April 15, 2015

Dear Health Law Section Members:

The Section website has been updated with the March 2015 articles on significant developments in the health law arena that may be of interest to you in your practice. These summaries are presented for general information only as a courtesy to Section members and do not constitute legal advice from The Florida Bar or its Health Law Section. On behalf of the Section, we extend my deepest appreciation to the following volunteers who have generously donated their time to prepare these summaries for your review:

Kevin Dewar, Esq.

Michael L. Ehren, Esq.

Rodney Johnson, Esq.

Timothy Moore, Esq.

Lucette Pierre-Louis, Esq.

Anushree Nakkana, Esq

Michael L. Smith, Esq.

Kimberly Speer Sullivan

We would also like to extend our appreciation ***to Chip Koval, Esq.,*** whose name was mistakenly omitted from our November/December 2014 update. Chip served for several years as a dedicated Practice Area Reporter and we appreciate his efforts.

Thank you.

Malinda R. Lugo, Esq. ***Co-chair of the HLS Monthly Updates***

Kimberly Speer Sullivan, Esq. ***Co-chair of the HLS Monthly Updates.***

You can download a copy of this month's update using the links below or read the updates in this article on the Section website.

FACILITY AND PROFESSIONAL LICENSURE

1Supervising Physician Extenders While Under Practice Restrictions

On February 6, 2015, the Board of Medicine clarified that a physician who is restricted from providing any examinations or treatment to female patients may not supervise a physician extender that cares for female patients. The physician requested clarification of the Board's Final Order imposing a restriction on the physician providing care to female patients. The physician specifically asked if the restriction prohibited him from supervising Advanced Registered Nurse Practitioners and Physician Assistants that provided examinations and treatment to female patients. The Board stated that a male physician prohibited from treating female patients could not supervise a nurse practitioner or physician assistant that treated female patients. The Board of Medicine also indicated that it would include additional language in all future final orders imposing restrictions on male physicians treating female patients.

Reported by Michael L. Smith, Esq.

FRAUD AND ABUSE

Eleventh Circuit Adheres to *Esquenazi's* Definition of "Instrumentality" Under FCPA

In *United States v. Duperval*, 777 F.3d 1324, 1333-34 (11th Cir. 2015), the Eleventh Circuit reiterated the broad definition of Foreign Corrupt Practices Act ("FCPA") "instrumentality" that the court first articulated in *United States v. Esquenazi*, 752 F.3d 912, 925 (11th Cir. 2014*), cert. denied*, —— U.S. ——, 135 S.Ct. 293 (2014).

Under the FCPA, an officer of a domestic concern cannot make a corrupt payment to a "foreign official," which includes "any officer or employee of a foreign government or any department, agency or instrumentality thereof." 15 U.S.C. § 78dd–2(a)(1), (h)(2)(A). Duperval was the Director of International Affairs at Telecommunications D'Haiti ("Teleco"), a company the government of Haiti owned. He participated in two schemes in which international companies bribed him in exchange for favors from his company. Based on that conduct, a federal grand jury indicted him for conspiring to commit money laundering and concealment of money laundering. Duperval's transactions also allegedly involved proceeds of FCPA violations. Accordingly, the government had to prove that Teleco was an instrumentality of Haiti. After conducting an analysis (which can be found in the case), the court concluded that the government had shown at trial that Teleco was an instrumentality of the Haitian government.

Reported by Timothy M. Moore, Esq.

Fourth and Sixth Circuits Narrow Public Disclosure Bar to FCA Liability

One of the hurdles *qui tam* relators must clear when pursuing a False Claims Act case is 31 U.S.C. § 3730(e)(4), the public-disclosure bar. The bar instructs courts to dismiss claims "if substantially the same allegations or transactions as alleged in the action or claim were publicly disclosed" in one of several statutorily-enumerated contexts, unless the government opposes dismissal or the relator is an original source of the information. *Id.*

The Fourth Circuit, in *United States ex rel. Wilson v. Graham County Soil & Water Conservation Dist.*, 777 F.3d 691 (4th Cir. 2015), held that the public disclosure bar was not triggered by disclosure of a government audit report or investigation report to other federal or state officials investigating the fraud. The Sixth Circuit, in *United States ex rel. Whipple v. Chattanooga-Hamilton County Hosp. Authority*, No. 13-6645, 2015 WL 774887 (6th Cir. Feb. 25, 2015), held that disclosures made to the government, or to contractors working on its behalf, during an audit were not "public" disclosures foreclosing a False Claims Act relator's case.

