June 21, 2016

Dear Health Law Section Members:

The Section website has been updated with the April – May 2016 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, its Health Law Section, or Section members. HLS thanks the following volunteers who have generously donated their time to prepare these summaries for our members:

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Thank you.

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FRAUD & ABUSE

Toxicology and Urine Drug Screening Tests: A New Area of Interest for Regulators

In the past few years, regulators have been increasingly focused on toxicology and urine drug screening tests for potential healthcare fraud and abuse. This scrutiny seems to be intensifying in the past few months. And it appears the spotlight is being shined on both providers that perform the diagnostic tests, as well as those providers that refer urine toxicology tests to outside labs.

In late 2014, the Wall Street Journal reported that Medicare expenditures on toxicology labs were exploding and that many providers were making more money from testing patients rather than actually seeing patients. Many Medicare-treating practitioners routinely tested patients for exotic substances, such as PCP, an illicit substance that a Medicare-aged patient would not likely abuse, and MDMA (commonly known as "Ecstasy" or "Molly"). Medicare's spending on 22 high-tech tests for drugs of abuse hit $445 million in 2012, up 1,423% in five years; $14 million that year just on tests for angel dust, or PCP.

In the last few months, major settlements were announced concerning toxicology testing. For example, last October, the Department of Justice settled with Millennium Laboratories, one of the largest labs in the country and one of the highest bidders to the Medicare program, for more than $250 million. The United States alleged that Millennium caused physicians to order excessive numbers of urine drug tests, in part through the promotion of "custom profiles," which, instead of being customized for individual patients, were in effect standing orders that caused physicians to order a large number of tests without an individualized patient assessment. Millennium's use of the so-called "custom profile" led to the over-billing of federal health care programs which limit payment to services that are reasonable and medically necessary for the treatment and diagnosis of an individual patient's illness or injury. The United States also alleged that Millennium violated the Stark Law and Anti-Kickback Statute by providing physicians with free drug test cups on the express condition that the physicians return the specimens to Millennium for hundreds of dollars' worth of additional confirmatory testing. Similar investigations are pending.

As noted above, the focus seems to be on a wide-array of conduct – including medical necessity concerns, reflexive testing without particularized need, Stark Law concerns, and Anti-Kickback Statute concerns.

Partially in response to this increased attention, First Coast Service Options issued a new Local Coverage Determination last year providing more explicit guidance on the necessity of toxicology lab testing. This LCD, L36393, describes the appropriate indications and expected frequency of drug screening patients for safe medication management of their prescribed controlled substances. The proper method includes risk stratified pain management patients along with documentation by the clinician in the patient's medical record of the medical necessity for ordered testing on an individual patient basis. Providers should be mindful of this new guidance and should adhere accordingly, particularly given this growing area of focus.

Reported by: Jason Mehta, Esq. and Mitch Blum, Esq.

HEALTH INFORMATION TECHNOLOGY & PRIVACY

HHS Issues Guidance to Improve Patient Awareness and Utilization of Legal Rights Regarding Protected Health Information Under HIPAA

On June 2, 2016, the Department of Health and Human Services Office of the National Coordinator for Health Information Technology (ONC) issued a series of new online health information and technology guidance resources entitled the HIPAA Access Videos and Patient Engagement Playbook. These resources are aimed at (i) improving awareness of patients' legal rights to access and utilize their protected health information under the Health Insurance Portability and Accountability Act (HIPAA), and (ii) assisting health care providers in better engaging their patients to utilize these rights through use of health information technology.

The HIPAA Access Videos address various topics including HIPAA patient access and privacy regulations, patient medical record cost and timing issues, and third-party access rights. These resources can be found here: https://www.healthit.gov/access.The Patient Engagement Playbook is the ONC's guidance tool for improving health care providers' utilization of health information technology (including electronic health record patient portals) to provide effective and efficient patient access to their protected health information and improve patient engagement in their health care. The Playbook features a compilation of best industry practices and solutions from innovative health care providers and health systems nationwide, and can be found here: https://www.healthit.gov/playbook/pe/introduction/.

Reported by Michael L. Ehren, Esq.

