressure forced Congress to intervene and significantly amend it.<sup>13</sup>

In issuing the Final Rule, CMS recognizes that healthcare is trending towards delivery of services through integrated delivery models,<sup>14</sup> and that the Stark Law can sometimes cause unintended hurdles that impede CMS' and Congress' intended goals.<sup>15</sup>

The Final Rule's provisions will generally be effective as of January 1, 2016. However, the definition of "ownership or investment interest" in 42 C.F.R. § 411.362(a), related to physician-owned hospitals, has a delayed effective date of January 1, 2017. Note that, regardless of the effective date(s), CMS views many of the Final Rule revisions as "clarifications" of "existing policy" with the attendant implication that the changes can arguably be effectively relied upon immediately/retroactively.

Regardless of the policy reasons behind the changes, healthcare providers/suppliers, and the attorneys who represent them, will welcome the Final Rule's clarifications as well as the wealth of regulatory guidance contained in the commentary issued with both the Proposed and Final Rules.

## **New Exception – Nonphysician Practitioner Assistance (42 C.F.R. § 411.357 (x))<sup>16</sup>**

*(See Table 1 on page 4)*

### **The Proposed NPP Assistance Exception: Assistance to Employ an NPP**

By way of background, the Stark Law sets forth an exception for remuneration provided by a hospital<sup>17</sup> to

a physician to induce the physician to relocate to the geographic area served by the hospital if certain requirements are met (the "Recruitment Exception").<sup>18</sup> In Stark's third final rulemaking ("Phase III"),<sup>19</sup> CMS declined to expand the Recruitment Exception to cover recruitment of nonphysician practitioners ("NPPs").<sup>20</sup> CMS now candidly recognizes the dichotomy between The Patient Protection and Affordable Care Act's ("PPACA's") goal of enabling greater access to primary care services and the need to increase the number of NPPs in the healthcare delivery system to meet greater demand.<sup>21</sup> CMS acknowledges that new and evolving delivery models, which often feature an increased role for NPPs, have been shown to improve patient outcomes while reducing costs.

In light of these changes, in the Proposed Rule CMS sought to establish a new Stark Law exception permitting payments from hospitals, federally qualified health centers ("FQHCs"), and rural health clinics ("RHCs") to physicians/physician groups to assist them in "employing a nonphysician practitioner in the geographic area served by the hospital, FQHC, or RHC providing the remuneration"<sup>22</sup> (the "Proposed NPP Assistance Exception"). The Proposed NPP Assistance Exception<sup>23</sup> applied only to recruiting physician assistants ("PAs"), nurse practitioners ("NPs"), certified nurse specialists ("CNSs"), and certified nurse midwives ("CNMs") (collectively, "NPPs")<sup>24</sup> because the purpose behind the new proposal is to promote access of care to primary care services. Under the proposal, CMS considered primary care services to include general family practice, general internal medicine, pediatrics, geriatrics, and obstetrics and gynecology patient care services.<sup>25</sup> Certified registered nurse anesthetists ("CRNAs") were specifically omitted because they do not furnish primary

care services.<sup>26</sup> The Proposed NPP Assistance Exception also contained a requirement that the NPP provide only primary care services to patients of the physician's practice. Thus, the exception would not cover arrangements where the NPP provides specialty care services, such as cardiology or surgical services, to the physician practice's patients.<sup>27</sup>

CMS solicited comments regarding whether the types of services considered "primary care services" should be expanded or narrowed, and whether there is a compelling need to expand the scope of the exception to NPPs who provide services that are not considered "primary care services."<sup>28</sup> For purposes of the new exception, CMS proposed two alternatives for determining the minimum amount of primary care services that it would require the NPP to provide: (1) at least 90 percent of the patient care services must be primary care services; or (2) "substantially all"<sup>29</sup> of the patient care services furnished by the NPP must be primary care services.

In order to protect against potential program and patient abuse, CMS proposed other requirements and limitations, including, for example, that the Proposed NPP Assistance Exception:

- Require that the NPP is a bona fide employee of the physician receiving the remuneration. CMS sought comments regarding whether protection should also extend to independent contractors, and what other requirements should govern such arrangements.<sup>30</sup>
- Include a cap on the amount of financial assistance from the hospital, FQHC, or RHC to the physician and include a requirement that the financial assistance be limited to the "first 2 consecutive years" of the NPP's employment. CMS proposed that the amount of remuneration be limited to the lower of:

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**TABLE 1**

Proposed Rule Summary	Final Rule Summary
Creates a new exception at 42 C.F.R. § 411.357(x) for remuneration from a hospital, FQHC or RHC to a physician to assist the physician with employing a NPP.	Finalizes with several modifications.
NPP must be an “employee.”	Expands to allow NPP to be a contractor if the contract is directly with physician/practice and does not include ownership.
NPP defined to include only PAs, NPs, CNSs, and CNMs.	Expands NPP definition to include clinical psychologists (“CPs”) and clinical social workers (“CSWs”).
NPP furnishes “primary care services.”	Expands type of services to include mental health services.
Minimum amount of “primary care services” provided by the NPP: (1) at least 90 percent of patient care services; or (2) “substantially all” of the patient care services.	Adopts the “substantially all” test.
Assistance applies only during the first two years of employment and would be capped at the lower of: (1) 50 percent of actual salary, signing bonus, and benefits; or (2) calculated amount derived by subtracting receipts attributable to services from actual salary, signing bonus, and benefits paid to the NPP.	Adopts “bright-line” approach capping the amount to 50 percent of the actual aggregate compensation, signing bonus, and benefits paid to the NPP.
NPP compensation not determined in a manner that takes into account volume/value of referrals by physician/practice or the NPP/or any NPP in practice, and does not exceed fair market value (“FMV”).	Finalizes as proposed.
Physician cannot impose unreasonable practice restriction on NPP.	Finalizes as proposed.
Frequency limitation allowing use of the exception no more than once every three years with respect to a particular physician organization, or no more than three times in the aggregate with respect to a particular physician (regardless of time period).	Adopts the three year frequency limitation, with an exception if the NPP does not remain with the physician’s practice for at least one year.
Questioned whether the exception should require that there be documented, objective need for additional primary care services in the geographic area.	No requirement finalized.
NPP must not have practiced in the geographic area within three years prior to employment.	Shortens the period from three years to within one year.
Creates definition for “referral” specific to NPP.	Finalizes proposed definition.
Arrangement set out in writing, signed by all parties, not conditioned on physician’s referrals or the NPP’s referrals.	Finalizes as proposed.
Arrangement does not violate the federal Anti-Kickback Statute (“AKS”) or any federal/state law or regulation governing billing or claims.	Finalizes as proposed.
Records of all remuneration maintained for at least six years.	Finalizes as proposed.
Proposes definition of “geographic area” for purposes of new exception to align with Physician Recruitment exception definitions applicable to hospitals, FQHCs, and RHCs.	Finalizes as proposed.

“(1) 50 percent of the actual salary, signing bonus, and benefits<sup>31</sup> paid by the physician to the nonphysician practitioner; or (2) an amount calculated by subtracting the receipts attributable to services furnished by the nonphysician practitioner from the actual salary, signing bonus, and benefits paid to the nonphysician practitioner by the physician.”<sup>32</sup> CMS noted that requiring a physician who receives assistance to employ an NPP to contribute to the costs of the NPP’s salary and benefits would limit any windfall to that physician that could influence the physician’s referrals to the hospital, FQHC, or RHC.<sup>33</sup>

- Require, like most Stark Law exceptions in 42 C.F.R. § 411.357, that the arrangement: be set out in writing and signed by the entity providing the remuneration, the physician receiving the remuneration, and the NPP; the remuneration not be conditioned on the physician’s or the NPP’s referral of patients, and not be determined (directly or indirectly) in a manner that takes into account the volume or value of any actual or anticipated referrals by the physician or NPP (or any other physician or NPP in the practice) or other business generated by the parties; the arrangement does not violate the federal AKS or any federal or state law or regulations governing billing claims submission; and records detailing the remuneration provided by the hospital, FQHC, and RHC to the physician, and by the physician to the NPP, must be maintained for a period of at least six years and be made available to the Secretary upon request.<sup>34</sup>
- Require that the aggregate salary, signing bonus and benefits paid to the NPP be consistent with FMV. However, in recognition of the changing status of many employment arrangements (e.g., full-time to part-time), CMS did not include a requirement that the compensation be set in advance.<sup>35</sup> Further,

consistent with the Physician Recruitment Exception at 42 C.F.R. § 411.357(e), CMS proposed that the physician cannot impose a practice restriction on the NPP that unreasonably restricts the NPP’s ability to provide patient care services in the geographic area served by the hospital, FQHC, or RHC.<sup>36</sup>

- Limit the exception’s applicability by preventing the hospital, FQHC, or RHC from providing financial assistance to a physician if: (1) the NPP has practiced in the geographic area served by the hospital, FQHC, or RHC within the three years prior to becoming employed by the physician; or (2) the NPP was employed or otherwise engaged by a physician with a medical office in the geographic area served by the hospital, FQHC, or RHC within the three years prior to becoming employed by the physician, even if the NPP did not provide patient care services in that office.<sup>37</sup> CMS sought to limit the Proposed NPP Assistance Exception, as it was concerned that some providers may engage in gaming by rotating or cycling NPPs through multiple physician practices located in the geographic area.<sup>38</sup>

The Proposed NPP Assistance Exception also contained a new definition of “referral,” specific only to this exception,<sup>39</sup> which is closely modeled on the general definition of referral under 42 C.F.R. § 411.351. The new proposed exception-specific definition defined the term “referral” as it relates to NPPs to include “a request by a nonphysician practitioner that includes the provision of any DHS for which payment may be made under Medicare, the establishment of any plan of care by a nonphysician practitioner that includes the provision of such DHS, or the certifying or recertifying of the need for such DHS, but not including any DHS personally performed or provided by the nonphysician practitioner.”<sup>40</sup> From a practical standpoint, this new definition of “referral” does not alter the Stark Law’s applicability, which is

triggered by physician referrals to a DHS entity. It also does not change the fact that referrals by NPPs can be imputed to a physician if such physician “controls referrals made by another person or entity.”<sup>41</sup>

In the Proposed Rule, CMS solicited comments regarding whether additional safeguards are necessary to protect against program or patient abuse that might result from arrangements covered by the Proposed NPP Assistance Exception. Examples given by CMS included whether the new exception should limit the number of times a hospital, FQHC, or RHC can assist the same physician, and whether there should be a requirement that there be a documented, objective need for additional primary care services in the geographic area serviced by the hospital, FQHC, or RHC.<sup>42</sup>

#### **The Final NPP Assistance Exception: Assistance to Compensate an NPP**

In response to the comments CMS received related to the Proposed Rule, in the Final Rule CMS finalizes, with several changes, the new NPP Assistance Exception (the “Final NPP Assistance Exception”).

As a starting point, CMS clarifies that the Final NPP Assistance Exception is a *direct* compensation exception. That is, it is available to protect a *direct* compensation arrangement between a hospital, FQHC, or RHC and a physician (including a compensation arrangement deemed to be a direct compensation arrangement because the physician stands in the shoes of his or her physician organization).<sup>43</sup> CMS makes clear that the Final NPP Assistance Exception is not available for *indirect* compensation arrangements, as parties wishing to except an indirect compensation arrangement must use the Indirect Compensation Exception at 42 C.F.R. § 411.357(p).<sup>44</sup>

In response to several commenters who requested expansion of the exception to cover assistance directly to NPPs/NPP’s practices, CMS clarifies

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(as it did in Phase III) that recruitment payments made by a hospital directly to an NPP do not implicate Stark unless the NPP serves as a conduit for physician referrals or is an immediate family member of a referring physician. CMS notes that even in a situation where the NPP joins a physician practice, if the remuneration flows “directly to” the NPP, provided that all of the remuneration from the hospital (or FQHC/RHC) remained with the NPP (*i.e.*, the physician practice does not retain any remuneration as overhead or other expense), the arrangement does not implicate Stark. CMS does caution, however, that these types of arrangements may implicate the AKS.<sup>45</sup>

In the Final Rule, in response to compelling arguments urging CMS to expand the types of services listed as “primary care services” to include mental health services, CMS expands the Final NPP Assistance Exception to permit financial assistance for the compensation of NPPs who furnish mental health services. CMS was persuaded by data and other studies that there is a high demand for mental health services and a substantial shortage of such providers.<sup>46</sup> CMS did reject several commenters’ suggestions to expand the scope of services under the exception to include specialty services, such as ongoing management of chronic conditions by specialists, or PAs or NPPs that specialize in surgical fields.<sup>47</sup> Thus, the Final NPP Assistance Exception applies to “primary care services” (*i.e.*, general or family practice, general internal medicine, pediatrics, obstetrics and gynecology, and geriatrics), and mental health services.<sup>48</sup>

As noted above, the definition of “NPP”<sup>49</sup> was originally proposed to include PAs, NPs, CNSs, and CNMs. In the Final Rule, CMS expands and finalizes the definition of NPP by also including CSWs<sup>50</sup> and CPs.<sup>51</sup> CSWs and CPs are now included in the final

definition of “NPP” because they provide mental health services. CMS specifically declined to expand the definition to include other types of providers suggested by commenters such as physical therapists, CRNAs, registered dieticians or nutritional professionals, as such professionals do not provide the types of services covered by the exception (*i.e.*, primary care and mental health).<sup>52</sup>

The Final NPP Assistance Exception is now referred to as an exception for assistance to compensate (as opposed to “employ”) an NPP. Specifically, in recognition of the fact that more flexibility was needed in allowing practitioners to be contractors and not just employees, especially in rural areas where often primary care providers are recruited from urban areas as part-time contractors, CMS expands the exception to permit assistance to a physician to employ, contract or otherwise engage an NPP under a compensation arrangement to furnish primary care or mental health services to patients of the physician’s practice. CMS believes that providing this flexibility will ultimately support the intended goal of increasing access to needed care.<sup>53</sup> However, in order to safeguard against program or patient abuse that could arise without the close nexus of an employment relationship, CMS is requiring that in situations where the NPP is an independent contractor, the contractual relationship addressing the assistance from the hospital, FQHC, or RHC must be directly between the physician (or the physician organization) and the NPP. For example, arrangements between physicians and staffing companies will not be permitted under the exception.

