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HEALTH LAW DISPATCH

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The Supreme Court of New Jersey Finds Health Insurance Fraud Based on Violations of the Corporate Practice of Medicine

By Brian M. Foley, Esq. and Sharmila D. Jaipersaud, Esq.

On May 4, 2017, by a unanimous decision, the Supreme Court of New Jersey held that the trial court correctly found the defendants knowingly violated the Insurance Fraud Prevention Act ("IFPA") N.J.S.A. 17:33A-1 to 30. In the case of Allstate Insurance Company v. Northfield Medical Center, P.C. (A-27-15)(076069), the Supreme Court reviewed an Appellate Division decision to overturn the trial court's ruling that the defendants, Robert P. Borsody, Esq. ("Borsody"), a New York attorney, and Daniel H. Dahan ("Dahan"), a California chiropractor, violated the IFPA by promoting and assisting in the creation of a practice structure that was designed to circumvent regulatory requirements with respect to the control, ownership, and direction of a medical practice.

Borsody and Dahan had engaged in conduct where they promoted the concept of inter-disciplinary medical practices, which created a circumstance where chiropractors were controlling a practice that was employing physicians. The practice was owned by physicians, but in name only. The Board of Medical Examiners prohibits a lesser licensed practitioner to be the employer of a plenary licensed practitioner. Allstate alleged that since defendants engaged in a practice that was in violation of the Board of Medical Examiners' regulations, the claims they submitted for services provided by such physicians and chiropractors constituted insurance fraud in violation of the IFPA. The trial court found in favor of Allstate and awarded it nearly $4 million for the IFPA violation. On appeal, the defendants argued that the IFPA required "knowledge" that their practice model violated regulatory requirements. Defendants also argued that even if there was evidence of knowledge, Allstate would have to prove that the defendants knew a violation of the regulations could constitute insurance fraud under the IFPA. In overturning the trial court, the Appellate Division found that the trial court erred in finding a "knowing" violation of the IFPA on the facts presented.

The Supreme Court granted Allstate's petition for certification. In its argument to the Supreme Court, Allstate maintained that the trial court had sufficient evidence to determine the impact of the chiropractor-owners control over the medical practice, through interconnected management and other agreements. In overturning the Appellate Division, the Supreme Court differentiated this case from an honest mistake made in submitting a claim for reimbursement. The Supreme Court found that bare legal title was vested in the physician, however, the physician was a "stranger to the medical practice and was not operationally in control…" The Supreme Court found there was an abundance of proof that placed control of the practice "in the hands of the chiropractor and not the physician." Furthermore, the Supreme Court said under the IFPA, "knowledge" should be inferred under these circumstances, with ample evidence to support the existence of the IFPA violation.

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Physician Contracts: Satisfying Stark's Writing Requirement

By Daniel O. Carroll, Esq.

On March 15, 2017, the United States District Court in United States ex rel. Emanuele v. Medicor Assocs., 2017 U.S. Dist. LEXIS 36593 (W.D. Pa. Mar. 15, 2017), provided judicial insight regarding what is needed to satisfy the writing requirement of the regulatory exceptions to the Stark law. Unless an exception applies, the Stark law prohibits a health care entity from submitting claims to Medicare based upon referrals from physicians who have a financial relationship with such entity. See 42 U.S.C. § 1395nn. The Emanuele decision analyzed the writing requirement for certain Stark law exceptions. The court relied heavily on guidance from the Center for Medicare and Medicaid Services ("CMS") in its comments to the final rule amending the Stark law exceptions in November 2015. See 80 Fed. Reg. 70886.

