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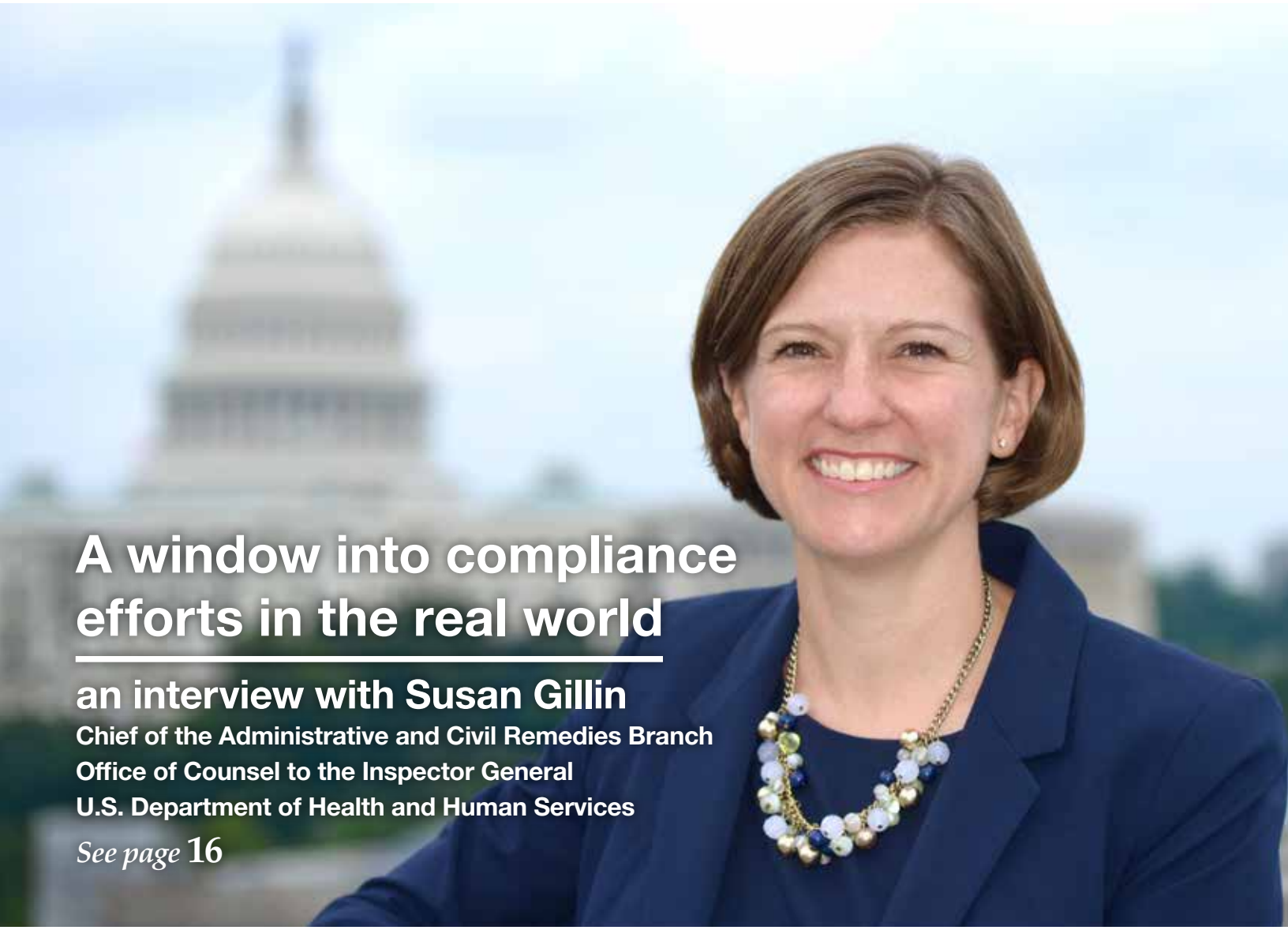

A window into compliance efforts in the real world

an interview with Susan Gillin

Chief of the Administrative and Civil Remedies Branch
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Physician-hospital relationships must be carefully assessed for risks and compliance with the Stark Law, including documenting any applicable exceptions.