In the Proposed Rule CMS put forward two alternatives for establishing the minimum amount of primary care services which must be furnished by the NPP to patients of the practice (*i.e.*, at least 90 percent or

“substantially all”). CMS agreed with commenters that a “substantially all” standard is the appropriate standard. Thus, the Final NPP Assistance Exception requires that substantially all (which is defined to mean at least 75 percent) of the patient care services furnished by the NPP must be primary care or mental health services.<sup>54</sup> Further, to ensure consistency in CMS regulations, CMS is requiring that “patient care services” be measured by one of the following: (1) the total time the NPP spends on patient care services documented by any reasonable means (including, but not limited to time cards, appointment schedules, or personal diaries); or (2) any alternative measure that is reasonable, fixed in advance of the performance of the services being measured, uniformly applied over time, verifiable and documented.<sup>55</sup>

With respect to the cap on the amount of assistance allowed under the new exception, in the Final Rule CMS agrees with many commenters that a clear objective standard would best serve the interest of the hospitals, FQHCs, and RHCs that provide assistance to physicians to compensate NPPs. CMS notes that establishing a clear standard will also help facilitate compliance with Stark (which CMS states is a primary purpose of certain updates in the Final Rule). Thus, CMS adopts what it calls a “bright-line” approach that permits a hospital, FQHC, or RHC to provide assistance to a physician an amount that does not exceed 50 percent of the actual aggregate compensation, signing bonus, and benefits paid to the NPP who joins the practice. CMS abandoned its previous proposal which included a cap at the lower of 50 percent or “receipts minus salary, signing bonus, and benefits” methodology.<sup>56</sup> Consistent with the Proposed Rule, in the Final Rule CMS does not include a set in advance requirement, as CMS does not consider it necessary because the Final NPP Assistance Exception

requires that the compensation paid to the NPP by the physician not exceed FMV and the assistance is capped at 50 percent.<sup>57</sup> Further, “benefits” under the Final NPP Assistance Exception will be interpreted as proposed to “include only health insurance, paid leave, and other routine non-cash benefits offered to similarly situated employees of the practice.”<sup>58</sup> In response to a commenter, CMS acknowledges that a hospital, FQHC, or RHC could provide remuneration to the physician to cover relocation costs of the NPP if such costs are included in the calculation of aggregate compensation, signing bonus, and benefits paid to the NPP (and all other requirements of the exception are met).<sup>59</sup>

Further, in the Final Rule CMS maintains its proposal to limit the financial assistance to the “first 2 consecutive years” of the NPP’s compensation arrangement<sup>60</sup> with the physician/practice. In response to commenters requesting a three-year assistance period, CMS rejects expanding the time period, noting that the exception is intended to promote beneficiary access to care and support the goals of healthcare delivery and payment reform. CMS believes that limiting the amount of time that a hospital, FQHC, or RHC can provide assistance remuneration to two years (as opposed to the requested three years) reduces risks of abuse.<sup>61</sup>

Similarly, CMS also finalized a three-year frequency limitation on a hospital’s, FQHC’s, or RHC’s use of the NPP Assistance Exception with a particular physician organization. CMS believes that the two-year limit on remuneration assistance is necessary to prevent abuse; likewise, CMS believes that the three year frequency limitation also limits abuse.<sup>62</sup> Several commenters expressed various concerns that a three-year frequency limitation could undermine the goal of the exception – so, although CMS in the Final Rule adopts the three-year frequency limitation, CMS also finalizes an exception to the frequency limitation to permit a hospital, FQHC,

or RHC to provide assistance to a physician more than once every three years in the event that an NPP from whom the physician received assistance (the original NPP) did not remain with the practice for one year or more. The three-year period begins on the date that the hospital, FQHC, or RHC initially provided the remuneration to the physician. Under the Final NPP Assistance Exception, the hospital, FQHC, or RHC may provide assistance to the physician to compensate a second (or subsequent) NPP, so long as: (1) the aggregate compensation from the hospital, FQHC, or RHC does not exceed 50 percent of the actual compensation, signing bonus, and benefits paid to the replacement NPP; and (2) the assistance is limited to the consecutive two-year period that begins on the date the original NPP commenced employment or a contractual arrangement with the physician/practice.<sup>63</sup>

As noted above, in the Proposed NPP Assistance Exception, in order to prevent gaming by rotating or cycling NPPs through multiple practices located in the geographic area, CMS originally proposed a so-called “disqualification period” for NPPs that had practiced in the geographic area served by the hospital, FQHC, or RHC within the three years prior to being employed by the practice; or for NPPs that were otherwise employed or engaged by a physician with an office in the geographic area served by the hospital, FQHC, or RHC within three years prior to beginning employment by the assisted-physician. In response to several commenters’ concerns with the three-year disqualification period, CMS finalizes a shorter one-year disqualification period. Specifically, the Final NPP Assistance Exception will not be available unless the NPP, within one year of being compensated by the physician (or physician organization): (1) has not practiced in the geographic area served by the hospital, FQHC, or RHC providing the assistance; and (2) has not been

employed or otherwise engaged to provide patient care services by a physician or physician organization that has a medical practice in the geographic area served by the hospital, FQHC, or RHC providing assistance, regardless of whether the NPP furnished services at the medical practice site located in the geographic area served by the hospital, FQHC, or RHC.<sup>64</sup> CMS believes that a disqualification period is important to protect against potential patient or program abuse but agreed with commenters that a shorter disqualification period was more appropriate to ensure that the goals of the exception can be achieved.

CMS also finalizes the definition of “referral” for purposes of the exemption as it was proposed.<sup>65</sup>

In summary, after careful consideration, in recognition of the ever-changing healthcare delivery models and severe shortage of access to primary care and mental health services, CMS finalizes a new exception designed to permit hospitals, FQHCs, and RHCs to provide remuneration to physicians so that they can compensate an NPP who will provide primary care or mental health services to patients in the practice.

## **New Exception — Timeshare Arrangements (42 C.F.R. § 411.357(y))<sup>66</sup>**

*(See Table 2 on page 8)*

### **Timeshare Arrangements Exception – The Proposed Rule**

In the Proposed Rule, CMS detailed a new exception for timeshare arrangements that meet certain criteria, including, but not limited to that “the arrangement is between a hospital or physician organization (licensor) and a physician (licensee) for the use of the licensor’s premises, equipment, personnel, items, supplies, or services...used predominantly to furnish evaluation and management services.”<sup>68</sup> Throughout Stark’s regulatory history, regulators and commentators

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TABLE 2

Proposed Rule Summary	Final Rule Summary
The arrangement must be in writing, signed by the parties, and specify the premises, equipment, personnel, items, supplies and services covered by the arrangement.	Finalizes as proposed.
The arrangement must be between a hospital or physician organization as <i>the licensor</i> , and a physician as <i>the licensee</i> for the use of the licensor’s premises, equipment, personnel, items, supplies, or services.	The arrangement must be between a hospital/physician organization and a physician, <i>but either may be the licensor/grantor or the licensee/grantee. The essential requirement is that the permission to use the premises, equipment, personnel, items, supplies, or services not include the transfer of a possessory leasehold interest in (i.e., dominion or control over) the property.</i>
The licensed premises, equipment, personnel, items, supplies, and services must be used <i>predominantly</i> to furnish evaluation/management (“E/M”) services to the physician-licensee’s patients.	Finalizes as proposed. <i>No definition of “predominantly” offered.</i>
Any equipment covered by the arrangement must: <ol style="list-style-type: none"> <li>1. Be located in the same office suite where the physician performs the E/M services;</li> <li>2. Be used only to furnish DHS that is incidental to the physician’s E/M services and furnished at the same time as those services;</li> <li>3. Not be advanced imaging, radiation therapy, or clinical or pathology laboratory equipment (other than for CLIA-waived laboratory tests).<sup>67</sup></li> </ol>	Any equipment covered by the arrangement must: <ol style="list-style-type: none"> <li>1. Be located in the same <i>building</i> where the physician performs the E/M services;</li> <li>2. Be used only to furnish DHS that is incidental to the physician’s E/M services and furnished at the same time as those services;</li> <li>3. Not be advanced imaging, radiation therapy, or clinical or pathology laboratory equipment (other than for CLIA-waived laboratory tests).</li> </ol>
The arrangement must not be conditioned on the licensee-physician’s referral of patients to the licensor.	Finalizes as proposed.
The compensation over the term of the arrangement must be set in advance, consistent with FMV, and not determined in a manner that takes into account (directly or indirectly) the volume or value of referrals or other business generated between the parties.	Finalizes as proposed. <i>Usage-based formulas (e.g., per-click, per-patient, revenue-based) not allowed under CMS’ authority to protect against program or patient abuse pursuant to § 1877(b) of the Act.</i>
The arrangement must be commercially reasonable even if no referrals were made between the parties.	Finalizes as proposed.
	Adds the requirement that all locations under the timeshare arrangement, including the premises where E/M services are furnished and the premises where DHS are furnished, <i>must be used on identical schedules.</i>

alike have grappled with which Stark exception should apply to timeshare arrangements – and if timeshare arrangements should qualify for any protection at all. Up until now, many timeshare arrangements have been unable to find protection under the current Stark exceptions.

For example, timeshare arrangements sometimes cannot meet the

“exclusive use” requirement of the “rental of office space” exception<sup>69</sup> (i.e., the rented space must not be shared with or used by the lessor or any other person or entity related to the lessor during the rental period).<sup>70</sup> Additionally, CMS has been unwilling to entertain proposals for timeshare arrangements to fall under the “payments by a physician” exception<sup>71</sup>

(which, in part, allows physician payments made as compensation for items or services furnished at FMV), or the “FMV” exception (which allows FMV compensation to be paid to physicians or their immediate family members for services furnished to a DHS entity, and vice versa).<sup>72</sup> In the 1998 proposed rule,<sup>73</sup> CMS precluded the use of the “payments by a physician” exception



for timeshare arrangements when it stated that Congress did not intend the term “service” as used in the exception to encompass the rental of office space because there was already an exception for the rental of office space.<sup>74</sup> Later, CMS refused to offer protection under the “FMV” exception for office space lease arrangements.<sup>75</sup> Instead, CMS stated that the rental of office space exception was the only appropriate exception for those arrangements.<sup>76</sup>

CMS’ shift in the Proposed Rule stems, at least in part, from information CMS gathered through the SRDP and from other stakeholder inquiries related to certain arrangements for the *license* of premises, equipment, personnel, items, supplies or services by a physician that do not fit into a traditional office space lease arrangement.<sup>77</sup> CMS found that, although these arrangements sometimes did not meet the requirements of the “rental of office space” exception, the arrangements served a legitimate purpose nonetheless and could be “structured in a way that does not pose a risk of program or patient abuse.”<sup>78</sup>

In delineating the scope of the term “timeshare arrangements,” CMS explained the difference between a *license* and a *lease*.<sup>79</sup> According to CMS, in many but not all instances, a *license* merely allows a licensee to *use* the property of the licensor without transferring dominion or control over the property to the licensee.<sup>80</sup> On the other hand, a *lease* transfers *dominion* and *control* over the property from the lessor to the lessee – thereby giving the lessee exclusive use<sup>81</sup> of the property.<sup>82</sup> In the new timeshare exception, CMS sought to afford protection to timeshare *license-type* arrangements, which often cannot meet the “exclusive use” or “one-year term” requirements of the “rental of office space” exception.<sup>83</sup> However, traditional lease arrangements and exclusive use arrangements are not afforded protection under the new exception, and must continue to meet the criteria of the “rental of

office space” exception so as to not run afoul of Stark.<sup>84</sup>

CMS hypothesized that the new exception may be used by hospitals or practices in rural or underserved areas that have a need for specialty services on a part-time or “as needed” basis, or by a new or relocating physician starting a medical practice.<sup>85</sup> In order to qualify for the exception, CMS proposed that the timeshare arrangements must meet certain criteria, including that:

1. The arrangement be in writing, signed by the parties, and specify the premises, equipment, personnel, items, supplies and services covered by the arrangement;
2. The arrangement be between a hospital or physician organization *as the licensor*, and a physician *as the licensee* for the use of the licensor’s premises, equipment, personnel, items, supplies, or services;
3. The licensed premises, equipment, personnel, items, supplies, and services be used *predominantly* to furnish E/M services to the physician-licensee’s patients;
4. Any equipment covered by the arrangement must:
  - Be located in the same office suite where the physician performs the E/M services;
  - Be used only to furnish DHS that is incidental to<sup>86</sup> the physician’s E/M services and furnished at the same time as those services;
  - Not be advanced imaging, radiation therapy, or clinical or pathology laboratory equipment (other than for CLIA-waived laboratory tests);
5. The arrangement not be conditioned on the licensee-physician’s referral of patients to the licensor;
6. The compensation over the term of the arrangement be set in advance, consistent with FMV, and not determined in a manner that takes into account (directly or indirectly) the volume or value of

referrals or other business generated between the parties;

7. The arrangement be commercially reasonable even if no referrals were made between the parties; and
8. The arrangement not violate the AKS or any other federal or state law or regulation governing billing or claims submission.<sup>87</sup>

In order to protect against fraud and abuse, CMS proposed that the exception not be available to clinical laboratories, diagnostic testing facilities, or other DHS entities that are not hospitals or physician organizations.<sup>88</sup> CMS believed that allowing clinical laboratories or diagnostic testing facilities to license space and other items under this exception would pose a “heightened level” of fraud and abuse due to the likelihood that referrals between the laboratory/facility and the licensee-physician would increase as a result of the shared office space.<sup>89</sup> Additionally, CMS limited this exception to situations where the licensee-physician predominately furnishes E/M services in the office space, and not solely or primarily DHS.<sup>90</sup> Similarly, the licensed equipment must be used for DHS that is incidental to the E/M services (*e.g.*, x-rays, rapid strep tests, urine dipstick tests for pregnancy diagnoses) as opposed to other DHS such as advanced imaging or radiation therapy.<sup>91</sup> CMS also noted that the compensation under the arrangement must be based on time (*e.g.*, hours or days) rather than based on the number of patients or amount billed or collected for the services.<sup>92</sup>

