

December 15, 2015

Dear Health Law Section Members:

The Section website has been updated with the November-December 2015 articles on significant developments in the health law arena that may be of interest to you in your practice. These summaries are presented to Section members for general information only and do not constitute legal advice from The Florida Bar or its Health Law Section. HLS thanks the following volunteers who have generously donated their time to prepare these summaries for our members:

**Kevin Dewar, Esq.**  
**Michael Ehren, Esq.**  
**Jamie B. Gelfman, Esq.**  
**Rodney Johnson, Esq.**  
**Jason Mehta, Esq.**  
**Michael Smith, Esq.**

Thank you.

**Trish Huie, Esq., HLS Team Editor**  
**Rachic' A. Wilson, Esq., HLS Team Editor**

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**

### **1 Allegations of Sexual Misconduct Not Proven by Clear and Convincing Evidence**

In Department of Health v. Davis, Case No.15-1868PL (Fla. DOAH September 11, 2015), the Administrative Law Judge (ALJ) from the Division of Administrative Hearings recently found that although the licensee acted outside the scope of his license by applying barrier cream to the patient's groin, the Department of Health failed to meet its burden of proof that a licensee engaged in sexual misconduct with a patient. The patient testified at the formal hearing that the alleged incidents occurred on two consecutive days and that he/patient complained of the incidents to the hospital on the day following the second alleged incident. According to the ALJ, "considered in its entirety, the patient's testimony is insufficient to produce 'in the mind of the trier of fact a firm belief or conviction, without hesitancy' that the Respondent committed the alleged sexual misconduct." Id. The ALJ noted that "the patient was capable of getting out of bed and exiting the room or calling for assistance, but he did neither." The ALJ relied upon the clear and convincing evidence test developed in Slomowitz v. Walker, 429 So. 2d 797, 800 (Fla. 4th DCA 1983). In Slomowitz, the court held:

clear and convincing evidence requires that the evidence must be found to be credible; the facts to which the witnesses testify must be distinctly remembered; the testimony must be precise and explicit and the witnesses must be lacking confusion as to the facts in issue. The evidence must be of such weight that it produces in the mind of the trier of fact a firm belief or conviction, without hesitancy, as to the truth of the allegations sought to be established.

Id. The Board of Nursing considered the Recommended Order at its December 2, 2015, meeting and imposed a fine of \$125.00, 1 year probation with direct supervision, and 8 hours of continuing education in each of the following areas: critical thinking, ethics and patient rights.

Reported by: Michael L. Smith

## **FRAUD & ABUSE**

### **Supreme Court to Address the Implied Certification Liability Theory under the False Claims Act**

On Friday, December 4, 2015, the United States Supreme Court agreed to hear a case addressing the validity of the implied certification theory of liability under the False Claims Act ("FCA"). The outcome of the case, *Universal Health Services v. United States ex rel. Escobar*, No. 15-7, -- S. Ct. --, 2015 WL 4078340 (Dec. 4, 2015), appealed from the First Circuit, may have a significant impact on future FCA claims brought by private plaintiffs.

Specifically, the Supreme Court has agreed to consider two significant questions arising from the case: (1) “Whether the ‘implied certification’ theory of legal falsity under the FCA – applied by the First Circuit below but recently rejected by the Seventh Circuit – is viable,” and (2) “If the ‘implied certification’ theory is viable, whether a government contractor’s reimbursement claim can be legally ‘false’ under that theory if the provider failed to comply with a statute, regulation, or contractual provision that does not state that it is a condition of payment, as held by the First, Fourth, and D.C. Circuits; or whether liability for a legally ‘false’ reimbursement claim requires that the statute, regulation, or contractual provision expressly state that it is a condition of payment, as held by the Second and Sixth Circuits.”

Under the implied certification theory, a party may be held liable for violating the FCA where that party has made a request for payment notwithstanding its noncompliance with applicable statutes, regulations or contract provisions that are material prerequisites to such payment. The circuits are currently split with respect to the application of the implied certification theory, with some circuits accepting the theory but applying it inconsistently, and other circuits rejecting the theory in its entirety. With respect to circuits that accept the theory, “courts differ as to whether a ‘condition of payment’ must be expressly identified as such, or whether a statute, regulation, or contractual provision can be a condition of payment even if it does not state that payment is conditioned on compliance.” *See* Petition for Writ of Certiorari at \*3, *Universal Health Servs., Inc. v. U.S.*, No. 15-7 (U.S. June 30, 2015), 2015 WL 4035937.