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Key Stark Law developments thus far in 2017

» Hospitals and other healthcare providers should adopt and strictly implement a physician contracting policy.

» Physician contracting practices should be closely monitored to ensure compliance with the "writing" requirement.

» Compliance personnel should look beyond written agreements (e.g., professional services agreements, leases) to identify any free items or services that are being provided to physicians.

» Compensation based on work relative value units (wRVUs) or other performance metrics should be verified with evidence of personally performed services.

» Hospitals and other healthcare providers should conduct periodic Stark Law audits of their existing physician arrangements.

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Recent developments in the first half of 2017 illustrate how physician-hospital relationships continue to generate significant compliance risks under the Stark Law. These developments offer valuable insight for detecting, preventing, and correcting Stark Law compliance risks. With the continuing rise of government enforcement actions and whistleblower lawsuits, compliance professionals should consider the updates discussed below in assessing their organization's risk areas and take proactive compliance efforts to address any problematic arrangements.

Guidance on the writing requirement

Two recent court rulings address the "writing requirement," which is a mandatory component of several Stark Law exceptions, such as the personal service arrangement (PSA) exception. These exceptions will only protect an arrangement that is set out in writing, signed by the parties, and specifies the services covered. The writing requirement is typically satisfied by a single written agreement that contains all of the required elements. However, a collection of contemporaneous documents may also satisfy the writing requirement. Multiple documents must, at minimum, outline identifiable services, a timeframe, a rate of compensation, and must also be signed.[1,2] Recent court decisions illustrate how substandard documentation practices can result in compliance risks.

Insufficient collection of documents

In *United States ex rel. Emanuele v. Medicor Associates*,[3] a federal Court found that a series of documents in lieu of a single written agreement failed to meet the writing requirement, while also finding that certain arrangements based on expired contracts were potentially compliant. Hamot Medical Center (Hamot) allegedly entered into "sham" directorship arrangements with non-employee cardiologists, with the intent of inducing referrals in violation of the Stark Law. Several of these

arrangements were not memorialized in signed written agreements.

Although there was never a signed written agreement for several of these arrangements, Hamot argued that the arrangements were protected under several exceptions to the Stark Law that contained the writing requirement. Although Hamot was not able to produce signed written agreements, it relied on several documents to demonstrate the arrangements in question were "in writing." These documents included emails and letters indicating that Hamot intended to offer a cardiology directorship position to certain physicians, and that the physicians would soon start submitting claims for services rendered at the hospital. Hamot also produced an unsigned draft directorship agreement.

However, the Court found that Hamot's documents failed to satisfy the writing requirement because they lacked several crucial elements. The emails and correspondence only indicated that physicians would start working at Hamot's Cardiology department and that there was a prospective directorship position available. However, these documents did not detail any of the specific services that would be performed by the physicians, the duration of the arrangement, or the compensation terms. The Court also discounted the unsigned draft directorship agreement, finding that it did not adequately evidence a written agreement. In absence of the necessary elements to satisfy the writing requirement, Hamot was unable to rely on these exceptions to the Stark Law for these types of documents.

Continuing performance under expired contracts

The Court in *Emanuele* also reviewed six directorship arrangements for which the parties continued to perform pursuant to the terms of expired contracts. These directorship arrangements were initially memorialized in signed written contracts and were set to expire at specified dates, unless extended or renewed prior to termination. Although the agreements expired and were not extended or renewed, the parties continued to perform under the initial directorship contracts. The parties exchanged invoices and payments, showing that the physicians continued to perform services and that Hamot continued to make payments under the terms of the expired contracts. The physicians and Hamot eventually executed "addendums" to extend the term of each arrangement and attempted to use retroactive effective dates to close any gaps following the expiration of the initial contracts.