#### **Timeshare Arrangements Exception – The Final Rule**

In the Proposed Rule, CMS solicited comments on: (i) whether the exception was broad enough to improve access to care; (ii) whether DHS entities other than hospitals and physician organizations should be allowed to enter into timesharing arrangements; (iii) whether the exception should

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apply if the licensor is a physician who refers DHS to the licensee; (iv) how to define “predominantly” with regard to the requirement that the licensee use the licensed premises predominantly for E/M services; (v) whether the licensed equipment should be required to be in the same office suite or just in the same building as where the E/M services are furnished; (vi) whether to allow the license of equipment without the simultaneous license of office space; and (vii) whether it is necessary to limit the compensation calculation method to a time-based calculation (as opposed to per-click or usage-based calculations). After reviewing the comments, CMS adopts the new exception in the Final Rule with four major modifications.<sup>93</sup>

First, in the Final Rule CMS further clarifies what it means by a timeshare arrangement. While in the Proposed Rule CMS in part focused on whether an arrangement provides for “exclusive use,” CMS clarifies in the Final Rule that the timeshare exception only applies to arrangements where permission to use the premises, equipment, personnel, items, supplies, or services is granted “without establishing a possessory leasehold interest (akin to a lease) in the medical office space that constitutes the premises.”<sup>94</sup> The exception will not be available for “arrangements that transfer control — that is, a ‘right against the world’ — over the premises” from the licensor to the licensee.<sup>95</sup> However, CMS leaves open the possibility that, depending on the specific facts, some “exclusive use” arrangements or arrangements with a term of one year or more may qualify for protection under the timeshare exception.<sup>96</sup>

Additionally, to avoid confusion with other laws or concepts that use the terms “license,” “licensor” and “licensee,” in the Final Rule CMS opts for the term “grant” and uses the

terms “grantor” or “party granting permission” for the party granting the right or permission to use its premises, equipment, personnel, items, supplies, or services.<sup>97</sup> CMS clarifies that the terms used in the arrangement’s written documentation (e.g., lease, license, grant, etc.) do not control whether the arrangement meets the exception.<sup>98</sup> Instead, one must look to the facts and circumstances to determine if there is compliance with the exception’s requirements.<sup>99</sup>

CMS emphasizes that the imperative requirement (albeit not the only requirement) of the new exception is that a “permission to use” is granted *without granting a possessory leasehold interest*.<sup>100</sup> That being said, CMS warns against potentially abusive arrangements that may be structured to fit within the four corners of the exception, but which CMS does not intend to protect. These include: “arrangements that essentially function as full-time leases for medical practice sites; arrangements in which physicians are selected or given preferred time slots based on their referrals to the party granting permission to use the premises, equipment, personnel, items, supplies, or services; or consecutive short-term arrangements that are modified frequently in ways that take into account a physician’s referrals.”<sup>101</sup>

Second, while the Proposed Rule only allowed the hospital or physician organization to be in the role of “licensor/grantor” and the physician to be in the role of “licensee/grantee,” the Final Rule allows the exception to apply “regardless of which party grants and which party receives permission to use the premises, equipment, personnel, items, supplies, and services of the other party.”<sup>102</sup> Nevertheless, the arrangement must be between a physician (or the physician organization in whose shoes the physician stands under 42 C.F.R. § 411.354(c)), on the one hand, and either a hospital or a

physician organization of which the physician is not an owner, employee or contractor, on the other.<sup>103</sup> After reviewing the comments, CMS concludes that it would not pose a risk of fraud and abuse to permit hospitals or physician organizations to be the “grantee” (i.e., the party to whom the use of the premises, equipment, personnel, items, supplies, or services is granted).<sup>104</sup> For example, some commenters noted that hospitals employ physicians and, therefore, hospitals (and physician organizations/corporations) should be able to sign as the grantee under the timeshare arrangement, and CMS agreed.<sup>105</sup> However, CMS found no justification for extending protection under the exception to other types of DHS entities (e.g., laboratories or diagnostic testing facilities).<sup>106</sup>

Third, the Final Rule loosens the restriction on the location of the licensed equipment. While the Proposed Rule required that the equipment be located in the same *office suite* where the E/M services are furnished, the Final Rule states that the equipment may be located in the same *building*<sup>107</sup> where the E/M services are furnished.<sup>108</sup> Additionally, CMS made a slight modification to the regulatory text of the new exception to clarify that the DHS furnished on the licensed equipment must be *both* incidental to the E/M services *and* furnished at the time the E/M service is furnished.<sup>109</sup>

Fourth, although the equipment need not be in the same office suite (only in the same building) where the E/M services are furnished, in order to combat fraud and abuse, the Final Rule introduces a new requirement that “all locations under the timeshare arrangement, including the premises where E/M services are furnished and the premises where DHS are furnished, must be used on *identical schedules*.”<sup>110</sup> CMS in the Final Rule makes this change to prevent

entities from allowing flexible use of the DHS portion only (hence, not paying for the E/M portion of the space/equipment/services), consistent with the focus on E/M services being provided in the timeshare.

Although CMS hopes that the timeshare exception will increase access to care in rural and underserved locations, CMS clarifies that the exception is not limited to those locations.<sup>111</sup> However, the commenters did not convince CMS to loosen the limitation that the DHS furnished on the licensed equipment must be incidental to the E/M services furnished at the same visit.<sup>112</sup> CMS explains that the purpose of the new exception is to increase access to care and outcomes for beneficiaries – “not to facilitate the ability of physicians to furnish a full array of DHS in supplemental medical practice sites.”<sup>113</sup>

Similarly, and not surprisingly, CMS would not budge on its requirement that the compensation formula not be based on per-click, per-patient or revenue-based formulas.<sup>114</sup> Such usage-based formulas “present a risk of program or patient abuse because they may incentivize overutilization and patient steering,” according to CMS.<sup>115</sup> For example, if the grantee-physician pays the grantor for the use of the office space, equipment, personnel, items, supplies, or services based on how many patients he or she sees in a day, then the grantor will have an incentive to refer more patients to the grantee.<sup>116</sup> Instead, flat-fee or time-based formulas should be used, and CMS does not prescribe a minimum amount of time for the time-based formulas.<sup>117</sup> It should also be noted that CMS only precludes the use of usage-based fees “to the extent that such fees reflect services furnished to patients referred by” the grantor to the grantee-physician.<sup>118</sup>

CMS also addresses the recent D.C. Circuit Court decision in *Council for Urological Interests v. Burwell*.<sup>119</sup> By way of background, in 2009 CMS established a prohibition against

per-click compensation formulas under the “rental of equipment” exception.<sup>120</sup> In establishing this prohibition, CMS referenced legislative history discussing the requirement that the equipment rental rate not be determined in a manner that takes into account the volume or value of referrals.<sup>121</sup> However, CMS ultimately based its authority to establish the prohibition, not on this legislative history, but on its authority to promulgate “other requirements” under Section § 1877(e)(1)(B)(vi) of the Act.<sup>122</sup> The court in *Council for Urological Interests v. Burwell* agreed that CMS has authority to prohibit per-click formulas under Section § 1877(e)(1)(B)(vi) of the Act because the “text of the statute does not unambiguously preclude the Secretary from using her authority to add a requirement that bans per-click leases.”<sup>123</sup> The court also stated that the legislative history did not preclude CMS from imposing additional requirements.<sup>124</sup> However, in the Final Rule, CMS notes that the court in *Council for Urological Interests v. Burwell* held that CMS’ interpretation of the legislative history was arbitrary and capricious, and the case was remanded to the agency to permit a fuller consideration of the legislative history.<sup>125</sup> Therefore, in the Final Rule, CMS is careful to clarify that its prohibition of per-click compensation formulas under the timeshare exception is based on its authority to protect against program or patient abuse pursuant to Section § 1877(b)(4) of the Act.

CMS also clarifies that the establishment of the timeshare exception “is not intended to call into question the compliance of any prior or existing arrangement or type of arrangement involving the use of office space, equipment, personnel, items, supplies, or services.”<sup>126</sup> Depending on the specific facts and circumstances, an arrangement may meet both the timeshare exception and, for example, the rental of office space exception.<sup>127</sup> It is CMS’ belief that timeshare arrangements often do not meet the “exclusive

use” requirement of the “rental of office space” exception, but CMS does not rule out the possibility that some timeshare arrangements may meet those requirements.<sup>128</sup> This is an important statement by CMS. In the Proposed Rule there were unartful statements in some, but not all, of the discussions of the timeshare exception that indicated that CMS thought merely using the word “license” or the like meant that the arrangement would not qualify for an exception.<sup>129</sup> This, of course, is inaccurate – a party could call a compliant block lease a sub-license so long as all applicable exception requirements are met (e.g., exclusivity).<sup>130</sup>

Perhaps the biggest challenge in structuring or scrutinizing arrangements for compliance with the new timeshare exception will be that CMS declined to define the term “predominantly.”<sup>131</sup> As mentioned above, the new exception requires that the licensed office space, equipment, personnel, items, supplies, and services be used *predominantly* to furnish E/M services to the physician-grantee’s patients. CMS reasons that defining the term “predominantly” could “inadvertently narrow the exception or constrain parties to a timeshare arrangement.”<sup>132</sup> Instead, parties “may determine predominant use through any reasonable, objective, and verifiable means, which, depending on the circumstances, may include assessing the volume of patients seen, the number of patient encounters, the types of CPT codes billed, or the amount of time spent using the timeshare premises, equipment, personnel, items, supplies, and services.”<sup>133</sup> Parties to a timeshare arrangement should be aware of this compliance requirement, which does not appear on the face of the regulatory text of the new exception.

The new exception evidences CMS’ willingness to enact exceptions to protect legitimate arrangements that increase access to care while still protecting against fraud and abuse. Given the need for hospitals to enable

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physicians to perform services on a short-term, non-exclusive use basis, the new exception is a welcome addition to the Stark exceptions. CMS put it best when it said that the new exception promotes “access to needed services and provide[s] parties with an option for structuring arrangements in the way that best suits the needs of the parties and the community in which the timeshare arrangement is located.”<sup>134</sup>

## Definition of “Geographic Area Served” by FQHCs and RHCs<sup>135</sup>

Under the existing Stark Law physician recruitment exception, FQHCs and RHCs, in addition to hospitals, can provide physicians and physician practices with monetary recruitment assistance in order to induce new providers to relocate to the entities’ geographic service area. Current regulations, however, lacked guidance with regard to how FQHCs and RHCs (as opposed to hospitals) determine the “geographic area into which such an entity may recruit a physician.”<sup>136</sup> Thus, in order to correct the regulations’ previous omission, in the Proposed Rule CMS introduced two (2) potential approaches to define the geographic area served by a FQHC or RHC:

1. The first proposed approach would have defined the geographic area served by a FQHC or RHC as “the area composed of the lowest number of contiguous zip codes from which the FQHC or RHC draws at least 90 percent of its patients, as determined on an encounter basis.”<sup>137</sup>
2. The second proposed approach defines the geographic area served by a FQHC or RHC as the area composed of the “lowest number of contiguous or noncontiguous zip codes from which the FQHC or RHC draws at least 90 percent of

its patients, as determined on an encounter basis.”<sup>138</sup>

In the Final Rule CMS adopts/modifies the second approach, noting that it sees no potential for program or patient abuse in selecting noncontiguous zip codes.<sup>139</sup> The Final Rule, based on comments received, adds the following to the Proposed Rule: “The geographic area served by the federally qualified health center or rural health clinic may include one or more zip codes from which the federally qualified health center or rural health clinic draws no patients, provided that such zip codes are entirely surrounded by zip codes in the geographic area described above from which the federally qualified health center or rural health clinic draws at least 90 percent of its patients.”<sup>140</sup> This allowance of the “hole” zip code provision is similar to CMS’ approach allowing the same for hospitals. CMS notes that it sees no risk of program or patient abuse in doing so.<sup>141</sup> Comments on the Proposed Rule also indicated that, given lack of knowledge of the exception and financial issues, FQHCs and RHCs do not widely utilize the recruitment exception; CMS noted that it will consider ways to provide better outreach to FQHCs and RHCs regarding Stark and its exceptions.<sup>142</sup>

## Use of “Takes Into Account” Terminology to Describe the Volume or Value Standard<sup>143</sup>

In the Proposed Rule, CMS recognized that numerous Stark Law exceptions contain differing verbiage when describing the “volume or value” standard of a physician’s referrals, but that the statutory Stark language is consistent that compensation cannot be determined in a manner that “takes into account” the volume or value of a physician’s referrals.<sup>144</sup> For

instance, select exceptions refer to compensation not being “based on,”<sup>145</sup> or “without regard to,” the volume or value of referrals,<sup>146</sup> which, according to CMS in the Proposed Rule, could lead reasonable individuals to believe that there are differing meanings that apply to different exceptions/Stark Law scenarios. Nevertheless, in both the Proposed and Final Rules, CMS states that its longstanding policy is to interpret the volume or value standard uniformly (e.g., regardless of whether the prefatory text says “based on” or “without regard to”).<sup>147</sup> This is an important clarification, indicating that providers/suppliers and their attorneys should apply the uniform standard for Stark Law analysis of relationships predating the effective date of the Final Rule.

In the Proposed Rule, CMS proposed to standardize the various terms (e.g., “based on” or “without regard to”) used to refer to the principle that volume or value of referral standard is uniform in the Stark exceptions – entities may not “take into account” the volume or value of referrals.<sup>148</sup> CMS adopted this change in the Final Rule, and makes several clarifying revisions to the Stark Law compensation exceptions at 42 C.F.R. § 411.357 to reflect the standardization.

Of interest in the Final Rule is CMS’ reticence to address particular comments requesting more specificity as to the meaning of what “takes into account” volume or value of referrals means, and questioning the meaning of “takes into account” in relation to the phrase “varies with” volume or value of referrals.<sup>149</sup> CMS’ reticence here is particularly troubling in light of the unwieldiness and multiple interpretations possible with these definitions, as best illustrated by the 4th Circuit decision in *United States ex. rel. Drakeford v. Tuomey Healthcare System, Inc.*<sup>150</sup> There, the court found that a reasonable jury could have found that the *Tuomey* contracts compensated



physicians in a manner that varied with the volume or value of referrals, since “the more procedures the physicians performed at the hospital, the more facility fees *Tuomey* collected and the more compensation the physicians received in the form of increased base salaries and productivity bonuses.”<sup>151</sup> In other words, the court said that personal productivity payments for personally performed services varied with volume/value since there was an associated facility fee/technical component billed along with the professional fee.<sup>152</sup> However, a physician’s personally performed services are *explicitly* carved out of the definition of “referral” in the Stark Law regulations, and the settled interpretation prior to *Tuomey*, and still the correct interpretation based upon the plain text of Stark, is that payments to a physician for personally performed services do not vary with or take into account the physician’s referrals. With *Tuomey*’s *contra* incorrect (on this issue) ruling, such payments for personally performed professional services can be viewed as suspect. CMS, unfortunately, has left the healthcare community without definitive guidance on this conundrum in the Final Rule.

