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## Don't Mail That Overpayment Disclosure Just Yet: Implications of CMS' Final Rule Expanding the Writing, Signature and Holdover Provisions of Stark Law Exceptions



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### I. Introduction

The Centers for Medicare and Medicaid Services (CMS) on Nov. 16, 2015<sup>1</sup> published the calendar year 2016 physician fee schedule final rule, fundamentally reducing the burden on entities seeking to demonstrate compliance with numerous Stark law exceptions requiring contracts between physicians and hospitals to be “set out in writing” and “signed by the parties.”

Acknowledging that a number of parties utilizing the Self Referral Disclosure Protocol (SRDP) to disclose potential overpayments have interpreted the exceptions to require a single written contract, the final rule “clari-

<sup>1</sup> Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2016, 80 Fed. Reg. 70886 (Nov. 16, 2015), available at <http://www.gpo.gov/fdsys/pkg/FR-2015-11-16/pdf/2015-28005.pdf>.

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fies” CMS’ “existing policy” that the writing and signature requirements may be satisfied by a collection of contemporaneous documents evidencing the arrangement between the contracting entities. Because this policy clarification is retroactive in effect, entities may assemble a collection of contemporaneous documents to demonstrate that past arrangements satisfy regulatory exceptions, potentially obviating any obligation to disclose what heretofore may have been perceived as technical violations of the Stark law.

The final rule also clarifies that no express written provision setting forth the length of an arrangement is necessary to comply with the various Stark exceptions requiring that an arrangement last at least one year. Accordingly, the failure to include such a term in a written agreement does not constitute a violation of the Stark law so long as the arrangement does, as a matter of fact, continue for a term of one year or greater.

Finally, effective Jan. 1, 2016 (the final rule’s effective date), the six-month holdover provisions applicable to the exceptions for rental of office space, rental of equipment and personal service arrangements will be modified to permit indefinite holdovers, provided that certain additional safeguards are met. The fair market value compensation exception—which currently permits arrangements of less than one year in duration to be renewed indefinitely—will be revised to permit indefinite renewal of arrangements lasting one year or greater. Although the indefinite holdover provisions will be available to entities within a valid six-month holdover term as of Jan. 1, 2016, these provisions are otherwise prospective in application.

CMS’ clarifications and revisions undoubtedly will prove advantageous going forward, but entities must be mindful of the limitations and complexities associated with the use of a compilation of contemporaneous documents to satisfy the writing and signature requirements. By no means will the expanded interpretations of “writing” and “signature” retroactively immunize all technical Stark law violations from potential overpayment liability.

Parties seeking to assemble a collection of documents with attributes adequate to satisfy CMS’ clarified interpretation of the writing and signature requirements must comply with the elaborate and, at times, opaque guidance provided in the final rule. A discus-

sion of the final rule's provisions, and the practical compliance implications associated with the rule, follows.

## II. The "Set Out in Writing" Requirement

Arguably the most impactful component of the final rule is CMS' clarification that an arrangement need not be reduced to a single written agreement. This permits entities to compile individual pieces of contemporaneous documentation to evidence that the terms and conditions of an existing or past compensation arrangement were reduced to writing. Although this will be welcomed by many as a broad expansion of the concept of "writing," CMS' clarification is accompanied by explicit and implicit limitations which require careful unraveling in order to correctly evaluate whether available documentation does, in fact, establish a writing as conceived by CMS.

In substituting the term "arrangement" for "agreement" in various provisions of 42 C.F.R. Sections 411.354 and 411.357,<sup>2</sup> the final rule revises language throughout the Stark exceptions to conform to CMS' policy that "there is no requirement under the physician self-referral law that an arrangement be documented in a single formal contract." Instead, the rule allows that "a collection of documents, including contemporaneous documents evidencing the course of conduct between the parties, may satisfy the writing requirement of the leasing exceptions and other exceptions that require that an arrangement be set out in writing."<sup>3</sup>

CMS' expanded interpretation of the writing requirement clarifies, and is retroactively applicable to, the following Stark law exceptions:

- Rental of Office Space (42 C.F.R. § 411.357(a));
- Rental of Equipment (42 C.F.R. § 411.357(b));
- Personal Service Arrangements (42 C.F.R. § 411.357(d));
- Physician Recruitment (42 C.F.R. § 411.357(e));
- Group Practice Arrangements with a Hospital (42 C.F.R. § 411.357(h));
- Fair Market Value Compensation (42 C.F.R. § 411.357(l));
- Indirect Compensation Arrangements (42 C.F.R. § 411.357(p));
- Obstetrical Malpractice Insurance Subsidies (42 C.F.R. § 411.357(r));
- Retention Payments in Underserved Areas (42 C.F.R. § 411.357(t));
- Electronic Prescribing Items and Services (42 C.F.R. § 411.357(v)); and
- Electronic Health Records Items and Services (42 C.F.R. § 411.357(w)).<sup>4</sup>