OCR Begins Phase 2 of HIPAA Audit Program

In March 2016, the HHS Office for Civil Rights ("OCR") announced the start of its second phase of its HIPAA Audits ("Phase 2 Audit Program"). OCR has indicated that it will review the policies and procedures that covered entities, and their business associates, have in put into place to comply with the HIPAA Privacy, Security and Breach Notification Rules. The Phase 2 Audit Program will primarily be conducted in the form of desk audits, although some on-site audits may be conducted as necessary.

According to OCR, the Phase 2 Audit Program has already commenced, with OCR working to verify the contact information of potential subjects so that pre-audit questionnaires can be sent to those entities. The objective of the pre-audit questionnaire is to gather information related to the size, type and operations of potential auditees. OCR plans to use the responses on those questionnaires to aide in developing the audit pool. It should be noted, however, that a lack of response will not exclude the potential subject from the audit pool as OCR has made it clear that it may also use publicly available information about entities to create the audit pool. A sample of the pre-audit questionnaire can be found here: http://www.hhs.gov/hipaa/for-professionals/compliance-enforcement/audit/questionnaire/index.html

For those entities that are selected for an audit, OCR will notify the auditee in writing to introduce the audit team, explain the process and outline expectations. The letter will also include the initial requests for information, which should be responded to within 10 business days electronically via OCR's secure portal. OCR has also shared that auditees will be asked to identify their business associates, and has suggested that covered entities prepare a list of their business associates now in preparation for a potential audit. The suggested (though not required) template for providing the business associate information to OCR is available here: http://www.hhs.gov/hipaa/for-professionals/compliance-enforcement/audit/batemplate/index.html

Once all documentation has been received, OCR will review the information submitted and prepare draft findings. The auditee will have 10 business days to provide comments to OCR, after which OCR will prepare a final audit report to be delivered to the audited entity within 30 business days.

The Audit Protocol used by OCR has also been updated for the Phase 2 Audit Program and can be found here: http://www.hhs.gov/hipaa/for-professionals/compliance enforcement/audit/protocol/index.html

More detailed information can be found here: http://www.hhs.gov/hipaa/for-professionals/compliance-enforcement/audit/index.html

Reported by: Lindsay Dosen, Esq.

LIFE SCIENCES

FDA issues Draft Guidance on 3D Medical Devices

On May 10, the U.S. Food and Drug Administration (FDA) issued draft guidance titled "Technical Considerations for Additive Manufactured Devices" providing its initial thoughts on regulatory requirements for additive manufactured (AM) devices, the category of manufacturing that includes 3-dimensional (3D) printing. The FDA described this as a "leapfrog" guidance through which the Agency intends to provide its "initial thoughts" on this emerging technology, acknowledging that its recommendations may change as more information becomes available.

AM is a process that builds an object layer-by-layer, joining each new layer to the one below. This process allows manufacturers to more easily develop and alter device designs, while also making complex and customizable medical devices more readily available. To address this technological innovation, the FDA is introducing standards for ensuring the quality and safety of AM medical devices, including determining optimal assessment methods for the final finished device, as well as process validation and acceptance methods.

While the draft guidance is not meant to be a comprehensive document addressing all regulatory requirements, it "outlines technical aspects of an AM device that should be considered through the phases of development, production process, process validation, and final finished device testing." The guidance is split up into two categories of considerations: (1) design and manufacturing, and (2) device testing. Design and manufacturing considerations are intended to provide technical

considerations that should be addressed when fulfilling quality system (QS) requirements for the finished device, while device testing considerations are intended to describe the type of information that should be submitted in premarket submissions for AM devices, recognizing that the type and amount of data needed to establish substantial equivalence or obtain approval will vary "depending on the intended use, risk profile, and classification and/or regulation for the device type."

FDA necessarily cautions that "point-of-care manufacturing" -- 3D printing of devices at doctor's offices or hospitals – "may raise additional technical considerations not addressed in this guidance". FDA is requesting comments on the draft guidance by August 8, 2016.

Reported by: Ann Marie Gaitan, Esq.

New FDA Guidance Targets Electronic Health Records in Clinical Trials

On May 12, 2016 the U.S. Food and Drug Administration (FDA) published a draft guidance titled "Use of Electronic Health Record Data in Clinical Investigation," which is intended to guide clinical trial sponsors, investigators, contract research organizations (CRO), and institutional review boards (IRB) on the use of electronic health record (EHR) data in FDA-regulated clinical investigations of human drugs and biological products, medical devices, and combination products.