### Clarification of CMS’ Policy Regarding Retention Payments in Underserved Areas<sup>153</sup>

In the Proposed Rule, CMS stated that there was inadvertent confusion in the regulatory text excepting retention payments made to a physician with a practice located in an underserved area.<sup>154</sup> To correct the regulatory language, CMS proposed to change the exception to clarify CMS’ policy, which CMS originally articulated in 2007 in the preamble of 72 Fed. Reg. 51066 (Stark Phase III). There, CMS stated that a retention payment based on a physician certification may “not exceed the lower of the following: (1) An amount equal to 25 percent of

the physician’s current annual income (averaged over the previous 24 months) using a reasonable and consistent methodology that is calculated uniformly; or (2) the reasonable costs the hospital would otherwise have to expend to recruit a new physician to the geographic area served by the hospital in order to join the medical staff of the hospital to replace the retained physician.”<sup>155</sup> The text of the current retention exception regulations, however, essentially allows for an interpretation where entities could consider only a portion of the prior 24 months (allowing, potentially, for “goosing” the amount paid), as opposed to the entire 24 months, when calculating retention incentive amounts. Thus, CMS proposed to modify the regulations at 42 C.F.R. § 411.357(t)(2)(iv) (A) to incorporate its intent articulated in the Phase III commentary.<sup>156</sup>

CMS adopted the Proposed Rule’s revisions in the Final Rule, with essentially no new commentary.

### “Arrangements” In Writing – Clarifications/Revisions to the In Writing Requirements and Signature Rules<sup>157</sup>

Many Stark exceptions require that arrangements be documented in writing. In administering the SRDP, CMS learned that there was considerable uncertainty as to whether, for the purposes of these exceptions, an arrangement must be reduced to a single “formal” all-encompassing written contract.<sup>158</sup>

In both the Proposed and Final Rules, CMS confirms that there is no requirement under the Stark Law that mandates that “an arrangement be documented in a *single* formal contract.”<sup>159</sup> Rather, “a collection of documents, including contemporaneous documents evidencing the course of conduct between the parties, may satisfy the writing requirement.”<sup>160</sup> Of course, in most instances a single

written document memorializing the key facts and business terms is optimal; however, CMS indicates that it is okay if an arrangement is “sufficiently documented to permit the government to verify compliance with the applicable exception.”<sup>161</sup>

Thus, in order to *clarify* that no single formal contract is required, and to establish uniformity among the various Stark exceptions, in the Proposed Rule CMS sought to replace numerous references to “contract” or “contracted for” or “agreement” in applicable Stark regulatory exceptions with the term “arrangement,” and replacing the phrase “written contract”<sup>162</sup> with “writing.”

The Final Rule confirms the Proposed Rule, and goes so far as to state that the foregoing is CMS’ “existing policy,” and that “[p]arties considering submitting self-disclosures to the SRDP for conduct that predates the proposed rule may rely on guidance provided in the proposed rule” on the writing issue.<sup>163</sup> CMS, in the Final Rule comments, promulgates a “reasonable person” standard, based on compliance with the exception at the time that the referral was made:

To determine compliance with the writing requirement, the relevant inquiry is whether the available contemporaneous documents (that is, documents that are contemporaneous with the arrangement) would permit a reasonable person to verify compliance with the applicable exception at the time that a referral is made.<sup>164</sup>

On occasion, documents are created after the arrangement between the parties has begun. However, the written documents may only be relied upon for referrals made after the documents were created – but not for referrals that predate the document.<sup>165</sup> Similarly, CMS clarifies that:

Parties cannot meet the set in advance requirement from the inception of an arrangement if the only documents stating the

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compensation term of an arrangement were generated after the arrangement began; however, depending on the facts and circumstances, if parties create contemporaneous documents during the course of the arrangement, and the documents set the compensation out in writing, then parties may be able to satisfy the set in advance requirement for referrals made after the contemporaneous documents are created.<sup>166</sup>

Interestingly, in the Final Rule CMS declines a request to rely on state contract law regarding what constitutes a binding and enforceable contract. For Stark purposes, since state contract law might vary on the issue, CMS did not want a multitude of standards, and instead wants providers/suppliers to utilize the standards related to arrangements in writing promulgated in the Proposed and Final Rules.<sup>167</sup> CMS does, however, allow for parties to utilize state law principles to inform the analysis at whether an arrangement is set out in writing.<sup>168</sup> CMS also states an intuitive matter – that the written arrangement must match the actual arrangement:

Nothing prevents a party from drawing on State law contract principles, as well as other bodies of relevant law, to inform the analysis of whether an arrangement is set out in writing. The important point is this: what determines compliance with the writing requirement of the physician self-referral law is not whether the writings form a valid and enforceable contract under State law, but rather whether the contemporaneous writings would permit a *reasonable person* to verify that the arrangement complied with an applicable exception at the time a referral is made. For this reason, a written contract that

is enforceable under State law may not satisfy the writing requirement if the actual arrangement differed in material respects from the terms and conditions of the written contract.<sup>169</sup>

CMS then goes on to make a similar comment in the Final Rule regarding signatures –

We do not believe that State law principles determine compliance with the [Stark Law]. Regarding the signature requirement as it relates to a collection of documents...parties also do not need to sign a *single* formal written contract to comply with the signature requirement of an applicable exception. Nor do we expect every document in a collection of documents to bear the signature of one or both parties. To satisfy the signature requirement, a signature is required on a contemporaneous writing documenting the arrangement. The contemporaneous signed writing, when considered in the context of the collection of documents and the underlying arrangement, must *clearly relate to the other documents in the collection and the arrangement underlying that the party is seeking to protect*.<sup>170</sup>

This statement by CMS, and CMS' disallowance of state law principles in interpreting Stark for some, but not all, purposes is somewhat problematic. For instance, prior to the Final Rule, CMS had never issued guidance on what exactly a "signature" is (so, signature, like many other Stark terms, remains undefined). This has forced providers/suppliers to look to other state and federal laws regarding the same. Is typing your name in an email, or in a fill-in box on a website, a signature? Under the Federal Electronic Signatures in Global and National Commerce Act and state Uniform Electronic Transactions Act laws (adopted by most states), the

answer is often "yes".<sup>171</sup> Stark, prior to the Final Rule, had no good answer to this question. However, later in the Final Rule, CMS gives a tentative "yes" to using federal and state laws to interpret what a signature is, stating that "parties may look to State law and other bodies of relevant law, including Federal and State law pertaining to electronic signatures, to inform the analysis of whether a writing is signed for the purposes of the physician self-referral law. Given evolving technologies, we are concerned that a prescriptive statement on our part regarding electronic signatures may unduly limit parties' ability to comply with the physician self-referral law in the future."<sup>172</sup> It remains to be seen how the tension between Stark's undefined terms, and interpretation of the same using state and federal laws, will play out in the future.

Finally, in response to a comment requesting a grace period (CMS denied the request), CMS published an extremely cogent and important recitation of its guidance, worth quoting in its entirety due to how well it encapsulates several core concepts and issues, such as the timing for when protections from a Stark exception take effect, and how the set in advance requirements work in the context of the "arrangement in writing" guidance:

For this reason, we believe that a grace period for the writing requirement poses a risk of program or patient abuse. For example, to the extent that the rate of compensation is not documented before a physician provides services to a DHS entity, the entity could adjust the rate of compensation during the proposed grace period in a manner that takes into account the volume or value of the physician's referrals. In this context, we note that the special rule at

§ 411.353(g)(1) for temporary noncompliance applies only to noncompliance with the signature requirement of an applicable exception. All other elements of an applicable exception, including the applicable writing requirement, must be satisfied once a compensation arrangement between the parties is established (that is, as soon as items, services, or compensation under the arrangement passes between the parties) and the physician makes referrals to the DHS entity. We remind parties that DHS entities have the burden of proof to establish that services were not furnished as a result of prohibited referrals, and that all requirements of an exception must be met at the time a referral is made. (See § 411.353(c)(2)(i) and 73 FR 48703.) If an arrangement with a physician fails to comply with the writing requirement of an applicable exception when the arrangement commences, then the entity is not permitted to bill for DHS furnished as a result of the physician's referrals unless and until the arrangement is sufficiently documented over the course of the arrangement (and all other requirements of the applicable exception are met). Contemporaneous documents evidencing the course of conduct between the parties cannot be relied upon to protect referrals that predate the documents. Likewise, parties cannot meet the set in advance requirement from the inception of an arrangement if the only documents stating the compensation term of an arrangement were generated after the arrangement began; however, depending on the facts and circumstances, if parties create contemporaneous documents during the course of the arrangement, and the documents set the compensation out in writing, then parties may be able to satisfy the set in advance requirement for referrals made after the contemporaneous

documents are created. We reiterate that the surest and most straightforward means of complying with the writing requirement of the physician self-referral law is to reduce the key facts of an arrangement to a single signed writing before either party provides items, services, space, or compensation to the other party under the arrangement.<sup>173</sup>

CMS' Proposed and Final Rules on the writing issue are an extremely welcome confirmation of a "defensive Stark" position that numerous health-care attorneys have advocated over the years. Thus, CMS states that, depending on the circumstances, "a collection of documents, including contemporaneous documents evidencing the course of conduct between the parties, may satisfy the writing requirement."<sup>174</sup> CMS cautions that a writing is still required (for instance, to ensure that "compensation . . . is set in advance, the rate of compensation must be documented in writing *before* the services are performed"), but CMS expressly clarifies that the regulations do not require a specific kind of writing, such as a single formal contract.<sup>175</sup> CMS includes a non-exhaustive list of examples of collections of documents that *could* satisfy the writing requirement.<sup>176</sup>

This is one of the numerous provisions in the Final Rule where CMS indicates a more flexible approach to the Stark Law's technical requirements.

### Clarification of the One-Year Term Requirement<sup>177</sup>

In the Proposed Rule, CMS described parties to the SRDP asking whether the Stark exceptions that require minimum one year terms must reflect that minimum term in writing.<sup>178</sup> CMS sought to clarify that exceptions requiring a contract term of at least one (1) year can be satisfied "as long as the arrangement clearly establishes a business relationship that will last for at least 1 year."<sup>179</sup> CMS indicated in the Proposed Rule

that parties to an arrangement can satisfy the Stark Law exceptions by demonstrating, with available documentation, including "contemporaneous documents evidencing the course of conduct between the parties . . . that the arrangement *in fact* lasted for the required period of time."<sup>180</sup> Thus, CMS indicated in the Proposed Rule that parties to an arrangement do not need to rely on one single document to establish the applicable term length; instead, the parties can look to "contemporaneous writings establishing that the arrangement *lasted for at least 1 year*, or be able to demonstrate that the arrangement was terminated during the first year and that the parties did not enter into a new arrangement for the same space, equipment or services during the first year . . . as applicable."<sup>181</sup>

In the Final Rule, CMS adopts the Proposed Rule's policy, namely that an arrangement need only last a year (or not be terminated during the first year and the parties did not enter into a new arrangement for the same space, equipment, or services), *as a matter of fact*.<sup>182</sup> CMS states that the use of the word "term" in the existing Stark regulations was ambiguous (preferring, instead, the duration of an arrangement), and also goes so far as to state that the foregoing is CMS' "existing policy" (thus, meaning it can be relied upon for existing arrangements predating the Proposed Rule when determining whether to submit to the SRDP).<sup>183</sup> CMS again stated that state law principles should not be used for determining the one year requirement.<sup>184</sup>

Note the interesting dichotomy established by CMS in the Final Rule between the "arrangement in writing" clarifications and the one-year duration clarification. When discussing the "arrangement in writing," CMS states that it "believe[s] that a grace period for the writing requirement poses a risk of program or patient abuse... [and] if an arrangement with a physician fails to comply with the writing requirement of an applicable

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exception when the arrangement commences, then the entity is not permitted to bill for DHS furnished as a result of the physician's referrals..., [and] [c]ontemporaneous documents evidencing the course of conduct between the parties cannot be relied upon to protect referrals that predate the documents."<sup>185</sup> So, CMS, for the arrangement in writing requirement, establishes the measuring stick as the time when the compensation arrangement begins, yet for the one-year duration requirement establishes what amounts to a "wait and see/demonstrate" standard. It will be interesting to see if this has any practical implications for healthcare attorneys and their clients.

In sum, CMS in the Final Rule blesses another "defensive Stark" position that has been advocated by some healthcare attorneys versed in the Stark Law. It is a very welcome confirmation of this position and, as indicated above, it appears that CMS has been receiving inappropriate self-disclosures under the SRDP. There has been an increasing, and regrettable, trend in the current Stark Law enforcement environment for reflexive self-disclosure of *potential* technical Stark Law issues, without what appears to be a full evaluation as to whether the relationships are defensible in good faith under current law. This is reflected by the Proposed and Final Rules' myriad "clarifications," where CMS states (in a round-about manner), that it is receiving disclosures for "technical" issues and that a "clarification" of existing law would obviate the need for the disclosures.<sup>186</sup> In the Proposed and Final Rules, CMS recognizes that it has received too many disclosures of the type that are not clearly violative/are defensible under the current Stark Law regulations.<sup>187</sup>

It will be interesting to see if the number of self-disclosures decline considerably following CMS'

clarifications in the Proposed and Final Rules. CMS clearly indicates that it hopes this will be the case for the issues it "clarified" in the Rules. Again, analytically and as explicitly stated, CMS' clarifications and their effect on Stark Law interpretations are effective immediately/retroactively.