However, as the implied certification theory is commonly utilized as the basis of an FCA case, the outcome of the Supreme Court’s decision, whether rejecting the application of the theory altogether, providing a uniform standard for the application of the theory, or limiting its scope, could have a significant impact on the number of FCA claims brought against a would-be defendant. Indeed, if the Supreme Court upholds the validity of the implied certification theory, it could address the second question presented in the case by providing clarification and a consistent standard of application of the theory among the circuits.

Reported by: Jamie B. Gelfman, Esq.

### **Fraud, Fraud, Waste, and Abuse Snapshot: Compound Pharmacies**

In the past few months, government regulators from coast to coast have cast an increasing focus on compounded pharmacies. As compared to traditional pharmacies, compounded pharmacies focus on mixing, combining or otherwise altering ingredients to make a custom-tailored medication. While the Medicare and Medicaid programs have historically been reticent to offer large reimbursements for compounded prescriptions – thereby obviating the supply and demand of these prescriptions – the federal healthcare program for military personnel and their dependents, TRICARE, offered very generous reimbursements until recently. Reimbursements reached upwards of \$30,000-\$40,000 per cream per month. Coupled with very large profit

margins (upwards of 90%), those dynamics spurred a cottage industry of pharmacies focusing on compounding – many using unscrupulous tactics to generate business.

In recent months, the government has focused on these pharmacies and has sought to recoup some of what the government deems as fraud and abuse. In Florida, for example, more than a dozen pharmacies have settled with federal prosecutors, for upwards of \$8 million. Criminal prosecutions are also now underway. For example, in early December, prosecutors in Houston indicted four individuals for their role in selling ketamine to patients without a valid prescription. In all, prosecutors have both indicted owners and marketers of pharmacies for violations of the Anti-Kickback Statute as well as recouped more than \$50 million in civil recoveries using the False Claims Act.

From a compliance perspective, healthcare professionals would benefit from a reminder regarding compliance obligations. Many of the hardest hit pharmacies used 1099 marketers on a commission-basis who pitched products to consumers and doctors. In prosecuting these cases, the government has taken the position that the use of commission-based marketers, in the absence of a *bona fide* employee/employer relationship, constituted an improper kickback, in violation of the Anti-Kickback Statute.

Relying on longstanding Health and Human Services (HHS) advisory opinions, the government has contended that “[p]ercentage compensation arrangements are potentially abusive, however, because they provide financial incentives that may encourage overutilization of items and services and may increase program costs.” HHS Advisory Opinion 98-01. Likewise, the government has taken the position that where percentage compensation schemes are blessed in advisory opinions, the government has done so only where the circumstances “adequately reduce the risk that the remuneration provided under the Arrangement could be an improper payment for referrals or the generation of Federal health care program business.” For example, in HHS Advisory Opinion No. 14-01, HHS blessed the percentage arrangement as it “did not involve ‘percentage compensation’ in relation to federal or state health care business.”

Whether clients are in the pharmaceutical business or elsewhere, lawyers should remind them about the highly regulated federal healthcare programs and the need to err on the side of caution, particularly with arrangements that might seem to run afoul of the Anti-Kickback Statute. As this wave of scrutiny has shown, the consequences for failing to do so are drastic.

Reported by: Jason Mehta<sup>1</sup>

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<sup>1</sup> Jason Mehta is an Assistant United States Attorney in Jacksonville, Florida. The opinions in this article are his own and do not necessarily reflect the view of the Department of Justice.

## HEALTH INFORMATION TECHNOLOGY & PRIVACY

### **Administrative Law Judge Dismisses Federal Trade Commission's LabMD Data Security Enforcement Action**

On November 13, 2015, the Federal Trade Commission's (FTC) Chief Administrative Law Judge, D. Michael Chappell, issued a highly-anticipated 92-page initial decision, dismissing the FTC's data security administrative complaint against medical testing company LabMD, Inc. (LabMD). Judge Chappell rejected the FTC's claim that LabMD failed to provide "reasonable and appropriate" data security for personal information maintained on its computer networks, constituting an "unfair" trade practice under Section 5 of the Federal Trade Commission Act (FTC Act). *See* 15 U.S.C. § 45.

