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HEALTH LAW
A SHIPMAN & GOODWIN® ALERT

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Prior To Pursuing The Self-Referral Disclosure Protocol, Consider Your Obligation To Do So

The U.S. Department of Health and Human Services ("DHHS") recently published what it has referred to as "Physician Self-Referral Updates" pursuant to Section 1877 of Social Security Act (also known as the "Stark Law"), resulting in several new Stark Law exceptions, along with much needed clarification with respect to the Stark Law itself. See 80 FR 70886, November 16, 2015 (the "Update") [http://www.shipmangoodwin.com/webfiles/2015-28005.pdf]. The focus of this Shipman & Goodwin Alert is to provide our readers with some high level guidance regarding DHHS's latest clarifications and their impact on a health care provider's determination of whether the Stark Law has been in fact violated and/or whether to proceed with a Stark Law self-disclosure pursuant to the Self-Referral Disclosure Protocol ("SRDP").

Recent consolidations in the health care industry have led to more and more health care providers considering possible affiliations and/or acquisitions. As a result of the associated due diligence processes, it is common to yield one or more physician arrangements that give rise to the concern that a Stark Law compliance issue may exist. When this happens, the party discovering the issue will typically want the perceived compliance issue resolved with a self-disclosure pursuant to the SRDP prior to closing on the transaction. Before proceeding with a disclosure pursuant to the SRDP, we suggest that you consider whether the clarifications provided in the Update will mitigate or even eliminate the need for pursuing the SRDP process. We provide below several of the categories that most frequently give rise to perceived Stark Law compliance issues along with a summary of the clarification provided by DHHS:

1. An Agreement between a Provider of Designated Health Services[1] and a Physician that Is Not Signed by one or Both Parties:

   Currently under the Stark Law, if the failure to comply with the signature requirement of an exception is "inadvertent," the parties must obtain the required signature(s)

i Please see 42 CFR § 411.351 [http://www.ecfr.gov/cgi-bin/text-idx?SID=41487e69ee690c33810325209b7ab750&mc=true&node=se42.2.411_1351&rgn=div8] for the definition of "Designated Health Services" or "DHS". In general, DHS includes: (a) Clinical laboratory services; (b) Physical therapy, occupational therapy, and outpatient speech language pathology services; (c) Radiology and certain other imaging services; (d) Radiation therapy services and supplies; (e) Durable medical equipment and supplies; (f) Parenteral and enteral nutrients, equipment, and supplies; (g) Prosthetics, orthotics, and prosthetic devices and supplies; (h) Home health services; (i) Outpatient prescription drugs; and (j) Inpatient and outpatient hospital services.

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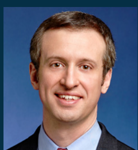

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within 90 days; otherwise, the parties must obtain the required signature(s) within 30 days. Acknowledging that "it is not uncommon for parties who are aware of a missing signature to take up to 90 days to obtain all required signatures," DHHS, pursuant to the Update, now allows parties 90 days to obtain the required signatures, regardless of whether the failure to obtain them was inadvertent.

2. An Agreement with a Provider of Designated Health Services and a Physician that Does Not Specify a Term of One Year:

The exceptions to the Stark Law for rental of office space, rental of equipment and personal service arrangements each require that the compensation arrangement between the Designated Health Service entity and referring physician has a term of at least 1 year. DHHS clarified that it is not necessary to have a written agreement identifying a term of 1 year or more. Instead, DHHS explained that as long as the parties have sufficient documentation to evidence that the arrangement in fact lasted for at least 1 year, the 1-year requirement is met. Significantly, DHHS emphasized that this interpretation is a clarification of its existing position on this issue, meaning that this interpretation applies to all past, current and future arrangements.

3. An Agreement between a Provider of Designated Health Services and a Physician that Expires with a Holdover Period:

Currently, the exceptions for space and equipment leases and personal service arrangements permit a "holdover" arrangement for up to 6 months if an arrangement of at least 1 year expires, the arrangement satisfies the requirements of the exception when it expires, and the arrangement continues on the same terms and conditions after its stated expiration. Effective January 1, 2016, indefinite holdovers will be permitted if all of the following conditions are met:

- The original arrangement expired after a term or duration of at least 1 year;
- The original arrangement was in compliance with the applicable Stark Law exception at the time of its expiration;
- The holdover arrangement continues on the same terms and conditions as the original arrangement; and
- The holdover arrangement, itself, complies for its duration with the terms of the applicable Stark Law exception.

This clarification can be very useful to health care providers who have inadvertently failed to renew or extend expired lease or personal service arrangements. However, as DHHS emphasized in its update, this increased flexibility only applies if certain conditions or safeguards are met. For example, the holdover arrangement must satisfy all of the elements of the applicable exception when the arrangement expires and on an ongoing basis throughout the holdover period. Thus, if rental amounts fall below fair market value during a holdover, the lease arrangement will no longer meet the fair market value

requirement of the applicable exception. Moreover, if the parties change the original terms and conditions during the holdover, the holdover exception will not apply. Instead, DHHS will consider this to be a completely new arrangement that must satisfy an applicable Stark Law exception. As noted in item 4 of this Alert, this new arrangement need not be reflected in one formal written agreement or contract.

Finally, please note that unlike some of the other clarifications in this Alert that apply retrospectively, the new holdover provisions apply prospectively as of January 1, 2016. More specifically, parties who are in a valid holdover arrangement under the current 6-month holdover provisions on January 1, 2016 may apply the indefinite holdover provisions to their arrangements. On the other hand, if an arrangement does not qualify for the 6-month holdover under the current regulations as of January 1, 2016 (for example, if the holdover has lasted for more than 6 months prior to January 1, 2016), the parties cannot make use of the indefinite holdover provisions.

4. An Agreement between a Provider of Designated Health Services and a Physician with No Single Written Agreement:

DHHS clarified that while "a single written document memorializing the key facts of an arrangement provides the surest and most straightforward means of establishing compliance with [the exception for personal service arrangements]… [t]here is no requirement under the physician self-referral law that an arrangement be documented in a single formal contract." DHHS made this clarification with respect to the lease of premises, lease of equipment, fair market value, bona fide employment and personal services exceptions.

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." DHHS provided several examples 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" including:

- Board meeting minutes, or other documents authorizing payments for specified services;
- Written communications between the parties;
- 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;
- Accounts payable or receivable records documenting the date and rate of payment and the reason for payment; and
- Checks issued for rent.

DHHS noted that “the documents must clearly relate to one another and evidence one and the same arrangement.”

5. Additional Clarification for “stand in the shoes rules”:

   DHHS clarifies that only physicians who stand in the shoes of their physician organization are considered parties to an arrangement for purposes of the signature requirements. This means that the Stark Law does not require that every physician sign all of the agreements between the provider of Designated Health Services and a physician organization. However, DHHS will look at all of the physicians in the organization, including non-owners, when determining volume variability of compensation paid to a physician organization. As a result, analysis under indirect compensation may no longer be necessary.

While consideration of these clarifications of the Stark Law may give your organization some comfort, it remains that the arrangement must provide compensation that is at fair market value, is commercially reasonable and does not take into account the volume or value of referrals by the physician.

Questions?

If you have any questions about this Alert or the Stark Law in general, please contact Joan Feldman (jfeldman@goodwin.com or 860.251.5104), Vincenzo Carannante (vcarannante@goodwin.com or 860.251.5096) or William Roberts (wroberts@goodwin.com or 860.251.5051).

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