## Extension of Holdover Arrangements<sup>188</sup>

Under current Stark Law regulations, holdover arrangements are limited to six months on the same terms and conditions of the original arrangement. In the Proposed Rule, CMS sought to provide greater flexibility — and thus, avoid potential self-disclosures — by extending *indefinitely* (or for another definite period of time) the holdover arrangements permitted by 42 C.F.R. § 411.357(a), (b), and (d). CMS stated that it had seen numerous self-disclosures through the SRDP on holdover issues that did not pose a risk of program or patient abuse.<sup>189</sup> However, CMS felt that there were still potential sources of program abuse for indefinite holdovers: (1) "frequent renegotiation of short term arrangements based on physician's referrals"; and (2) compensation or rental changes that become inconsistent with fair market value over time.<sup>190</sup> So, coupled with the Proposed Rule's indefinite holdover provisions, CMS proposed three safeguards: (a) the arrangement must comply with an applicable exception when it expires by its own terms; (b) the holdover continues on the same terms and conditions; and (c) the relationship continues to meet all of the applicable Stark exception requirements (*e.g.*, FMV, does not vary with volume or value or other business, and is commercially reasonable).<sup>191</sup> CMS gave the example of the above safeguards being necessary since, for example, "if office space

rental payments are fair market value when the lease arrangement expires, but the rental amount falls below fair market value at some point during the holdover, the lease arrangement would fail to satisfy the requirements of the applicable exception at § 411.357(a) as soon as the fair market value requirement is no longer satisfied, and DHS referrals by the physicians to the entity that is [a] party to the arrangement would no longer be permissible."<sup>192</sup>

In the Proposed Rule, CMS stated that if the terms and conditions are changed during the holdover term, it would then treat that changed relationship as a new compensation arrangement which must meet an applicable exception (including the requirement that the duration of the new arrangement be for one year, and not be renegotiated within that year).<sup>193</sup> Further, CMS proposed that if, during the holdover, the arrangement at some time becomes not-FMV, the relationship becomes non-compliant at that point.<sup>194</sup>

In the Final Rule, CMS adopts its proposed changes related to indefinite holdover arrangements.<sup>195</sup> CMS notes in the Final Rule the importance of contemporaneous documents so that the provider/supplier can demonstrate compliance with the holdover safeguards (*e.g.*, same terms and conditions).<sup>196</sup> Note, however, that with the clarifications to the "arrangement in writing" provisions, "even without a holdover provision, an arrangement that continued after a contract expired on its own terms could potentially satisfy the writing requirement of an applicable exception, provided that the parties had sufficient contemporaneous documentation of the arrangement."<sup>197</sup>

One item of interest is when FMV is measured. In its response to comments, CMS confirms, importantly, that:

Regarding the fair market value



requirement during the original term, we expect parties to make a determination of fair market value at the time the financial relationship is created.<sup>198</sup>

However, CMS leaves in place the confusing web of guidance it has woven with respect to long-term relationships and the timing of the FMV requirement, stating that:

The exception at § 411.357(a)(4) requires rental charges to be consistent with fair market value “over the term of the arrangement,” but we note that fair market value is expressed as a range of values. We caution that *rental payments may cease to be consistent with fair market value in long-term arrangements.... Parties relying on a holdover provision bear the risk of fluctuations in the relevant market that may cause an arrangement to no longer satisfy the applicable fair market value requirement.* In most instances, fair market value is expressed as a range, and minor fluctuations in market value may not cause an arrangement to become noncompliant. (See 73 FR 48739.) However, as soon as a holdover arrangement ceases to meet all the requirements of an applicable exception, including the fair market value requirement, referrals for DHS by the physician to the entity that is a party to the arrangement are no longer permissible. It is up to the parties to determine the best way to analyze fair market value during a holdover. The best means of ensuring ongoing compliance is to enter into a new agreement in a timely manner after a previous contract expires, and to reassess fair market value to the extent that is necessary at the time of the renewal.<sup>199</sup>

So, while adding to the body of CMS’ oft-conflicted comments on FMV, CMS also adds to the uncertainty inherent with FMV assessments in longer term contracts. For instance, in rental arrangements it is standard and commercially reasonable outside

of the healthcare industry for shared-risk/benefit between a landlord and tenant with fixed long-term negotiated rents. Yet CMS promulgates guidance that what is commercially reasonable in industries absent the possibility for referrals may not meet the FMV prong of applicable exceptions (which also, incidentally, have commercial reasonableness requirements). As is often the case, stakeholders should await further guidance from CMS/the courts on this issue, and use their best good faith interpretation efforts in the interim.

CMS also issues important guidance on lease-holdover rent escalators in the Final Rule. CMS confirms that a pre-negotiated and documented rent escalator during a holdover can be appropriate, but also noted that “failure to apply a holdover premium that is legally required by the original arrangement may constitute a change in the terms and conditions,” and that such a failure to charge “may constitute the forgiveness of a debt, thus creating a secondary financial relationship between the parties that must satisfy the requirements of an applicable exception.”<sup>200</sup> This commentary serves as an important reminder of the dangers attendant to any relationship that triggers the Stark law, and the never-ending diligence that must be applied to the same.

CMS also issues guidance and commentary in the Proposed and Final Rules related to the FMV exception in holdover renewal situations.<sup>201</sup> Anyone evaluating renewals or holdovers in the context of reliance on the FMV exception should carefully review the vagaries of the Proposed and Final Rules.

Finally, CMS states that the indefinite holdover requirements can be relied on retroactively, so long as: (i) as of January 1, 2016, the holdover was in compliance with the current holdover regulations prior to the Final Rule’s changes (e.g., the holdover was less than six months as of

January 1, 2016); and (ii) the safeguard requirements of the indefinite holdover provisions in the Final Rule (outlined above) are met.

CMS’ revisions to the holdover allowances are extremely welcome. Attorneys’ stomachs have dropped when a client begins a call with “so we have a contract that has expired.” Further, one cannot conduct a Google search on Stark compliance without running across thousands of results stressing the need for contract management and the dangers of expired/lapsed contracts. The sage advice from Google regarding contracting processes stands, but with the Final Rule attorneys will likely have more flexibility advising clients in light of CMS’ enshrinement of previously used “defensive Stark” principles with respect to holdover arrangements.

## Remuneration Definition Changes<sup>202</sup>

The Stark Law defines “remuneration” as “any remuneration, directly or indirectly, overtly or covertly, in cash or in kind,” *unless* statutorily excepted.<sup>203</sup> Qualifying for an exception means that there is no “remuneration” and thus no “financial relationship,” which is one of the triggering elements of the Stark Law’s application.

In the Proposed Rule, CMS sought to clarify the Stark Law definition of “remuneration” to reflect that if one of the six statutory exceptions to remuneration listed at 42 U.S.C. § 1395nn(h)(1)(C) applies, then the term “used solely” in such provision does not mean that the exception does not apply if the item, device, or supply is used for *more than* one of the six statutorily allowed purposes.<sup>204</sup> So, if there are *two purposes* for the item, device, or supply that fall within the six listed purposes, CMS in the Proposed Rule took the position that the carve-out to the definition of remuneration does apply. However, CMS clarified that such “item, device, or supply cannot be used for any purpose

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other than the six purposes listed in the statute. Thus, if an item is used for two or more purposes listed in the statute, and it is not used for any other purpose (that is, any purpose not listed in the statute), then under the Proposed Rule the provision of the item does not constitute remuneration between the parties.”<sup>205</sup> CMS adopts this change in the Final Rule with no further commentary.<sup>206</sup>

Further, in the Proposed Rule CMS addressed the Third Circuit Court of Appeals decision in *United States ex rel. Kosenske v. Carlisle HMA*,<sup>207</sup> which held that “a physician’s use of a hospital’s resources (for example, examination rooms, nursing personnel, and supplies) when treating hospital patients constitutes remuneration under the physician self-referral law, even when the hospital bills the appropriate payor for the resources and services it provides (including the examination room and other facility services, nursing and other personnel, and supplies) and the physician bills the payor for his or her professional fees only.”<sup>208</sup> CMS sought to use the Proposed Rule to appropriately clarify that it does not deem such an arrangement (so-called “split-bill” arrangements) to be remuneration, since there is no “remuneration” between the parties.<sup>209</sup>

In the Final Rule, CMS confirms its position in the Proposed Rule, stating:

In a “split bill” arrangement, a physician makes use of a DHS entity’s resources (for example, examination rooms, nursing personnel, and supplies) to treat the DHS entity’s patients.

The DHS entity bills the appropriate payor for the resources and services it provides (including the examination room and other facility services, nursing and other personnel, and supplies) and the physician bills the payor for his

or her professional fees only. We do not believe that such an arrangement involves remuneration between the parties, because the physician and the DHS entity do not provide items, services, or other benefits to one another. Rather, the physician provides services to the patient and bills the payor for his or her services, and the DHS entity provides its resources and services to the patient and bills the payor for the resources and services. There is no remuneration between the parties for the purposes of section 1877 of the Act.

In contrast, if a physician or a DHS entity bills a non-Medicare payor (that is, a commercial payor or self-pay patient) globally for both the physician’s services and the hospital’s resources and services, a benefit is conferred on the party receiving payment. Specifically, the party that bills globally receives payment for items or services provided by the other party. Such a global billing arrangement involves remuneration between the parties that implicates the physician self-referral law.<sup>210</sup>

For an extreme example, if a hospital were to provide space, personnel, and supplies (e.g., a timeshare space), and a physician utilizes that space and bills globally for the same as a physician office (as opposed to provider-based billing by the hospital), then CMS’ payment to the physician is de facto paying for the space/personnel/supplies provided by the hospital. Thus, the hospital has provided remuneration to the physician, and that remuneration must meet an applicable exception (e.g., the physician pays the hospital using the newly proposed Timeshare exception for equipment, space, supplies, services, *et cetera*).

CMS, in the Final Rule, affirms that the foregoing is CMS’ existing policy, and thus may be relied on in

evaluating whether arrangements constitute “remuneration” prior to the effective date of the Final Rule.<sup>211</sup> CMS declines to answer an inquiry regarding whether “exclusive use” of a hospital’s space constitutes remuneration, presumably due to the “loaded nature” of the question absent requisite facts and circumstances.<sup>212</sup>

## Stand in the Shoes Signature Requirement Clarification<sup>213</sup>

For purposes of the Stark Law, “stand in the shoes” (or “SITS”) is particularly important for determining when an arrangement is to be analyzed as a “direct” or “indirect” compensation arrangement. Further, if a physician stands in the shoes of a physician organization, that physician is deemed to have the same compensation arrangements (with the same parties and on the same terms) as the physician organization in whose shoes the physician stands.

In the Proposed Rule, CMS sought to clarify that employees or independent contractors do not stand in the shoes of their physician organization’s arrangements for the purposes of Stark Law signature requirements (e.g., they do not have to sign the arrangement), “unless they *voluntarily* stand in the shoes of the physician organization as permitted under [42 C.F.R. §] 411.354(c)(1)(iii) or [42 C.F.R. § 411.354](c)(2)(iv)(B).”<sup>214</sup> In the Proposed Rule CMS further reiterated that physicians who do stand in the shoes satisfy the signature requirements themselves when an authorized signatory of the physician organization has signed the writing evidencing the arrangement.<sup>215</sup>

CMS adopts this provision in the Final Rule.<sup>216</sup> Only the signature requirements change, to clarify that physician employees and independent contractors do not have to be direct

signatories to contractual arrangements for certain Stark Law purposes.<sup>217</sup>

CMS disagrees with commenters who asserted that the revisions would create direct compensation arrangements between DHS entities and physician employees of a physician organization who *do not* SITS with respect to the organization – CMS states that the revisions in the Final Rule do not impact the analysis regarding whether an indirect compensation arrangement exists between a physician and a DHS entity.<sup>218</sup>

Importantly, CMS reiterates in the Proposed and Final Rules that this provision related to signatures/SITS *does not* change the clarified general (and existing) rule that CMS will consider *all referrals from all physicians* in a physician organization to determine whether a compensation arrangement with a physician organization takes into account the volume or value of referrals (as opposed to just considering the referrals of the signatory or physicians that SITS of the organization).<sup>219</sup> Several commenters, in various ways, submitted comments to the Proposed Rule on this issue, indicating that they believed that this was a policy shift as opposed to a clarification. It is fairly clear that this is not the case, and CMS responded as such.<sup>220</sup>

## Locum Tenens<sup>221</sup>

In the Proposed Rule, CMS sought to remove the phrase “stands in the shoes” from the definition of “locum tenens physician.”<sup>222</sup> CMS believed that the definition of locum tenens is clear without the use of “stand in the shoes,” and that the “stand in the shoes concept” of “indirect” and “direct” compensation arrangements are separate and distinct from the definition of “locum tenens physician.”<sup>223</sup> Thus, to avoid the confusion of concepts, CMS proposed to delete the reference to “stand in the shoes” in the locum tenens definition. CMS adopts this change in the Final Rule.

## Ownership of Publicly Traded Securities<sup>224</sup>

In the Proposed Rule, CMS sought to expand the exception for ownership of publicly traded securities to include protection for “trading on an electronic stock market or [over-the-counter (OTC)] quotation system in which quotations are published on a daily basis and trades are standardized and publicly transparent.”<sup>225</sup> Trades made through “a physical exchange” (such as the New York Stock Exchange or the American Stock Exchange) are considered “standardized and transparent.”<sup>226</sup> However, CMS sought to exclude “any electronic stock markets or OTC quotation systems that trade unlisted stocks or that involve decentralized dealer networks.”<sup>227</sup>

CMS adopts this provision in the Final Rule.<sup>228</sup>

## Temporary Noncompliance with Signature Requirements<sup>229</sup>

Currently, if parties to an arrangement otherwise meet all requirements of an applicable exception, but fail to obtain a signature, then there is a grace period only for the purpose of obtaining the signature – within ninety (90) days if the missing signature is inadvertent, and within thirty (30) days if the missing signature is not inadvertent.<sup>230</sup>

Under the Proposed Rule, CMS sought to change this requirement such that parties would have “90 days to obtain the required signatures, regardless of whether or not the failure to obtain the signature(s) was inadvertent,” since it believed that this poses a low risk of program or patient abuse.<sup>231</sup> In making the proposal, CMS noted that all other aspects of the current Temporary Noncompliance with Signature rule’s safeguards would remain in place, such as an entity only being able to make use of the Temporary Noncompliance rules once every three years with respect to the same referring physician.<sup>232</sup>

CMS adopts the Proposed Rule in the Final Rule and gives guidance in response to comments that will be valuable for stakeholders in the healthcare industry.