### A. Documentation Satisfying the "Writing" Requirement

Although CMS provides a nonexhaustive list "of individual documents that a party might consider as part of

a collection of documents when determining whether a compensation arrangement complied with the writing requirement," the final rule cautions that "a party could have documents of each type listed and nevertheless not satisfy the writing requirement of an applicable exception." Among other things, "the **documents must clearly relate to one another and evidence one and the same arrangement between the parties.**"<sup>5</sup> The examples provided by CMS are as follows:

- 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>6</sup>

It appears from the diversity of documentation listed that CMS is taking a relatively liberal stance regarding the types of documentation permitted to be utilized by parties to satisfy the writing requirement during a relevant time period. Nearly all providers will possess one or more of the foregoing documents in either paper or electronic form. However, neither the list nor the final rule as a whole provides anything approaching a bright line standard governing the requisite detail and content to be evidenced in a collection of documents.

On this point, CMS rather obliquely articulates that "it is the arrangement (that is, the underlying financial relationship between the parties) that must be set out in writing,"<sup>7</sup> and, in turn, defines the "underlying financial relationship" as "payments for the use of office space or equipment [or for services, as the case may be] for a period of time."<sup>8</sup>

In other words, documentation must be sufficient to demonstrate that one party was receiving certain services (or the use of certain space or equipment) in exchange for certain compensation from the other party.

In the interest of infusing some much needed clarity into this abstraction, let's suppose that a hospital and an independent contractor physician possess between them a job description evidencing the physician's duties, time sheets accounting for the physician's time investment, cancelled checks representing the physician's compensation, and an electronic record memorializing the number of wRVUs personally performed by the physician during a particular time period for the purpose of computing the physician's compensation. Assuming that the parties are able to make the following showings, such documentation arguably would evi-

<sup>2</sup> 80 Fed. Reg. at 71315.

<sup>3</sup> *Id.* at 71314-15.

<sup>4</sup> *Id.* at 71314.

<sup>5</sup> *Id.* at 71316 (emphasis added).

<sup>6</sup> *Id.*

<sup>7</sup> *Id.*

<sup>8</sup> *Id.* at 71314.

dence compliance with the Stark law's Personal Service Arrangements exception: (1) the documents pertain to the same arrangement and time period; (2) the compensation was "set in advance"; (3) the compensation constituted fair market value; (4) the arrangement was commercially reasonable; and (5) the "signature" requirement (discussed further below) was met.

It is unclear, however, to what extent the analysis would differ if a job description was missing from the compilation of documents set forth in the prior example. What level of detail would constitute a sufficient description of the services performed by the physician? Would identification on time sheets of the floor or department in which the services were rendered, together with a contemporaneous version of medical staff by-laws (assuming such bylaws address physician responsibilities), sufficiently evidence the services performed by an attending physician? Could an electronic file recording a physician's key card swipes upon entrance to and egress from a hospital department, or even a physician parking lot, substitute for a time sheet? The final rule leaves such questions unresolved.

Because CMS provides little guidance on the threshold level of specificity necessary for a series of writings to evidence a compensation arrangement, the final rule manifests a substantial gray area subject to widely variable interpretation. The decision of whether to disclose a compensation arrangement not reduced to a formal writing is thus left largely to the discretion of the entity, based on its assessment as to whether the assembled documentation meets the vague strictures of the final rule. Such decisions, in turn, will be informed in large part by the party's risk tolerance.

## B. Reliance on State Law Principles to Establish a "Writing"

CMS' acknowledgment in the final rule that nothing in the Stark law "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"<sup>9</sup> introduces even further flexibility to the writing requirement.

CMS cautions, however, that state law governing the existence of a valid and enforceable contract is not determinative of whether a written arrangement exists for the purpose of the Stark law compensation arrangement exceptions. Rather, "what determines compliance with the writing requirement of the physician self-referral law is . . . 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."<sup>10</sup>

In sum, an entity's conclusion that a document constitutes a writing may be grounded in state law principles but CMS will look to the terms of the arrangement *as performed* to evaluate whether the proffered documentation does, in fact, memorialize the actual financial relationship between the parties during the relevant time period.