Those opinions rejected the Seventh Circuit's interpretation of "public disclosure" to include disclosure of an allegedly false claim to a competent public official having managerial responsibility for that claim. *Wilson*, 777 F.3d at 697 (rejecting *United States ex rel. Mathews v. Bank of Farmington*, 166 F.3d 853, 861 (7th Cir. 1999), *overruled on other grounds by Glaser v. Wound Care Consultants, Inc.*, 570 F.3d 907 (7th Cir. 2009)); *Whipple*, 2015 WL 774887, at *5-6 (same).

In so doing, the Fourth and Sixth Circuits joined five other circuits, including the Eleventh Circuit, and established a majority position: disclosure is not public when made only to or within the government. *United States ex rel. Williams v. NEC Corp*., 931 F.2d 1493, 1499–1500 (11th Cir. 1991); *United States ex rel. Oliver v. Philip Morris USA, Inc.*, 763 F.3d 36, 42 (D.C. Cir. 2014); *United States ex rel. Meyer v. Horizon Health Corp.*, 565 F.3d 1195, 1200 & n.3 (9th Cir. 2009); *United States ex rel. Rost v. Pfizer, Inc.*, 507 F.3d 720, 730 (1st Cir. 2007), *overruled on other grounds by Allison Engine Co. v. United States ex rel. Sanders*, 553 U.S. 662 (2008); *Kennard v. Comstock Res., Inc.*, 363 F.3d 1039, 1043 (10th Cir. 2004).

Reported by Timothy M. Moore, Esq.

HHS OIG Advisory Opinion 15-03

Advisory Opinion 15-03, which mirrors Advisory Opinion 14-07, approves a Medigap insurer's use of a preferred-hospital network. Under the insurer's contract with the network, (A) network hospitals will waive up to 100% of Medicare Part A inpatient hospital deductibles for the insurer's policyholders, (B) the insurer will pay the network a fee each time it admits one of the insurer's Medicare policyholders, and (C) the insurer will credit Medicare enrollees with $100 towards the next policy premium. The insurer will inform its policyholders that they may choose any hospital without penalty, and the network will be open to any Medicare-certified hospital compliant with applicable state laws. The insurer will also include its realized savings in its annual experience exhibits filed with state insurance departments. Those conditions and others described in the opinion led OIG to conclude that the program presented a sufficiently low risk of fraud or abuse.

Reported by Timothy M. Moore, Esq.

HHS OIG Advisory Opinion 15-02

Advisory Opinion 15-02 confirms that a physician excluded from federal healthcare programs may receive federal healthcare program payments for services lawfully performed by the physician or the physician's practice before exclusion.

Reported by Timothy M. Moore, Esq.

HHS OIG Advisory Opinion 15-01

Advisory Opinion 15-01 approves advertising and providing free diapers and playpens in connection with the prenatal and postnatal services provided under a home visiting program for at-risk mothers and infants. Eligible Medicaid beneficiaries may receive one pack of diapers during the initial consultation and up to nine more packs during subsequent visits. Eligible Medicaid beneficiaries may receive a playpen only after completing all ten visits. The diapers are valued at less than $5 per pack, and the playpen is valued at less than $50. OIG reasoned that program would not trigger civil monetary penalties because the diapers have nominal value and the diapers and playpen fit within the preventative care exception.

Reported by Timothy M. Moore, Esq.

HEALTH INFORMATION AND PRIVACY

House Bill to Prohibit Sharing of Health Information Obtained Through HealthCare.gov

On January 30, 2015, U.S. Rep. Don Young (R-AK) introduced the Protecting Rights Online To Ensure Consumers' Trust Act of 2015 (H.R. 633) ("PROTECT Act"), a bill to amend the Patient Protection and Affordable Care Act to prohibit the sharing of protected health information obtained through the Federally Facilitated Marketplace (located at HealthCare.gov) for marketing purposes. Specifically, the PROTECT Act would prohibit the federal government from permitting personally identifiable information – including information protected under HIPAA privacy regulations – collected through the Federally Facilitated Marketplace to be shared with any non-governmental entity for any type of marketing purposes, including the marketing of health insurance coverage. The PROTECT Act would apply to any information sharing occurring after the effective date thereof. The text of the proposed bill can be found here: https://www.congress.gov/bill/114th-congress/house-bill/633/text

Reported by Michael L. Ehren, Esq.