Emanuele involved certain financial arrangements between a physician practice, Medicor Associates, Inc. ("Medicor"), and The Hamot Medical Center of the City of Erie ("Hamot") for Medicor's provision of various cardiovascular services to Hamot. Specifically at issue in this case were certain medical director agreements and other professional services agreements, some of which were signed but allowed to expire ("Expired Arrangements") and others of which were never signed or reduced to a formal written agreement ("Unsigned Arrangements"). Notwithstanding the fact that the Expired Arrangements had lapsed and the Unsigned Arrangements had yet to be reduced to a formal writing signed by the parties, the parties continued to operate as if such arrangements were in effect. Plaintiff sought summary judgment against Medicor and Hamot on the limited basis that the Expired Arrangements (due to the expiration of the term) and the Unsigned Arrangements (due to the lack of a signed agreement) failed to satisfy the regulatory requirement that any such arrangement be in writing. See 42 C.F.R. § 411.357(d)(1), (f) or (l).

While a single written document memorializing an arrangement provides the best means of establishing compliance with the applicable Stark exceptions, there is no requirement that an arrangement be documented in a single formal contract. The court held that the Expired Arrangements evidenced by the medical director agreements, which were allowed to lapse, considered together with subsequent signed addenda and related checks and invoices exchanged by the parties throughout the duration of the arrangements, were sufficient to allow the defendants to survive summary judgment. The court noted that the writing requirement for the applicable Stark exceptions can be satisfied by a "collection of documents, including contemporaneous documents evidencing the course of conduct between the parties." However, the court also held that the Unsigned Arrangements, which were never signed or initially reduced to a formal written agreement could not be deemed to satisfy the writing requirement. The collection of documents offered to evidence the Unsigned Arrangements did not memorialize the material terms and conditions of the arrangement, such as timeframe, compensation and identifiable obligations of the parties. Moreover, none of the documents contained the signature of the parties evidencing their express assent to the arrangement. Therefore, the defendants could not rely on any exception to the Stark law for the Unsigned Arrangements.

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OIG & HCCA Publish New Guide for Measuring Compliance Program Effectiveness

By Meghan V. Hoppe, Esq.

The U.S. Department of Health and Human Services, Office of Inspector General ("OIG"), in conjunction with the Health Care Compliance Association ("HCCA"), recently published a new guidance document entitled *Measuring Compliance Program Effectiveness: A Resource Guide* (the "Guide"). The Guide stems from a January roundtable meeting among compliance professionals and OIG staff that was aimed at developing ideas for measuring

the various elements of a compliance program. These ideas were compiled to create the final Guide, which is intended to help health care organizations measure the effectiveness of their compliance programs. The OIG's stated purpose for publishing the Guide is to "give health care organizations as many ideas as possible, be broad enough to help any type of organization, and let the organization choose which ones best suit its needs."

The Guide highlights seven key elements of an effective compliance program, which were taken from the *Detailed Content Outline* developed by the HCCA in its *Certified in Healthcare Compliance (CHC) Candidate Handbook*:

1. Standards, Policies and Procedures;
2. Compliance Program Administration;
3. Screening and Evaluation of Employees, Physicians, Vendors and other Agents;
4. Communication, Education and Training on Compliance Issues;
5. Monitoring, Auditing and Internal Reporting Systems;
6. Discipline for Non-Compliance; and
7. Investigations and Remedial Measures.

The Guide provides metrics for "what to measure" and "how to measure" in order to evaluate the effectiveness of an organization's compliance program with respect to each element. The 54-page Guide lists hundreds of metrics that can be used to evaluate compliance programs, however, the authors emphasize that it should not be used as a "checklist" to be applied wholesale to assess a compliance program. Instead, the authors urge compliance professionals to use the Guide in accordance with each organization's needs, including specific risk areas, size, resources, and industry segment. The Guide can be used as a starting point for creating a health care compliance program or as a tool to evaluate the effectiveness of an organization's existing compliance program.

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Third Circuit Court of Appeals Affirms Dismissal of False Claims Action Based on Immateriality of Misrepresentations

By Divya Srivastav-Seth, Esq.