Nevertheless, state law still may play an important role in evaluating whether a particular electronic record constitutes a writing for the purposes of Stark compliance. For example, although the final rule identifies

"checks issued for items, services, or rent" as writings on which a party may potentially rely, it is silent as to whether a series of direct deposits would constitute viable writings. State statutory or decisional law may set broad parameters for the definition of "writing," providing a favorable foundation from which an entity may assess compliance.

## C. Adequate Documentation Must Exist at the Time of Referral

Even if parties possess documentation sufficient to exhibit their "underlying financial relationship," failure to satisfy the temporal element of the "set out in writing" standard may result in compliance gaps—and resultant overpayments—requiring disclosure under the SRDP. As articulated in the final rule, "[c]ontemporaneous documents evidencing the course of conduct between the parties cannot be relied upon to protect referrals that predate the documents."<sup>11</sup>

Rather, in assessing 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>12</sup> Accordingly, an "entity is not permitted to bill for [Designated Health Services (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)."<sup>13</sup>

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."<sup>14</sup>

The foregoing presents a significant obstacle to entities seeking to satisfy the writing requirement with a collection of documents. In many situations, professional services may be performed (or equipment or space utilized) prior to the existence of a document memorializing a compensation or rental fee term (or the modification of an existing compensation or rental fee term). Under CMS' guidance, any referrals associated with such services or utilization would be prohibited until the payment term was documented.

For example, an independent contractor physician may receive her paycheck from a hospital in arrears. If the check is the first writing evidencing the payment term, all referrals pre-dating the check will have been prohibited, resulting in compliance gaps. On the other hand, a memorandum setting forth compensation terms dated prior to the performance of services for which that compensation constitutes remuneration may serve to eliminate any such gaps. Similarly, a time-stamped electronic entry recording the enrollment of a physician (and setting forth his or her compensation) into a hospital's payroll system may, depending on the circumstances, be sufficient evidence that the payment term was reduced to writing prior to the rendering of services by the physician.

<sup>11</sup> *Id.* at 71317 (emphasis added).

<sup>12</sup> *Id.* at 71315.

<sup>13</sup> *Id.* at 71317.

<sup>14</sup> *Id.* (emphasis added).

<sup>9</sup> *Id.* at 71316.

<sup>10</sup> *Id.*

## D. Limitation on the Use of an Expired Written Agreement to Establish the Terms of a New Arrangement

In distinguishing between the new indefinite holdover provisions (which are not retroactive) and its clarification of the writing requirement (which is), CMS significantly limits the extent to which an expired written agreement can be proffered as evidence that a continuing arrangement complies with the writing requirement:

If a written contract with an explicit term provision expires on its own terms, but the parties nevertheless continue the arrangement past the expiration, **the expired written contract by its own terms does not apply to the continued arrangement.** For this reason, without a holdover provision, **an expired written contract, on its own, could not satisfy the writing requirement of an applicable exception.**<sup>15</sup>

In other words, an arrangement continuing after expiration of a written agreement cannot **solely** be evidenced by the expired contract itself, even if the terms are identical. CMS neglects, however, to elaborate on the extent, if any, to which an expired written agreement can be used **in conjunction with** post-dated documentation exhibiting the terms of the new arrangement, resulting in an apparent ambiguity in the final rule.

Notwithstanding the foregoing, CMS is clear that an entity must demonstrate the terms of the new arrangement through independent writings post-dating expiration of the original written agreement. In the absence of such “additional supporting documentation, there may be gaps in compliance, as it may take some time after the expiration of the written contract to generate sufficient documents evidencing the course of conduct between the parties after the contract expired.”<sup>16</sup>

Fortunately, the rule does not prohibit entities from assembling writings dated within six months after expiration of the written agreement (the post-expiration period through which a new arrangement remains compliant under the current holdover provisions for rental of office space, rental of equipment and personal service arrangements)<sup>17</sup> to demonstrate the terms of the new arrangement. Accordingly, most entities should have a six month post-expiration period from which they may select documents to evidence the terms of the new office lease, equipment lease or personal service arrangement while remaining compliant with the applicable Stark exception. Depending on the circumstances, such documentation presumably would permit an entity to bridge the gap between the expiration of the initial written agreement and referrals made pursuant the new arrangement.