PRIVACY ISSUE: FERPA v. HIPAA

Recently, the University of Oregon has been under scrutiny for using a student's mental health records to prepare its defense in a lawsuit initiated by the student. Jane Doe, a student, claims that the University mishandled her sexual assault involving three basketball players. While at the University, Doe also sought therapy at the campus health clinic. However, after filing suit, and without her consent, the University used Doe's mental health records to prepare their defense. In her lawsuit, among other things, Doe claimed "emotional distress," a medical claim, which triggered the applicability of the Family Educational Rights and Privacy Act ("FERPA"). Although FERPA was enacted to protect the privacy of student health records; however, it also permits a university to use or disclose a student's health records for a number of listed exceptions including, the preparation of a legal defense. Specifically, FERPA states, in part, that "[i]f a parent or eligible student initiates legal action against an educational agency or institution, the educational agency or institution may disclose to the court, without a court order or subpoena, the student's education records that are relevant for the educational agency or institution to

defend itself." 34 C.F.R. § 99.31. Significantly, HIPAA did not apply because, under FERPA, campus health clinics fall under "education records" or "treatment records" which are expressly excluded from coverage under the HIPAA Privacy Rule (even when the university is a HIPAA covered entity).

For additional news on this issue, visit:
http://www.npr.org/blogs/health/2015/03/09/391876192/college-rape-case-shows-a-key-limit-to-medical-privacy-law

Reported by Anushree Nakkana, Esq.

LIFE SCIENCES

Mobile Medical Applications: Guidance for Industry and Food and Drug Administration Staff

The way consumers interact with health information has changed greatly over the past decade as a result of constant innovation in the world of health IT. Mobile medical application and other electronic health product developers have been unsure about how their evolving technology fits within the current regulatory framework, and have been requesting specific guidance.

On February 09, 2015, the Food and Drug Administration (FDA) issued "Mobile Medical Applications: Guidance for Industry and Food and Drug Administration Staff," a guidance document to educate manufacturers, distributors, and other entities about how the FDA will regulate certain software applications intended for use on mobile platforms (mobile applications or "mobile apps"). In line with the FDA's current oversight approach which considers functionality over platform, the FDA is taking a risk-based approach and will regulate only mobile apps that are medical devices and whose functionality could present a risk to a patient's safety if the mobile app did not function as it was supposed to.

The guidance document states that FDA will apply its regulatory oversight to only the subset of mobile apps that are considered medical mobile apps. The following are mobile medical apps the FDA considers to be subject to regulatory oversight:

1. Mobile apps that are an extension of one or more medical devices by connecting to such device(s) for purposes of controlling the device(s) or for use in active patient monitoring or analyzing medical device data.

2. Mobile apps that transform the mobile platform into a regulated medical device by using attachments, display screens, or sensors or by including functionalities similar to those of currently regulated medical devices.

3. Mobile apps that become a regulated medical device (software) by performing patient-specific analysis and providing patient-specific diagnosis, or treatment recommendations.

Mobile apps the FDA will exercise enforcement discretion over include:

1. Mobile apps that provide or facilitate supplemental clinical care, by coaching or prompting, to help patients manage their health in their daily environment.

2. Mobile apps that provide patients with simple tools to organize and track their health information.

3. Mobile apps that provide easy access to information related to patients' health conditions or treatments.

4. Mobile apps that are specifically marketed to help patients document, show, or communicate to providers potential medical conditions.

5. Mobile apps that perform simple calculations routinely used in clinical practice.

The FDA guidance document can be found at:
http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM263366.pdf

Reported by Kevin Dewar, Esq.

Influential Advisory Panel Will Consider Hepatitis C Drugs' Costs in Guidelines

A 30-member panel of doctors and health care experts will soon address the cost-effectiveness of hepatitis C drugs in updated guidelines that could affect the prescribing and coverage for the medications. The panel is being led by the American Association for the Study of Liver Diseases and the Infectious Diseases Society of America, which collectively represent more than 10,000 physicians, health works and scientists.

Reported by Kevin Dewar, Esq.