Section 5 of the FTC Act provides that the FTC has no authority to deem an act or practice "unfair" unless: (1) the act or practice causes or is likely to cause substantial injury to consumers, (2) the injury is not reasonably avoidable by consumers themselves, and (3) the injury is not outweighed by countervailing benefits to consumers or to competition. 15 U.S.C. § 45(n). Judge Chappell ruled that the FTC failed to demonstrate a "likely substantial injury" to consumers as a result of LabMD's alleged unfair data security practices and, at best, only demonstrated a possibility (but no probability or likelihood) of harm. Judge Chappell further reasoned that, "to impose liability for unfair conduct under Section 5(a) of the FTC Act, where there is no proof of actual injury to any consumer, based only on an unspecified and theoretical 'risk' of a future data breach and identity theft injury, would require unacceptable speculation and would vitiate the statutory requirement of 'likely' substantial consumer injury." Judge Chappell's ruling makes clear his belief that the FTC does not have unrestricted enforcement authority regarding alleged "unfair" data security practices.

On November 24, 2015, the FTC filed a notice of appeal of Judge Chappell's initial decision before the full FTC, which will review the matter *de novo*. If upheld, Judge Chappell's ruling may provide companies with potential grounds to challenge FTC's authority in future data security enforcement actions. The text of Judge Chappell's initial decision can be found here: [https://www.ftc.gov/system/files/documents/cases/151113labmd\\_decision.pdf](https://www.ftc.gov/system/files/documents/cases/151113labmd_decision.pdf).

By: Michael L. Ehren, Esq.

## LIFE SCIENCES

### **CDC Publishes Draft Opioid Prescribing Guidelines**

On December 15, 2015, The Centers for Disease Control and Prevention ("CDC") released draft guidelines for prescribing opioids for chronic pain. The draft guidelines are aimed at providing primary care providers with evidence-based information regarding patients who need help with pain. The draft guidelines are applicable only for patients who are eighteen years or older with chronic pain unrelated to active cancer treatment, and outside of palliative and end-of-life care.

The notice in the Federal Register seeks comments on the draft guidelines and also points the public to previously-unreleased documents.

The draft guidelines can be viewed at the following website:

<http://www.regulations.gov/#!documentDetail;D=CDC-2015-0112-0002>

Reporter by: Kevin Dewar, Esq.

## **PUBLIC HEALTH**

**Webinar: Healthy People 2020 Law and Health Policy Project.** The American Bar Association Health Law Section's Public Health and Policy Interest Group, along with PHLP and HHS's Office of Disease Prevention and Health Promotion, are offering a complementary three-part webinar series. The second webinar in the series, *The Healthy People 2020 Law and Policy Project: A Focus on Older Adults*, is scheduled for Monday, November 16, 2015, 1:00–2:30 (EST).

**Webinar Series on the Intersection of Public Health and Health Care—The Role of Law.** The American Health Lawyers Association and PHLP are co-hosting a six-part, free webinar series focused on legal issues at the intersection of public health and health care. The final webinar in the series, *One Year of Ebola—Legal Issues and Considerations*, will take place Friday, November 20, 2015, 1:00–2:30 pm (EST). This webinar will examine the current state of Ebola in West Africa, the legal considerations implicated in the US response to the outbreak, state screening and monitoring policies and their evolution over the past year, and how healthcare settings are legally preparing for the next threat.

**2016 Public Health Law Conference.** The Public Health Law Conference will take place September 15–17, 2016, at the Grand Hyatt, in Washington, DC. The conference, hosted by the Network for Public Health Law, is for public health lawyers, practitioners, officials, policymakers, researchers, and advocates. Conference attendees will learn about laws and policies affecting critical public health issues such as disease prevention, drug overdose, health data sharing, and access to care. Early bird registration is available now.

By: Rodney Johnson, Esq.