## III. The Signature Requirement

In addition to an arrangement set out in writing, many Stark exceptions, including those for personal service arrangements and space leases, require that the writing be “signed by the parties.”<sup>18</sup>

For the same rationale provided in its discussion of the writing requirement, CMS interprets the signature

requirement expansively—“parties . . . do not need to sign a single formal written contract to comply with the signature requirement of an applicable exception. **Nor do[es CMS] expect every document in a collection of documents to bear the signature of one or both parties.**”<sup>19</sup> (emphasis added). Instead, “a signature is required on a contemporaneous writing documenting the arrangement . . . [that] must clearly relate to the other documents in the collection and the arrangement that the party is seeking to protect.”<sup>20</sup>

According to the final rule, it is the “arrangement”—the underlying financial relationship between the parties – that must be signed to satisfy exceptions requiring the parties’ signatures.<sup>21</sup>

As with the writing requirement, CMS’ clarification to the signature requirement is consistent with its existing policy and, therefore, is retroactive in effect.

Because the signature requirement may be satisfied by a series of documents bearing the signatures of individual parties (i.e., although the signatures of all parties are required, they need not appear on the same document), entities will invariably be tasked with assessing whether a particular entry on a document or data in an electronic file constitutes a party’s signature. The final rule provides scant guidance for making such determinations.

CMS expressly declined the opportunity to answer a commenter’s inquiry whether an electronic signature, a typed name, the name of the sender in the “from” line of an email, the signature of the maker of a check or the signature of an endorser of a check constitute a “signature” for the purposes of Stark law exceptions.<sup>22</sup> Instead, CMS advised that “whether an arrangement is signed by the parties depends on the facts and circumstances of the arrangement and the writings that document the arrangement.”<sup>23</sup> Even a “document bearing the handwritten signature of one of the parties will not satisfy this requirement if the document,” when examined in context, “does not clearly relate to the arrangement.”<sup>24</sup>

Aside from this rather cryptic guidance, CMS did acknowledge that, while not determinative, “**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.”<sup>25</sup>

Bringing the focus back to concrete examples, assume, once again, that a physician receives compensation from a hospital in the form of a direct deposit. Authorization for a direct deposit generally requires either the handwritten or electronic signature of the recipient. Pursuant to the foregoing guidance, it would appear that such a signature may satisfy the signature requirement, at least for the physician. However, it would still be necessary to consider the temporal element of the writing requirement. If the physician did not sign the direct deposit authorization until after performing services, then the services pre-dating the signed authorization could constitute prohibited referrals in the absence

<sup>19</sup> 80 Fed. Reg. at 71316 (emphasis added).

<sup>20</sup> *Id.*

<sup>21</sup> *Id.*

<sup>22</sup> *Id.* at 71334.

<sup>23</sup> *Id.*

<sup>24</sup> *Id.*

<sup>25</sup> *Id.*

<sup>15</sup> *Id.* at 71319 (emphasis added).

<sup>16</sup> *Id.*

<sup>17</sup> 42 C.F.R. § 411.357(a)(7), (b)(6), (d)(1)(vii).

<sup>18</sup> See, e.g., 42 C.F.R. § 411.357(a)(1), (b)(1), (d)(1)(i); 80 Fed. Reg. at 71320-21.

of any other relevant writing containing the physician's signature. Moreover, the signature of a hospital representative must also appear on a writing related to the arrangement prior to the performance of services by the physician. A signed job offer, or perhaps even the enrollment of the physician to the direct deposit system (to the extent a formal authorization from the hospital is required to do so), may constitute a signature. With respect to the latter, an entity may look to state or federal law in evaluating whether such an authorization constitutes a "signature."

#### IV. The Term of an Arrangement Need Not Be Stated in Writing

The final rule clarifies that a "formal contract or other document with an explicit 'term' provision" is not necessary to comply with Stark law exceptions requiring that an arrangement be for a term of one year or greater.<sup>26</sup> Rather, "[a]n arrangement that lasts as a matter of fact for at least 1 year satisfies this requirement."<sup>27</sup>

Entities must possess contemporaneous writings demonstrating that an arrangement lasted for at least one year. Alternatively, parties can demonstrate compliance with Stark exceptions' one-year term provisions by "demonstrat[ing] that the arrangement was terminated during the first year and that the parties did not enter into a new arrangement of the same space, equipment, or services during the first year."<sup>28</sup>

This component of the final rule dispenses with any residual doubt as to whether an arrangement's term must be reduced to writing. It also permits parties to enter into indefinite compensation arrangements so long as they satisfy applicable exceptions requiring particular agreements to last at least one year. Caution is advised, however, because, as noted below, an indefinite arrangement must periodically be reevaluated to ensure that compensation remains within fair market value.