Unlike the first collection of documents that lacked any signed written agreements, the Court held that a jury could find that the expired contracts, addendums, invoices, and checks collectively satisfied the writing requirement. The original expired contracts and the addendums (which incorporated the terms of the prior agreements) outlined the identifiable services to be provided, the timeframe for the arrangements, and the compensation to be paid to the physicians. Although there was a gap of time between the expiration of the original contracts and the commencement of the addendums, the checks and invoices could serve as proof of the identified services provided, relevant dates, and payments made during this period. These documents, together with the original contracts and the addendums, can evidence the course of conduct between the parties and satisfy the writing requirement.

Deficient written agreements

Another recent case demonstrates how a single written agreement can fail the writing requirement for applicable Stark Law exceptions. In *United States ex rel. Salters v. Am. Family Care, Inc.*,[4] an arrangement between an urgent care entity and a physician-owned professional

corporation (PC) allegedly violated the Stark Law. In defense of these allegations, the defendants unsuccessfully relied on several Stark Law exceptions that contain the writing requirement.

Defendants produced a signed written agreement to evidence the arrangement between the urgent care entity and the PC and argued that the contract evidenced their compliance with the writing requirement. However, the Court found issues with the contract, primarily due to ambiguities concerning the signatures on the agreement and the identity of the parties to the arrangement. Although the agreement was signed, the identity of the individuals and their capacity to sign on behalf of the defendants was unclear. The Court noted that the name of the individuals was not printed next to the signatures.

Additionally, the contract had several blank fields where the name of the PC should have been inserted. Due to this oversight, the Court could not confirm that the agreement was intended to document an arrangement between the urgent care entity and the PC. If the template for the agreement was used for corporate entities as well as individuals, the failure to identify the PC in the blank fields could evidence an arrangement with the physician in his/her individual capacity. Even assuming the professional corporation was intended to be a party to the agreement, it was unclear whether the physician who signed the contract had the authority to bind the professional corporation. Without specifying the PC's name and the title of the physician-signatory next to a signature, the Court could not confirm that the agreement adequately documented the arrangement between the parties at issue.

These cases emphasize the importance of proper documentation and contract management protocols. Compliance personnel should incorporate the writing requirement when developing protocols for analyzing and reviewing hospital–physician relationships.

Free parking services and leasing arrangements

A hospital's provision of items or services to physicians on a free or at below-market rate is a long-standing compliance risk area. A recent court case displays the potential risks of providing free parking to physicians under a leasing arrangement. In *United States ex rel. Bingham v. BayCare Health Systems*, a hospital allegedly induced referrals by providing physicians with free access to the hospital's garage and the free use of valet services.[5] These perks were provided to physicians who were employed by an organization that had a written lease agreement with the hospital. Ultimately, the Court ruled in favor of the hospital, finding that there was no evidence of a direct compensation arrangement between the hospital and the physicians who received free parking.

A hospital's provision of items or services to physicians on a free or at below-market rate is a long-standing compliance risk area.

Nonetheless, this case emphasizes the importance of considering every aspect of physician-hospital arrangements, including any tangential items or services provided to physicians outside of the written agreement. Leasing arrangements can qualify for a Stark Law exception, provided that the parties specify the entirety of the premises and services provided under the written agreement.

Any aspect that is unaccounted for or is not considered in the arrangement can lead to compliance issues.

The parking services provided to the physicians in *Baycare* were protected under the office leasing exception, because the lease sufficiently referenced the parking benefits and accounted for these costs in the compensation. If these components were missing from the lease, the arrangement may not have satisfied the Stark exception by failing to specify the entirety of the arrangement.

Compliance personnel should look beyond a written agreement when analyzing physician-hospital arrangements. Anything provided to physicians, such as free parking, should be referenced in the written agreement and should satisfy an applicable exception.