CMS declines requests to remove the once every three years per same physician safeguard, stating that: “The signature requirement of certain compensation exceptions is statutory, and we believe that the requirement plays a role in preventing fraud and abuse. Among other things, the signature of the parties creates a record of the fact that the parties to an arrangement were aware of and assented to the key terms and conditions of the arrangement. Requiring parties to sign an arrangement encourages parties to monitor and review financial relationships between DHS entities and physicians. In contrast, permitting parties to make frequent use of the special rule for noncompliance with signature requirements would not incent parties to exercise diligence with our rules. (See 73 FR 48707). We believe that repeated use of the special rule (that is, use more than once in a 3-year period) for the same physician may pose a risk of program or patient abuse.”<sup>233</sup>

CMS also issues comments that correlate with the SITS requirements. Under the SITS requirements, a physician who SITS is deemed to have the same financial relationship as his or her physician organization. Thus, under the Final Rule, CMS states that if a DHS entity has a compensation arrangement with a physician organization, then with respect to any physician that SITS for such organization, the once every three-year requirement applies if the parties utilize the Temporary Noncompliance rule.<sup>234</sup>

CMS, as in other sections of the Final Rule, disavows reliance on state law in response to requesters asking for CMS to deem an arrangement to be signed if that arrangement was binding (but not signed) under state law. CMS indicates that “a signature

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is necessary to provide a written record of the assent of the parties to the arrangements.”<sup>235</sup> However, as previously discussed above on the “arrangements in writing” clarifications, CMS then goes on to bless looking to state and federal law to determine what, exactly, is a “signature” for Stark purposes.<sup>236</sup> In doing so, CMS issues commentary that indicates that it would like the “signature” (whatever that may be) to: (i) clearly relate to the arrangement when considered in the context of a collection of documents related to the underlying arrangement; and (ii) show some manner of intent to relate to the same.<sup>237</sup> CMS indicated that it does not wish to unduly narrow parties’ ability to comply with the signature requirement.<sup>238</sup>

## Physician-Owned Hospitals<sup>239</sup>

### Website Requirements

Physician-owned hospitals must “disclose the fact that the hospital is partially owned or invested in by physicians on any public web site for the hospital and in any public advertising for the hospital.”<sup>240</sup> Following self-disclosures and industry stakeholders’ inquiries, CMS put forth in the Proposed Rule, and reiterates in the Final Rule, that social media web sites will not be considered public websites/public advertising for the hospital.<sup>241</sup> CMS articulates that it does not believe that “a hospital’s communications (such as maintaining an individual page on a Web site, posting a video, or posting messages) via a social media Web site should be construed as a Web site that is ‘for the hospital,’ given that the Web site is operated and maintained by a social networking service and that a multitude of users typically can become members of such a service.”<sup>242</sup>

In response to comments on the Proposed Rule, CMS states in the

Final Rule that networking websites are commonly understood to be social media websites.<sup>243</sup> CMS also declines to list specific websites among its examples, considering the ongoing development of such technology.<sup>244</sup> Further, CMS proposed, and reaffirms in the Final Rule, that “public advertising for the hospital” *does not include* “communication[s] made for the primary purpose of recruiting hospital staff (or other similar human resources activities), public service announcements issued by the hospital, and community outreach issued by the hospital.”<sup>245</sup> CMS also proposed and reaffirms excluding “electronic patient payment portals, electronic patient care portals, [and] electronic health information exchanges, as these are not available to the general public.”<sup>246</sup>

CMS, in the Proposed and Final Rules, defines “public advertising for the hospital,” for Stark purposes, as “any public communication *paid for* by the hospital that is *primarily intended* to persuade individuals to seek care at the hospital.”<sup>247</sup> In response to comments on the Proposed Rule, CMS states in the Final Rule that the standard for whether a communication qualifies as “public advertising for the hospital” is whether the *primary intention* of the communication is to persuade patients to seek care at the hospital, among other factors.<sup>248</sup> The ultimate decision regarding whether a communication will be considered public advertising for the hospital, however, will be determined by the facts and circumstances.<sup>249</sup>

CMS also states in the Final Rule that determining the period of non-compliance for a hospital’s failure to disclose depends on the facts and circumstances surrounding the hospital’s public advertisement.<sup>250</sup> CMS finalizes its proposals regarding the public website and public advertising disclosure requirements of § 411.362(b)(3)(ii)(C) without modification.<sup>251</sup> In response

to comments on the Proposed Rule, CMS states in the Final Rule that § 411.362(b)(3)(ii)(C) will be amended to specify that language putting a reasonable person on notice that the hospital may be physician-owned is a sufficient statement of physician ownership or investment.<sup>252</sup>

### Bona Fide Investments in Hospitals<sup>253</sup>

In prior guidance,<sup>254</sup> CMS articulated that bona fide investment levels in physician-owned hospitals “should be calculated without regard to any ownership or investment interests held by physicians who do not make any referrals to the hospital, including physicians who are no longer practicing medicine.”<sup>255</sup> In the Proposed Rule, however, CMS indicated that it planned to reconsider its previous guidance to now “require that the baseline bona fide investment level and the bona fide investment level include direct and indirect ownership and investment interests held by a physician if he or she satisfies the definition of ‘physician’ in section 1861(r) of the Act and in § 411.351, regardless of whether the physician refers patients to the hospital (and therefore, irrespective of whether he or she is a “referring physician” for the purposes of our regulatory definition of ownership or investment interest at § 411.354).”<sup>256</sup> Thus, a proper calculation of a physician-owned hospital’s baseline bona fide investment level would include the ownership and investment interests held by all physicians, regardless of referral status, and can include those physicians that are retired.<sup>257</sup>

In the Final Rule, CMS has finalized, without revision, this proposal. Thus, CMS is amending the regulations to specify that the ownership or investment interests held by both referring and non-referring physicians are included for purposes of § 411.362.<sup>258</sup> CMS is also finalizing the provision



that includes non-referring physicians for purposes of determining the baseline bona fide investment level and the bona fide investment level thereafter.<sup>259</sup> CMS states that this definition of ownership or investment interest established solely for § 411.362 would apply to all types of owners or investors, regardless of whether they are referring or non-referring physicians.<sup>260</sup>

So, as affirmed in the Final Rule, CMS defines “ownership or investment interest at § 411.362(a) as a direct or indirect ownership or investment interest in a hospital.”<sup>261</sup> “Physician” as used in § 411.362 has the same meaning as set forth in § 411.351: an individual who is a physician as defined in § 1861(r) of the Act.<sup>262</sup> Under the Final Rule:

- **“Direct ownership or investment interest in a hospital exists** if the ownership or investment interest in the hospital is held without any intervening persons or entities between the hospital and the owner or investor . . . .”<sup>263</sup>
- **“...indirect ownership or investment interest in a hospital exists:** if (1) between the owner or investor and the hospital there exists an unbroken chain of any number (but no fewer than one) of persons or entities having ownership or investment interests; and (2) the hospital has actual knowledge of, or acts in reckless disregard or deliberate ignorance of, the fact that the owner or investor has some ownership or investment interest (through any number of intermediary ownership or investment interests) in the hospital.”<sup>264</sup>

Given the fact that CMS reconsidered its previous guidance (and that physician-owned hospitals relied on such guidance), CMS is delaying the effective date of the new regulation to January 1, 2017 to enable the physician-owned hospitals an opportunity to comply with the new policy.<sup>265</sup> Given the intense lobbying and the number of lawsuits currently pending against CMS related to

physician-owned hospitals, the authors do not believe that the Final Rule will be the final word on this subject matter.

## Further Stark Guidance Coming Related to Payment System Reform<sup>266</sup>

In the Final Rule, CMS states that it is reviewing and soliciting comments regarding the impact of Stark on healthcare delivery and payment reform.<sup>267</sup> CMS specifically requested comments regarding the “volume or value” and “other business generated” standards in relation to the APM Report<sup>268</sup> and Gainsharing Report<sup>269</sup> required under the Medicare Access and CHIP Reauthorization Act of 2015 (“MACRA”).<sup>270</sup> In the Proposed Rule, CMS stated that it is “moving away from Medicare payments to providers and suppliers that do not incorporate the value of the care provided.”<sup>271</sup> By 2016, CMS’ goal is to tie 85 percent of all traditional Medicare payments to quality or value,<sup>272</sup> with a further goal of reaching 90 percent by 2018 through the use of the Hospital Value Based Purchasing (“VBP”) Program and the Hospital Readmissions Reduction Program.<sup>273</sup> By the end of 2016, CMS’ goal is to tie 30 percent of “traditional, fee-for-service Medicare payments to quality or value through alternative payment models.”<sup>274</sup> By 2018 CMS would like to tie 50 percent of payments to these models.<sup>275</sup>

The Stark Law separates entities furnishing DHS from physicians who refer Medicare patients to them. Because all inpatient and outpatient services are considered DHS under Stark,<sup>276</sup> hospitals must consider every service referred by a physician when making sure compensation paid to a physician does not take into account the volume or value of the physician’s referrals to the hospital. There is concern that, outside of the Medicare Shared Savings Program or certain Center for Medicare and Medicaid Innovation-sponsored care delivery and

payment models (for which there are waivers of the prohibitions), the Stark Law prohibits financial relationships and incentive/performance payment structures necessary to achieve the clinical and financial integration required for successful healthcare delivery and payment reform.

In the Final Rule, CMS indicates that it is reviewing comments regarding the impact of Stark on healthcare delivery and payment reform in response to its request for comments on the “volume or value” and “other business generated” standards. CMS indicates that its required report to Congress should contain its response to the comments.<sup>277</sup>

## Technical Corrections<sup>278</sup>

The Final Rule includes minor technical corrections, such as an update to correct citations for the definitions, change “web site” to “website,” remove the hyphen from “publicly-traded,” and correct typographical errors.

## Discussion of Final Rule

Although CMS is maintaining protections to prevent program and patient abuse, it is loosening the strict technical nature of certain requirements for numerous Stark Law exceptions. This is exciting news for those individuals and entities navigating the balance between providing proper patient care and inadvertently running afoul of the Stark Law’s technical strict liability standard.<sup>279</sup> CMS’ Proposed and Final Rules make it clear that CMS is aware of the significant number of unnecessary SRDP self-disclosures that have resulted from the current technical and strict Stark Law regulations. Thus, CMS is attempting to loosen the regulatory constraints by trying to incorporate practical solutions to situations that have unnecessarily resulted in self-disclosures. Numerous arrangements that *could be* construed to violate current regulations, and have

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resulted in self-disclosures, are potentially technically defensible given specific facts and circumstances.

CMS' Final Rule also updates current regulations to reflect the changing nature of healthcare. For instance, the new NPP Assistance Exception will have significant practical implications for those hospitals, FQHCs and RHCs that are finding it challenging to keep up with healthcare delivery changes following PPACA and the attendant shortage of primary care service providers. Given that the new NPP Assistance Exception is structured very similarly to the Physician Recruitment Exception, CMS is comfortable that the requisite safeguards are in place to curb program and patient abuse while allowing hospitals, FQHCs and RHCs to provide physicians with remuneration to enable such physicians to recruit NPPs.

Moreover, given the need for hospitals to enable physicians to perform services in timeshare arrangements, the new Timeshare Exception is good news. First, the new exception will enable providers to utilize space for short-term uses on a non-exclusive basis, provided other criteria are met. Such an arrangement will enable healthcare providers to utilize short-term, non-exclusive office space, equipment, personnel, and supplies which they have not historically been able to easily utilize given current regulatory constraints. Additionally, CMS' modification to holdover arrangements allows providers, who are focused on patient care issues (and not contractual term lengths) to avoid a self-disclosure as a result of a lease or independent contractor agreement expiring, provided that the arrangement remains FMV and other conditions are satisfied. This seemingly "minor" modification will have vast implications in practice, as it will alleviate many perceived technical violations that could potentially result

in self-disclosures (absent healthcare regulatory counsel taking good-faith "defensive Stark" positions).

Healthcare industry stakeholders, however, will still believe that the Final Rule does not go far enough. It is this perception in the health law and provider/supplier community that has led to proposals like H.R. 776: the Stark Administrative Simplification Act of 2015, which would correct the disproportionate penalties that can be incurred under the Stark Law for "technical" violations. There is a school of thought by many Stark Law attorneys that the Proposed and Final Rules are an attempt by CMS to potentially prevent Congress from stepping in from perceived Stark Law overreach. This can be best summed up by the concurrence in the recent *Tuomey* case:

But I write separately to emphasize the troubling picture this case paints: An impenetrably complex set of laws and regulations that will result in a likely death sentence for a community hospital in an already medically underserved area.... It seems as if, even for well-intentioned providers, the Stark Law has become a booby trap rigged with strict liability and potentially ruinous exposure – especially when coupled with the False Claims Act.<sup>280</sup>

## Conclusion

The Final Rule's changes and clarifications, as a whole, are beneficial for healthcare providers and suppliers. Although the Stark Law is very rigorous and complex, these modifications are a step in the right direction to enable healthcare providers and suppliers to focus more on patient care issues, and less on technical Stark Law provisions that *sometimes* prevent fraud and abuse.