#### V. Revised Indefinite Holdover Provisions

In contrast to the clarifications addressed thus far in this article, the indefinite holdover provisions promulgated in the final rule do not apply retroactively. At the very least, an entity seeking to avail itself of the indefinite holdover revisions must be within a valid 6 month holdover period under the current iteration of the Stark exceptions on the effective date of the final rule—Jan. 1, 2016.<sup>29</sup>

As of the effective date, the current six-month holdover limitation applicable to the exceptions for rental of office space, rental of equipment and personal service arrangements will be eliminated, permitting parties to indefinitely renew an arrangement set out in writing by course of conduct after the written arrangement expires on its own terms.<sup>30</sup> The fair market value compensation exception similarly will be modified to permit arrangements for one year or longer to be renewed by course of conduct (currently, only arrangements with terms of less than year can be indefinitely held over).<sup>31</sup>

The indefinite holdover provisions will be available only when the following elements are satisfied:

1. "the arrangement must comply with the applicable exception when it expires by its own terms";<sup>32</sup>
2. "the holdover must continue on the same terms and conditions as the original arrangement";<sup>33</sup>
3. The holdover arrangement must meet all elements of the applicable Stark law exception "when the arrangement expires and on an ongoing basis during the holdover";<sup>34</sup> and
4. "the parties must have documentary evidence that the arrangement in fact continued on the same terms and conditions [throughout the term of the holdover]."<sup>35</sup>

The second requirement is designed to preclude frequent negotiation of short term arrangements during the holdover in a manner that could take into account the volume or value of referrals. In the event the parties subsequently modify any terms or conditions of the original arrangement, CMS shall consider the putative holdover an entirely new arrangement subject to all elements of any applicable exceptions.

The third requirement "ensure[s] that compensation is consistent with or does not exceed fair market value, as applicable."<sup>36</sup>

A party may satisfy the fourth requirement with "the expired written agreement and a collection of documents, including contemporaneous documents evidencing the course of conduct between the parties."<sup>37</sup>

Under the rule, "an arrangement that continued after a contract expired on its own terms could potentially satisfy the writing requirement of an applicable exception"<sup>38</sup> in the absence of the indefinite holdover provisions. However, CMS' express authorization permitting parties to rely on an expired written agreement to establish compliance offers a clear advantage by simplifying avoidance of compliance gaps. CMS does caution that parties relying on an expired written agreement under "the holdover provisions must still have contemporaneous documents establishing that the holdover continued on the same terms and conditions as the immediately preceding arrangement."<sup>39</sup>

Notwithstanding the benefits conferred by the indefinite holdover provisions, parties would be remiss in permitting arrangements to renew indefinitely without consideration of changes in fair market value over time. Although fair market value is expressed as a range of values, there is a significant risk that payments may cease to be consistent with fair market value over the course of a long term arrangement. Once an arrangement falls outside of fair market value, it "ceases to meet all the requirements of an applicable exception . . . [and] referrals for DHS by the physician to the entity that is a party to the arrangement are no longer permis-

<sup>26</sup> *Id.* at 71317.

<sup>27</sup> *Id.*

<sup>28</sup> *Id.*

<sup>29</sup> *Id.* at 71321.

<sup>30</sup> *Id.* at 71318-19.

<sup>31</sup> *Id.*

<sup>32</sup> *Id.* at 71318.

<sup>33</sup> *Id.* at 71318-19.

<sup>34</sup> *Id.* at 71318.

<sup>35</sup> *Id.*

<sup>36</sup> *Id.*

<sup>37</sup> *Id.*

<sup>38</sup> *Id.* at 71319.

<sup>39</sup> *Id.*

sible.”<sup>40</sup> Accordingly, CMS advises that “[t]he 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>41</sup>

## **VI. Pulling the Pieces (of Documentation) Together**

CMS’ clarifications to Stark law exceptions requiring arrangements be “set out in writing” and “signed by the parties” provide entities and physicians with valuable tools to demonstrate past compliance and avoid

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<sup>40</sup> *Id.* at 71320.

<sup>41</sup> *Id.*

disclosure under the SRDP. When effective, the new indefinite holdover provisions will offer an even more reliable method to establish the continued validity of a lapsed agreement. However, compliance with the clarified writing requirement and the revised holdover provisions will require ongoing diligence by providers and their counsel in order to circumvent potential stumbling blocks lurking in the complexities and ambiguities of the final rule.

Though the provisions discussed in this article may serve to blunt the harsh repercussions of technical non-compliance with Stark exceptions, a single writing, as stressed by CMS in the final rule, remains the “surest and most straightforward means of establishing compliance with [an] applicable exception.”<sup>42</sup>

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<sup>42</sup> *Id.* at 71314.