Improper wRVU compensation arrangements

A recent settlement between the Department of Justice (DOJ) and defendants Mercy Hospital Springfield and Mercy Clinic Springfield illustrate the risks of improper work relative value unit (wRVU)-based compensation arrangements.[6] Mercy Clinic Springfield, an oncology infusion center, entered into contractual arrangements with physicians that contemplated the provision of a productivity bonus tied to the physicians' drug administration wRVUs. However, these wRVUs were allegedly calculated in a manner that was not based on the physicians' personally performed services. Rather, the wRVUs were allegedly inflated to enhance the physicians' compensation to a particular amount to reward and/or induce referrals.

The Mercy settlement illustrates that a wRVU-based compensation structure that is compliant in its written form can still violate the Stark Law if improperly implemented. Compensation for wRVUs that are not actually performed can result in arrangements that violate the Stark Law.

Internal monitoring and auditing activities should look beyond the agreement and verify wRVUs or similar metrics used in calculating physician compensation. Compensation paid for referrals under the guise of wRVUs or personally performed services can lead to serious consequences, particularly if it is found that the parties' conduct was fraudulent.

New guidance on CMP Law in connection with Stark Law overpayments

Recent updates to regulations implementing the Civil Monetary Penalties (CMP) Law (42 U.S.C. §1320a-7a) indicate heightened liabilities and scrutiny for Stark Law violations.[7] The CMP Law permits the Office of Inspector General (OIG) for the Department of Health & Human Services to impose CMPs on individuals and entities for certain Stark Law violations. The final rule indicates that the OIG may increase its enforcement participation in connection with Stark Law violations.

Notably, the final rule indicates that CMPs for untimely Stark Law self-disclosures and refunds will be imposed differently as compared to other types of self-disclosures. CMPs can be imposed for failing to refund overpayments on a "timely basis."[8] For most overpayment refunds, "timely basis" means 60 days from the date of identification (or the due date of any corresponding cost report). However, in connection with Stark Law self-disclosures, the OIG defines "timely basis" as 60 days from the time the prohibited amounts are collected.

Conclusion

As illustrated by the developments discussed above, physician-hospital relationships must be carefully assessed for compliance with the Stark Law, including

any applicable exceptions that are relied upon by the parties. Because the Stark Law is a strict liability statute (i.e., intent of the parties is immaterial), seemingly technical violations or instances of non-compliance can result in significant liability. Compliance personnel should be mindful of these developments, as well as any other recent updates, in formulating risk assessments and compliance policies and procedures.

1. See 42 C.F.R. §411.357(l) Exceptions to the referral prohibition related to compensation arrangements. Available at http://bit.ly/2w8BVNd
2. 80 Fed. Reg. 70886, 71314-71315 The Writing requirement. November 16, 2015. Available at http://bit.ly/2wstHSv
3. *United States ex rel. Emanuele v. Medicor Associates*. No. 10-245 Erie, 2017 U.S. Dist. LEXIS 36593 (W.D. Pa. Mar. 15, 2017).
4. *United States ex rel. Salters v. Am. Family Care, Inc*. No. 5:10-cv-2843-LSC, 2017 U.S. Dist. LEXIS 58806 (N.D. Ala. Apr. 18, 2017).
5. *United States ex rel. Bingham v. BayCare Health Systems*. No. 8:14-cv-73-T-23JSS, 2017 U.S. Dist. LEXIS 58839 (M.D. Fla. Apr. 18, 2017).
6. See Settlement Agreement by and among the OIG, HHS, Mercy Hospital Springfield f/k/a St. John's Regional Health Center, Mercy Clinic Springfield Communities f/k/a St. John's Clinic, Inc., and Relator Viran Roger Holden, MD, dated April 19, 2017. Available at http://bit.ly/2vk8IOh.
7. 81 Fed. Reg. 88334 Revisions to Civil Monetary Penalty Rules. December 7, 2016. Available at http://bit.ly/2wKa88c
8. See 42 C.F.R. §1003.300 Basis for civil money penalties, assessments, and exclusions. Available at http://bit.ly/2vkm8tj