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## Endnotes

- 1 Special thanks to Leslie Rojas, Esq., for her contributions to this article.
- 2 42 U.S.C. § 1395nn.
- 3 *Id.* Stark also prohibits the DHS entity from filing claims with Medicare (or billing another individual, entity, or third party payor) for those referred services.
- 4 80 Fed. Reg. 70885 (November 16, 2015), Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2016, available at: <https://federalregister.gov/a/2015-28005>.
- 5 73 Fed. Reg. 48434 (August 19, 2008), Medicare Program; Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2009 Rates, available at <https://federalregister.gov/a/E8-17914>.
- 6 80 Fed. Reg. 41685 (July 15, 2015), Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2016; Proposed Rule, available at <https://federalregister.gov/a/2015-16875>.
- 7 CMS states that the purpose of the Final Rule is to “update[] the physician self-referral regulations to accommodate delivery and payment system reform, to reduce burden, and to facilitate compliance . . . [and] expanding access to needed health care services.” 80 Fed. Reg. 70885, 71301.
- 8 80 Fed. Reg. 41685, 41910.
- 9 *Id.* “We have learned from stakeholder inquiries, review of relevant literature, and self-disclosures submitted to the SRDP that additional clarification of certain provisions of the physician self-referral law would be helpful.” Throughout the Proposed and Final Rules, CMS references that it has received valuable feedback via information submitted through the SRDP that indicates that some of the self-disclosures being submitted are not actual technical violations of the Stark Law (*i.e.*, could be defensible), and that such unnecessary self-disclosures could be based on current regulations not being explicitly clear. Additionally, the self-disclosures to-date, and the changes in the current healthcare environment, have partially been the impetus to cause certain regulations to change. Thus, CMS utilized the Proposed and Final Rules to make certain clarifications and relaxations to those regulations that it thought would reduce self-disclosures that were of an overly-cautious nature based on current Stark Law regulations.
- 10 Many healthcare providers are under the impression that self-disclosing actual or potential violations of the Stark Law

through the SRDP will automatically reduce amounts owing for violating the Stark Law. However, § 6409(b) of the Patient Protection and Affordable Care Act (“PPACA”) gives the Secretary of the Department of Health and Human Services the *authority* (but not the obligation) to reduce the amounts owing for violations of the Stark Law. Thus, self-disclosures will not automatically be the best course of action for all healthcare providers.

- 11 CMS does not routinely publish the number of self-referral disclosure protocol disclosures that it receives. The last published figures were in 2012. Nevertheless, anecdotal evidence (as well as the Final Rule and the Proposed Rule) suggest that the number is extremely high.
- 12 “Section 6409 of the Patient Protection and Affordable Care Act required the Secretary, in cooperation with the Inspector General of the Department of Health and Human Services, to establish a Medicare self-referral disclosure protocol (SRDP) that sets forth a process to enable providers of services and suppliers to self-disclose actual or potential violations of the Physician self-referral law.” 80 Fed. Reg. 41685, 41909.
- 13 Numerous individuals and entities have lobbied Congress to amend the Stark Law to alleviate perceived technical violations.  
*See, for instance, H.R.776: the Stark Administrative Simplification Act of 2015* (<https://congress.gov/bill/114th-congress/house-bill/776>), which would correct the disproportionate penalties a hospital can incur under the Stark Law for having an unwritten, unsigned or lapsed agreement that is otherwise compliant with federal fraud and abuse laws. Importantly, the measure would limit the penalty to \$5,000 if one of these violations is disclosed within one year of the date of non-compliance. A violation disclosed more than one year from the date of noncompliance would be limited to a penalty of \$10,000. The bipartisan proposal would also create a streamlined process for disclosure and resolution at CMS within 90 days.
- 14 “Significant changes in our health care delivery and payment systems, as well as alarming trends in the primary care workforce shortage projections, have occurred since the publication of Phase III.” 80 Fed. Reg. 41685, 41910. 80 Fed. Reg. 70885, 71301.
- 15 For example, and as discussed more fully herein, under the Stark Law and current regulations, it is impermissible for hospitals, federally qualified health centers (“FQHCs”), and rural health clinics (“RHCs”) to provide remuneration to a physician to assist with the recruitment and employment of a nonphysician practitioner (“NPP”). CMS recognizes that one of the goals of PPACA was to expand access to healthcare coverage and the need for primary care providers (especially in remote areas). Thus, hospitals, FQHCs, and RHCs would need the ability to assist physicians in recruiting NPPs who could provide primary care services. However, under current regulations, such actions would be violative of the Stark Law. Thus, the Final Rule aims to provide a new exception to enable providers to further the intent of PPACA’s goals without violating the Stark Law.
- 16 80 Fed. Reg. 41685, 41910-41913. 80 Fed.

Reg. 70885, 71301-71311. The new exception will be at 42 C.F.R. § 411.357 (x).

- 17 The recruitment exception at 42 C.F.R. § 411.357(e) also applies to remuneration provided by a FQHC or a RHC in the same manner as it applies to a hospital, provided that the arrangement does not violate the AKS, or any federal or state law or regulation governing billing or claims submission. *See* 42 C.F.R. § 411.357 (e)(6)(i).
- 18 *See* 42 C.F.R. § 411.357(e).
- 19 Phase III was published in 72 Fed. Reg. 51012 (September 5, 2007).
- 20 72 Fed. Reg. 51012, 51049.
- 21 “Significant changes in our health care delivery and payment systems, as well as alarming trends in the primary care workforce shortage projections, have occurred since the publication of Phase III. A primary care workforce shortage has been a concern for years. The Affordable Care Act expanded access to health care coverage to those previously uninsured. As a result, the need for primary care providers (including nonphysician practitioners) has increased, particularly in remote and underserved areas.” (citations omitted). 80 Fed. Reg. 41685, 41910.
- 22 80 Fed. Reg. 41685, 41910-41913.
- 23 The proposed exception is designed similarly to the physician recruitment exception (42 C.F.R. § 411.357(x)) and contains similar requirements.
- 24 PA is defined in § 1861 (aa) (5) of the Social Security Act, NP and CNS are defined in § 1861 (aa) (5) of the Social Security Act, and CNM is defined in § 1861 (gg) of the Social Security Act.
- 25 80 Fed. Reg. 41685, 41911.
- 26 *Id.*
- 27 *Id.*
- 28 *Id.*
- 29 *Id.* CMS defined “substantially all” consistent with regulations at 42 C.F.R. §§ 411.352 (d) and 411.356 (c) (1) (*i.e.*, 75 percent of the NPP services furnished to patients of the practice must be “primary care services”), Proposed Rule at 41911.
- 30 *Id.*
- 31 *Id.* CMS proposed that “benefits” should include only health insurance, paid leave, and other routine non-cash benefits offered to similarly situated employees of the practice.
- 32 *Id.* The two (2) year limitation is designed to curb the potential for ongoing payments from the hospital, FQHC and RHC to the physician for past or future referrals.
- 33 *Id.*
- 34 80 Fed. Reg. 41685, 41912.
- 35 *Id.*
- 36 *Id.*
- 37 80 Fed. Reg. 41685, 41912-41913. Note that for consistency and ease of administrative burden, CMS proposed to define “geographic service area serviced by the hospital” to have the same meaning assigned to this term in the Assistance Exception at 42 C.F.R. § 411.357(e), and to define

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- the term “geographic area served” by an FQHC or RHC to have the same meaning assigned as defined in 42 C.F.R. § 411.357 (e)(6)(ii).
- 38 80 Fed. Reg. 41685, 41912.
- 39 *Id.* The proposed new exception-specific definition of referral is to be at 42 C.F.R. § 411.357 (x)(4).
- 40 *Id.*
- 41 42 C.F.R. § 411.351.
- 42 80 Fed. Reg. 41685, 41913.
- 43 The stand in the shoes (“SITS”) doctrine transforms an otherwise indirect financial relationship into a direct financial relationship. See 42 C.F.R. § 411.354 (c)(ii). Note that only “true” owners of a physician organization are required to SITS of their physician organization. A “physician organization” is defined at 42 C.F.R. § 411.351 and means “a physician, a physician practice, or a group practice that complies with the requirements of 42 C.F.R. § 411.352.”
- 44 80 Fed. Reg. 70885, 71303.
- 45 80 Fed. Reg. 70885, 71304.
- 46 80 Fed. Reg. 70885, 71304-71306.
- 47 80 Fed. Reg. 70885, 71306-71307.
- 48 42 C.F.R. § 411.357 (x)(1)(vi)(B).
- 49 Note that the definition of “NPP” for purposes of the exception is at 42 C.F.R. § 411.357 (x).
- 50 CSW is defined in § 1861(hh) of the Social Security Act.
- 51 CP is defined in 42 C.F.R. § 410.71 (d), 42 C.F.R. § 411.357 (x)(3).
- 52 80 Fed. Reg. 70885, 71304.
- 53 80 Fed. Reg. 70885, 71305.
- 54 80 Fed. Reg. 70885, 71308.
- 55 *Id.*
- 56 80 Fed. Reg. 70885, 71308. 42 C.F.R. § 411.357 (x) (1) (iii) (A).
- 57 80 Fed. Reg. 70885, 71308-71309. 42 C.F.R. § 411.357 (x) (1) (iv) requires that the compensation, signing bonus, and benefits paid to the NPP by the physician does not exceed FMV.
- 58 80 Fed. Reg. 70885, 71308.
- 59 80 Fed. Reg. 70885, 71309.
- 60 Note that the Proposed Rule used the term “employment” but because the Final NPP Assistance Exception is expanded to include contractors, the terminology has been slightly modified at 42 C.F.R. § 411.347 (x)(1)(3)(A).
- 61 80 Fed. Reg. 70885, 71309-71310.
- 62 80 Fed. Reg. 70885, 71310. 42 C.F.R. § 411.357 (x)(7)(i).
- 63 *Id.* 42 C.F.R. § 411.357 (x)(7)(ii) (A) and (B).
- 64 80 Fed. Reg. 70885, 71310-71311. 42 C.F.R. § 411.357 (x)(1)(v) (A) and (B).
- 65 See 42 C.F.R. § 411.357(x)(3) and *supra* at 39.
- 66 80 Fed. Reg. 41685, 41920-41922. 80 Fed. Reg. 70885, 71325-71333. The new exception will be at 42 C.F.R. § 411.357(y).
- 67 CLIA-waived tests are simple laboratory examinations and procedures that have an insignificant risk of an erroneous result, such as urine pregnancy and blood glucose testing that can be done in a physician’s office with little or no specialized equipment or training. See [www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/downloads/howobtaincertificatesofwaiver.pdf](http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/downloads/howobtaincertificatesofwaiver.pdf).
- 68 80 Fed. Reg. 41685, 41921.
- 69 42 C.F.R. § 411.357(a).
- 70 80 Fed. Reg. 41685, 41920.
- 71 42 C.F.R. § 411.357(i).
- 72 42 C.F.R. § 411.357(l).
- 73 63 Fed. Reg. 1658, 1703 (January 9, 1998).
- 74 *Id.* See also 80 Fed. Reg. 41685, 41920.
- 75 66 Fed. Reg. 856, 917-919 (January 4, 2001).
- 76 *Id.*
- 77 80 Fed. Reg. 41685, 41921.
- 78 *Id.*
- 79 *Id.*
- 80 *Id.*
- 81 However, at 80 Fed. Reg. 70885, 71325-71326, CMS notes that a license can convey the exclusive use of the property, but does not always do so.
- 82 80 Fed. Reg. 41685, 41921.
- 83 *Id.*
- 84 80 Fed. Reg. 41685, 41921-41922.
- 85 80 Fed. Reg. 41685, 41922.
- 86 CMS noted that this terminology has no effect on how the services are billed in that the services need not be billed as “incident to” services. 80 Fed. Reg. 41685, 41922.
- 87 80 Fed. Reg. 41685, 41921-41922.
- 88 80 Fed. Reg. 41685, 41922.
- 89 *Id.*
- 90 *Id.*
- 91 *Id.*
- 92 *Id.*
- 93 *Id.*
- 94 80 Fed. Reg. 70885, 71327.
- 95 *Id.*
- 96 80 Fed. Reg. 70885, 71328.
- 97 *Id.*
- 98 *Id.*
- 99 *Id.*
- 100 *Id.*
- 101 *Id.*
- 102 80 Fed. Reg. 70885, 71333.
- 103 *Id.*
- 104 80 Fed. Reg. 70885, 71329.
- 105 *Id.*
- 106 *Id.*
- 107 As defined in 42 C.F.R. § 411.351.
- 108 80 Fed. Reg. 70885, 71331.
- 109 *Id.*
- 110 *Id.*
- 111 80 Fed. Reg. 70885, 71325.
- 112 80 Fed. Reg. 70885, 71326.
- 113 80 Fed. Reg. 70885, 71330.
- 114 80 Fed. Reg. 70885, 71331.
- 115 *Id.*
- 116 *Id.*
- 117 80 Fed. Reg. 70885, 71332.
- 118 *Id.*
- 119 790 F.3d 212 (D.C. Cir. 2014).
- 120 This exception is found in 42 C.F.R. § 411.357(b) (4)(ii)(B).
- 121 80 Fed. Reg. 70885, 71332.
- 122 *Id.*
- 123 790 F.3d at 219-222.
- 124 80 Fed. Reg. 70885, 71332.
- 125 *Id.*
- 126 80 Fed. Reg. 70885, 71329.
- 127 *Id.*
- 128 *Id.*
- 129 80 Fed. Reg. 41685, 41921.
- 130 In any event, parties to space rental arrangements of any type should review their existing arrangements for compliance and to see if restructuring under the new timeshare exception would be beneficial.
- 131 80 Fed. Reg. 70885, 71326.
- 132 *Id.*
- 133 80 Fed. Reg. 70885, 71330.
- 134 80 Fed. Reg. 70885, 71327.
- 135 80 Fed. Reg. 41685, 41913. 80 Fed. Reg. 70885, 71312 – 71313.
- 136 80 Fed. Reg. 41685, 41913.
- 137 *Id.*
- 138 *Id.* (emphasis added).
- 139 80 Fed. Reg. 70885, 71312.
- 140 *Id.* 42 C.F.R. § 411.357(e)(6)(ii).
- 141 *Id.*
- 142 80 Fed. Reg. 70885, 71312-71313.
- 143 80 Fed. Reg. 41685, 41914. 80 Fed. Reg. 70885, 71313.
- 144 *Id.*
- 145 The physician recruitment exception found at 42 C.F.R. § 411.357(e)(1)(iii) references “based on”: “The hospital does not determine