The Third Circuit Court of Appeals recently affirmed the dismissal of a lawsuit which claimed that Genentech Inc. violated the False Claims Act, 31 U.S.C. § 3729(b)(4) ("FCA"), when it knowingly misrepresented a drug's adverse side effects to physicians and led them to incorrectly certify that their prescriptions were "reasonable and necessary" on claims for Medicare reimbursement. United States of America, ex rel. Gerasimos Petratos etc. v. Genentech, 2017 U.S. App. LEXIS 7667 (3d Cir. May 1, 2017) ("Genentech"). The Genentech court determined that the complaint did not plead the facts necessary to satisfy the materiality element of the FCA under the rigorous standard established by the United States Supreme Court ("Supreme Court") in its decision in Universal Health Services. v. United States ex rel. Escobar, 136 S. Ct. 1989, 1993 ("Escobar").

The Supreme Court in Escobar stated that the FCA is not a means to punish garden-variety violations, and that, although the Government's decision to expressly identify a provision as a condition of payment is relevant, it is not automatically dispositive to an inquiry about materiality under the FCA. Conversely, it is very strong evidence that requirements are not material, if the Government pays a particular claim despite its knowledge that those requirements were violated.

In its analysis, the Genentech court noted that many years prior to the FCA action, the relator had notified both the Food and Drug Administration and Department of Justice ("DOJ") of the alleged deficiencies and that neither had taken any adverse action against Genentech. The court applied the Escobar standard and determined that the government's prior knowledge of the misrepresentations and its lack of enforcement and continued payment on the claims despite this knowledge was indicative of immateriality under the FCA. The court also interpreted the DOJ's decision to not intervene in the

action, as is its prerogative under the FCA, as demonstrative of a lack of materiality. The appellate court further found persuasive the lack of any allegations that argued that CMS would not have paid if it had knowledge of the purported non-compliance. The failure to plead or to dispute that the misrepresentations influenced the government's decision to pay rendered the misrepresentations immaterial and not subject to relief under the FCA.

The Genentech decision demonstrates that the Escobar standard may be a formidable obstacle to the survival of a FCA claim and a determination of materiality under the FCA may be made at the pleading stage of a case.

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Recent IRS Private Letter Ruling Discusses Unrelated Business Taxable Income (UBTI)

By Farah N. Ansari, Esq.

In a recent ruling, IRS Private Letter Ruling 201703005, the IRS concluded that the leasing of property by a public charity (the "Association") to a State University, on behalf of University Hospital which is a division of State University, will be substantially related to its exempt purposes and, consequently, rental income on certain debt-financed property will not result in unrelated business taxable income ("UBTI"). The Association was formed to maintain a Community Hospital and to lease property in furtherance of its purposes. In order to better serve the health care needs of the region, the Association integrated the Community Hospital operations with University Hospital, pursuant to an affiliation agreement with State University. The Association also leased certain of its premises, including the Community Hospital building, to State University. The Community Hospital building was subject to tax-exempt bond financing. The lease could be terminated for specified reasons, including if Community Hospital was not operated in furtherance of its mission. The rent due was limited to the Association's obligations pursuant to the tax-exempt bond financing and certain administrative expenses. The rent would decrease once the payments pursuant to the tax-exempt bonds were satisfied.

UBTI is defined under Internal Revenue Code (the "Code") Section 512 as gross income derived by an organization from any unrelated trade or business regularly carried on by it, less deductions. "Unrelated trade or business" is defined as a trade or business that is not substantially related to the organization's exempt purposes. Code Section 513. Rents from real property are generally excluded from UBTI, but if the rent is derived from debt-financed property, as defined in the Code, then the portion of income that is derived from the debt-financed property is included in UBTI. However, if the rental activity is "substantially related" to the organization's exempt purposes, then the rental income remains excluded from UBTI. The IRS concluded that the lease of the premises to State University would further the Association's exempt purposes and the use of the premises by State University, through University Hospital, will be substantially related to the Association's exempt purposes, and therefore, any rent would not be included in UBTI.

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RECENT HEALTH LAW LEGAL ALERTS:

Covered Entity Penalized for Lack of Business Associate Agreement

The Substance Use Disorders Law, P.L. 2017, c. 28, Imposes New Requirements and Limitations on Prescribing of Controlled Dangerous Substances, and Special Requirements for the Management of Acute and Chronic Pain