PUBLIC HEALTH

Webinar—Health System Transformation: The Changing Legal Landscape. CDC's Public Health Law Program (PHLP) and the American Bar Association Health Law Section are co-hosting a three-part webinar series focused on three components of health system transformation: social impact bonds, workplace wellness programs, and electronic health information. The second webinar in the series will take place on Law and Quality: Addressing Healthcare-Associated Infections and is scheduled for **April 20, 2015 from 1:00-2:30pm EST**. The third seminar is titled Electronic Health Information: Assessing the Impact of Law and is scheduled for **May 11, 2015 from 1:00-2:30pm EST**. You can find more information at: http://www.americanbar.org/groups/health_law/news/2015/02/health_system_transf.html

Reported by Rodney Johnson, Esq.

The Changemaker's Guide. *The Changemaker's Guide* is ChangeLab Solutions' new interactive curriculum to help residents and advocates envision and create healthy neighborhoods. This guide can help trainers build community groups' capacity to effect change, influence policy, and engage with the planning processes that shape neighborhoods, cities, and regions. The workshop activities, icebreakers, and accompanying materials are available in both Spanish and English.

Reported by Rodney Johnson, Esq.

New LawAtlas Map: Air Quality Laws Pertaining to Oil and Gas Development. Air quality degradation is a concern in areas where directional drilling and hydraulic fracturing ("fracking") has increased. This map examines laws pertaining to air quality for operations and equipment on the fracking well pad site. It includes statutes and regulations from Colorado, Louisiana, Montana, New Mexico, North Dakota, Ohio, Oklahoma, Pennsylvania, Texas, Utah, West Virginia, and Wyoming.

Reported by Rodney Johnson, Esq.

New LawAtlas Map: Long-Term Involuntary Commitment Laws. Long-term involuntary commitment laws allow psychiatric facilities to accept a patient for an extended amount of time, without the patient's consent, if the patient displays dangerous symptoms of mental illness. This map depicts varying state laws on the duration of commitment, the rights that must be provided to a committed patient, and the subsequent limitations, if any, on a patient's right to possess a firearm under state gun laws.

Reported by Rodney Johnson, Esq.

THIRD PARTY PAYERS

Obama Administration Outlines Plan to Shift Medicare toward Alternative Payment Models

On January 26, the Obama Administration announced its plan to aggressively shift Medicare towards value-based payments and away from fee-for-service. Sylvia Burwell, the U.S. Secretary of Health and Human Services, announced the Administration wants a greater percentage of Medicare payments to go toward alternative payment models such as Accountable Care Organizations (ACOs) and bundled-payment arrangements. Last year, roughly 20% of traditional Medicare spending went to alternative models such as ACOs, but the Administration would like 30% of Medicare payments tied to alternative payment models by the end of 2016 and 50% of payments by the end of 2018. Secretary Burwell also explained the Administration is focused on increasing Medicare spending with a quality component, stating, the "goal is to have 85% of all Medicare fee-for-service payments tied to quality or value by 2016, and 90% by 2018." The announcement marks the first time explicit goals for alternative payment models and value-based payments have been set for the Medicare program.

While many welcome the new alternative payment models, many providers, industry experts, and consultants say it is too early to know whether these alternative payments actually improve

the health of patients and fear the purported benefits of alternative payment models may never materialize or may diminish over time. Of the existing ACOs, roughly one-fourth saved enough money to win bonuses in 2014. In the Medicare Shared Savings Program, the largest ACO experiment, 53 ACOs saved money and received bonuses, but 41 ACOs failed to save the money the government estimated they should have saved. ACOs that fail to save money or meet the many benchmarks set by the government will eventually be penalized financially.

Reported by Kimberly Speer Sullivan, Esq.

TRANSACTIONS

St. Luke's Seeks a Rehearing

In late March, St. Luke's Health System ("St. Luke's) asked the U.S. Court of Appeals for the 9th Circuit to rehear its case before a full panel of judges; thus, extending the highly-publicized anti-trust case, which questioned whether the health system violated Section 7 of the Clayton Act when it acquired Saltzer Medical Group, an Idaho-based physician group practice. On February 10, 2015, the 9th Circuit found St. Luke's and Saltzer genuinely intended to move toward a better healthcare system and found the merger would "improve patient outcomes" if left intact. However, the court also held the "huge market share" of the post-merger entity "creates a substantial risk of anti-competitive price increases…" In other words, it was not enough for St. Luke's to show the deal would improve care; instead, St. Luke's had to show the deal would not harm competition. Ultimately, the court ordered a complete divestiture and the FTC celebrated its first victory against a physician acquisition merger. This case has been watched closely by the healthcare community as providers look towards consolidation as a way to lower costs.

Reported by Lucetta Pierre-Louis, Esq.