- (directly or indirectly) the amount of the remuneration to the physician based on the volume or value of any actual or anticipated referrals by the physician or other business generated between the parties.” (emphasis added). The obstetrical malpractice insurance subsidies exception found at 42 C.F.R. § 411.357(r)(2)(iv) references “based on”: “The hospital, federally qualified health center, or rural health clinic does not determine (directly or indirectly) the amount of the payment based on the volume or value of any actual or anticipated referrals by the physician or any other business generated between the parties.” (emphasis added).
- <sup>146</sup> The medical staff incidental benefits exception found at 42 C.F.R. § 411.357(m)(1) references “without regard to”: “The compensation is offered to all members of the medical staff practicing in the same specialty (but not necessarily accepted by every member to whom it is offered) without regard to the volume or value of referrals or other business generated between the parties.” (emphasis added). The professional courtesy exception found at 42 C.F.R. § 411.357(s)(1) references “without regard to”: “The professional courtesy is offered to all physicians on the entity’s bona fide medical staff or in such entity’s local community or service area without regard to the volume or value of referrals or other business generated between the parties[.]” (emphasis added).
- <sup>147</sup> 80 Fed. Reg. 41685, 41914. 80 Fed. Reg. 70885, 71313.
- <sup>148</sup> 80 Fed. Reg. 41685, 41914.
- <sup>149</sup> 80 Fed. Reg. 70885, 71313.
- <sup>150</sup> *United States ex rel. Drakeford v. Tuomey Healthcare System, Inc.*, 792 F.3d 364 (4th Cir. 2015).
- <sup>151</sup> *Id.* at 379.
- <sup>152</sup> *Id.*
- <sup>153</sup> 80 Fed. Reg. 41685, 41914-41915. 80 Fed. Reg. 70885, 71313 – 71314.
- <sup>154</sup> 42 C.F.R. § 411.357(t).
- <sup>155</sup> 80 Fed. Reg. 41685, 41915.
- <sup>156</sup> *Id.*
- <sup>157</sup> 80 Fed. Reg. 41685, 41915-41916. 80 Fed. Reg. 70885, 71314 – 71317.
- <sup>158</sup> 80 Fed. Reg. 41685, 41915. 80 Fed. Reg. 70885, 71314.
- <sup>159</sup> 80 Fed. Reg. 41685, 41915 (emphasis added). 80 Fed. Reg. 70885, 71314-71315.
- <sup>160</sup> 80 Fed. Reg. 41685, 41915. 80 Fed. Reg. 70885, 71315.
- <sup>161</sup> 80 Fed. Reg. 41685, 41915. 80 Fed. Reg. 70885, 71314.
- <sup>162</sup> 80 Fed. Reg. 41685, 41916. Note that the “written contract” to “writing” change was not made in certain specific Stark exceptions.
- <sup>163</sup> 80 Fed. Reg. 70885, 71315.
- <sup>164</sup> *Id.*
- <sup>165</sup> 80 Fed. Reg. at 71317.
- <sup>166</sup> *Id.*
- <sup>167</sup> 80 Fed. Reg. 70885, 71315-71316.
- <sup>168</sup> 80 Fed. Reg. 70885, 71316.
- <sup>169</sup> *Id.* (emphasis added).
- <sup>170</sup> *Id.* (emphasis added).
- <sup>171</sup> <http://gpo.gov/fdsys/pkg/PLAW-106publ229/html/PLAW-106publ229.htm>; <http://uniform-laws.org/Act.aspx?title=Electronic%20Transactions%20Act>.
- <sup>172</sup> 80 Fed. Reg. 70885, 71334.
- <sup>173</sup> 80 Fed. Reg. 70885, 71317.
- <sup>174</sup> 80 Fed. Reg. 41685, 41915.
- <sup>175</sup> 80 Fed. Reg. 41685, 41915 (emphasis added).
- <sup>176</sup> 80 Fed. Reg. 70885, 71316. “Board meeting minutes or other documents authorizing payments for specified services; written communication between the parties, including hard copy and electronic communication; fee schedules for specified services; check requests or invoices identifying items or services provided, relevant dates, and/or rate of compensation; time sheets documenting services performed; call coverage schedules or similar documents providing dates of services to be provided; accounts payable or receivable records documenting the date and rate of payment and the reason for payment; and checks issued for items, services, or rent.”
- <sup>177</sup> 80 Fed. Reg. 41685, 41916-41917. 80 Fed. Reg. 70885, 71317 – 71318.
- <sup>178</sup> 80 Fed. Reg. 41685, 41916.
- <sup>179</sup> *Id.*
- <sup>180</sup> 80 Fed. Reg. 41685, 41917 (emphasis added).
- <sup>181</sup> 80 Fed. Reg. 41685, 41916 (emphasis added).
- <sup>182</sup> 80 Fed. Reg. 70885, 71317.
- <sup>183</sup> 80 Fed. Reg. 70885, 71318.
- <sup>184</sup> *Id.*
- <sup>185</sup> *Id.* (emphasis added).
- <sup>186</sup> *E.g.*, Proposed Rule:
- “Since the SRDP was established, we have received numerous submissions to the SRDP disclosing actual or potential violations relating to the writing requirements of various compensation exceptions (for example, failure to set an arrangement out in writing, failure to obtain the signatures of the parties in a timely fashion, or failure to renew an arrangement that expired on its own terms after at least 1 year). This Proposed Rule would clarify the writing requirements of various compensation exceptions by making the terminology in the compensation exceptions more consistent and by providing policy guidance on the writing and 1-year minimum term.” 80 Fed. Reg. 41685, 41915 (emphasis added).
- There are further examples of this type in the Proposed Rule and Final Rule. Nevertheless, this is illustrative of the issue at play. Per CMS guidance, the SRDP is only for submitting actual violations of the Stark Law. In fact, by submitting to the SRDP, SRDP guidance makes it clear that the provider/supplier is acknowledging and admitting to the Stark Law violation. CMS has directed that issues regarding applicability/potential violations are to be addressed, if at all, through its FAQ process or Stark Law Advisory Opinion process. However, in the Final Rule CMS describes submissions to the SRDP as being for “actual or potential violations of the physician self-referral law,” which is not the SRDP standard. 80 Fed. Reg. 70885, 71300. CMS then goes to great lengths to prevent numerous potential self-disclosures of the type where a “defensive Stark” analysis would have indicated that no disclosure was necessary. Based on informal conversations with CMS, CMS was kicking providers/suppliers out of the SRDP for the issues addressed in the Proposed and Final Rules, which, again, is indicative that there was a reflexive “self-disclosure without analysis” problem/recommendation being promulgated by certain healthcare attorneys.
- <sup>187</sup> 80 Fed. Reg. 41685, 41915. 80 Fed. Reg. 70885, 71314.
- <sup>188</sup> 80 Fed. Reg. 41685, 41917-41918. 80 Fed. Reg. 70885, 71318 – 71321.
- <sup>189</sup> 80 Fed. Reg. 41685, 41917.
- <sup>190</sup> *Id.*
- <sup>191</sup> *Id.*
- <sup>192</sup> *Id.*
- <sup>193</sup> *Id.*
- <sup>194</sup> *Id.*
- <sup>195</sup> 80 Fed. Reg. 70885, 71319.
- <sup>196</sup> *Id.*
- <sup>197</sup> 80 Fed. Reg. 71319
- <sup>198</sup> *Id.*
- <sup>199</sup> 80 Fed. Reg. 70885, 71319-71320 (emphasis added).
- <sup>200</sup> 80 Fed. Reg. 70885, 71320.
- <sup>201</sup> 80 Fed. Reg. 41685, 41917. 80 Fed. Reg. 70885, 71320.
- <sup>202</sup> 80 Fed. Reg. 41685, 41918; 80 Fed. Reg. 70885, 71321 – 71322.
- <sup>203</sup> 42 U.S.C. § 1395nn(h)(1)(B) and (C).
- <sup>204</sup> 80 Fed. Reg. 41685, 41918.
- <sup>205</sup> *Id.*
- <sup>206</sup> 80 Fed. Reg. 70885, 71321.
- <sup>207</sup> 554 F.3d 88 (3d Cir. 2009).
- <sup>208</sup> 80 Fed. Reg. 41685, 41918.
- <sup>209</sup> *Id.*
- <sup>210</sup> 80 Fed. Reg. 70885, 71321. *See also* 80 Fed. Reg. 41685, 41918.
- <sup>211</sup> 80 Fed. Reg. 70885, 71321.
- <sup>212</sup> 80 Fed. Reg. 70885, 71322.
- <sup>213</sup> 80 Fed. Reg. 41685, 41919. 80 Fed. Reg. 70885, 71322 – 71324.
- <sup>214</sup> 80 Fed. Reg. 41685, 41919.
- <sup>215</sup> *Id.*
- <sup>216</sup> 80 Fed. Reg. 70885, 71324.
- <sup>217</sup> “For purposes other than satisfying the signature requirements of the exceptions, we remain concerned about the referrals of all physicians who are part of a physician organization that has a compensation arrangement with a DHS entity when we analyze whether the compensation between the DHS entity and the physician organization takes into account the volume or value of referrals or other business generated between the parties. If we did not consider the referrals of all the

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- physicians in the physician organization, and instead only considered the referrals of those physicians who stand in the shoes of the physician organization, DHS entities would be permitted to establish compensation methodologies that take into account the volume or value [of] referrals or other business generated by non-owner physicians in a physician organization when entering into a compensation arrangement with the physician organization. Therefore, our proposal would amend § 411.354(c)(3)(i) to clarify that, for all purposes other than the signature requirements, all physicians in a physician organization are considered parties to the compensation arrangement between the physician organization and the DHS entity.” 80 Fed. Reg. 41685, 41919.
- <sup>218</sup> 80 Fed. Reg. 70885, 71323.
- <sup>219</sup> 80 Fed. Reg. 41685, 41919. 80 Fed. Reg. 70885, 71323.
- <sup>220</sup> 80 Fed. Reg. 70885, 71324.
- <sup>221</sup> 80 Fed. Reg. 41685, 41919-41920. 80 Fed. Reg. 70885, 71324.
- <sup>222</sup> 80 Fed. Reg. 41685, 41920.
- <sup>223</sup> *Id.*
- <sup>224</sup> *Id.*
- <sup>225</sup> *Id.*
- <sup>226</sup> *Id.*
- <sup>227</sup> *Id.*
- <sup>228</sup> 80 Fed. Reg. 70885, 71324.
- <sup>229</sup> 80 Fed. Reg. 41685, 41922-41923. 80 Fed. Reg. 70885, 71333 – 71334.
- <sup>230</sup> 42 C.F.R. § 411.353(g). 80 Fed. Reg. 41685, 41923.
- <sup>231</sup> 80 Fed. Reg. 41685, 41923.
- <sup>232</sup> *Id.*
- <sup>233</sup> 80 Fed. Reg. 70885, 71333.
- <sup>234</sup> *Id.*
- <sup>235</sup> 80 Fed. Reg. 70885, 71334.
- <sup>236</sup> *Id.*
- <sup>237</sup> *Id.*
- <sup>238</sup> *Id.*
- <sup>239</sup> 80 Fed. Reg. 41685, 41923-41926. 80 Fed. Reg. 70885, 71334-71340.
- <sup>240</sup> 80 Fed. Reg. 41685, 41923. 80 Fed. Reg. 70885, 71335.
- <sup>241</sup> 80 Fed. Reg. 41685, 41924. 80 Fed. Reg. 70885, 71335.
- <sup>242</sup> *Id.*
- <sup>243</sup> 80 Fed. Reg. 70885, 71336-71337.
- <sup>244</sup> 80 Fed. Reg. 70885, 71337.
- <sup>245</sup> 80 Fed. Reg. 41685, 41924. 80 Fed. Reg. 70885, 71335 (emphasis added).
- <sup>246</sup> *Id.*
- <sup>247</sup> *Id.* (emphasis added).
- <sup>248</sup> 80 Fed. Reg. 70885, 71337.
- <sup>249</sup> 80 Fed. Reg. 41685, 41924. 80 Fed. Reg. 70885, 71337.
- <sup>250</sup> 80 Fed. Reg. 70885, 71337.
- <sup>251</sup> *Id.*
- <sup>252</sup> 80 Fed. Reg. 70885, 71336.
- <sup>253</sup> 80 Fed. Reg. 70885, 71337.
- <sup>254</sup> 75 Fed. Reg. 71799 (November 24, 2010).
- <sup>255</sup> 75 Fed. Reg. 71799, 72250-72251.
- <sup>256</sup> 80 Fed. Reg. 41685, 41926.
- <sup>257</sup> *Id.*
- <sup>258</sup> 80 Fed. Reg. 70885, 71340.
- <sup>259</sup> 80 Fed. Reg. 70885, 71339.
- <sup>260</sup> *Id.*
- <sup>261</sup> 80 Fed. Reg. 41685, 41926. 80 Fed. Reg. 70885, 71340.
- <sup>262</sup> 80 Fed. Reg. 70885, 71340.
- <sup>263</sup> *Id.* (emphasis added).
- <sup>264</sup> *Id.* (emphasis added).
- <sup>265</sup> *Id.*
- <sup>266</sup> 80 Fed. Reg. 41685, 41929. 80 Fed. Reg. 70885, 71341.
- <sup>267</sup> 80 Fed. Reg. 70885, 71341.
- <sup>268</sup> Section 101(e)(7) of MACRA requires CMS and the Department of Health and Human Services’ Office of Inspector General (“OIG”) to study and report to Congress on fraud related to alternative payment models under Medicare (the “APM Report”).
- <sup>269</sup> Section 512(b) of MACRA requires CMS and OIG to submit to Congress a report containing options for amending existing fraud and abuse laws to permit gainsharing and similar arrangements between physicians and hospitals that allow them to improve care while reducing waste and increasing efficiency (the “Gainsharing Report”).
- <sup>270</sup> 80 Fed. Reg. 41685, 41929. The Medicare Access and CHIP Reauthorization Act of 2015, H.R. 2, 114th Cong. §§ 101, 512 (2015).
- <sup>271</sup> 80 Fed. Reg. 41685, 41928.
- <sup>272</sup> *Id.*
- <sup>273</sup> *Id.*
- <sup>274</sup> *Id.*
- <sup>275</sup> *Id.*
- <sup>276</sup> 42 U.S.C. § 1395nn(h)(6).
- <sup>277</sup> 80 Fed. Reg. 41685, 41929.
- <sup>278</sup> 80 Fed. Reg. 41685, 41930. 80 Fed. Reg. 70885, 71341.
- <sup>279</sup> 42 U.S.C. § 1395nn.
- <sup>280</sup> *U.S. ex rel. Drakeford v. Tuomey Healthcare System, Inc.*, 4th Cir., No. 13-2219 (July 2, 2015) (Wynn, Circuit Judge, concurring).

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