Through this draft guidance the FDA seeks to modernize and streamline clinical investigations, with the goal of providing recommendations for: (1) facilitating the use of EHR data in clinical investigations; and (2) promoting interoperability between EHRs and electronic systems widely used in clinical investigations. This guidance expands upon recommendations found in earlier guidance for the use of electronic source data from EHRs in clinical investigations, namely: "Computerized Systems Used in Clinical Investigations" (May 2007) and "Electronic Source Data in Clinical Investigations" (September 2013).

The draft guidance provides FDA's current thinking on the evaluation and use of EHRs as a source of clinical investigation data, using EHRs that are interoperable with systems that produce electronic records supporting clinical investigations, ensuring the quality and integrity of data collected and used, and ensuring that use of EHR data meets inspection, recordkeeping, and record retention requirements.

Generally speaking, FDA neither regulates EHRs nor the health care professionals and institutions that use them. Rather, HHS's Office of the National Coordinator for Health Information Technology (ONC) is primarily responsible for establishing the standards and certification criteria for EHRs. However, in order to accept data from clinical investigations for decision-making purposes, FDA must be able to verify the quality and the integrity of such data during FDA on-site inspections and audits; and sponsors must be able to assess the validity, reliability, and integrity of the data used when submitting a marketing application to the FDA. Therefore, this guidance clarifies FDA's expectations when EHRs are used as a source of data in clinical investigations. Since the FDA cannot force clinical investigations to use only EHRs that have been certified by the ONC, it has provided some criteria for reviewing a system's internal security

safeguards and for ensuring adherence to best practices in data collection and use. Notwithstanding, the FDA continues to encourage the use of certified EHR technology, stating that when used, this "would give FDA confidence during inspections that the EHR data is reliable and that the technical and software components of privacy and security protection requirements have been met."

FDA is requesting comments on the draft guidance by July 18, 2016.

Reported by: Ann Marie Gaitan, Esq.

FDA Targets Online Sales of Illegal Prescription Drugs

On June 9, 2016, The U.S. Food and Drug Administration (FDA) announced that it took action against 4,402 websites illegally selling unapproved prescription drugs to U.S. consumers. With the assistance of U.S. Customs and Border Protection, the FDA conducted inspections at International Mail Facilities (IMFs) and served formal complaints on domain registrars "requesting the suspension of the 4,402 websites." Additionally, FDA issued warning letters to "operators of 53 websites illegally offering unapproved and misbranded prescription drug products for sale to U.S. consumers."

The effort was part of "Operation Pangea IX, the Ninth Annual International Internet Week of Action (IIWA), a global cooperative effort, led by INTERPOL, to combat the unlawful sale and distribution of illegal and potentially counterfeit medical products on the internet."

Reported by: Ann Marie Gaitan, Esq.

PUBLIC HEALTH

Epinephrine Stocking Laws

In the United States, about 15 million Americans have food allergies; one in every 13 children has this potentially deadly condition. A food allergy reaction sends a patient to the emergency department every three minutes, totaling over 200,000 visits per year. Epinephrine is the first-line treatment for severe or life-threatening allergic reactions, or anaphylaxis. In recent years, a growing number of states have adopted epinephrine entity stocking laws. These laws allow authorized entities like restaurants, amusement parks and sports arenas to obtain and store auto-injectable epinephrine, or EpiPens, and administer the drug to individuals experiencing anaphylaxis. This issue brief and 50-State Survey examine epinephrine stocking laws across the U.S.

Reported by: Rodney M. Johnson, Esq.

Primer: Emergency Legal Preparedness Concerning Zika Virus

Several hundred cases of Zika infection have been reported across nearly all U.S. states. Our Primer outlines public health concerns underlying Zika virus and lays out current and anticipated

legal preparedness and response issues internationally and in the U.S. These include issues related to testing and screening, public health preparedness, funding, mosquito abatement efforts, and reproductive health rights. This Primer is updated regularly as events develop. Link: https://www.networkforphl.org/resources_collection/2016/02/02/738/primer_emergency_legal_preparedness_concerning_zika_virus/?utm_source=Network+Report+6-9-16&utm_campaign=Network+Report+6-9-16&utm_medium=email&utm_content=216

Reported by: Rodney M. Johnson, Esq.

Issue Brief: Disclosure of Identifiable Information by the Veterans Health Administration for Public Health Purposes

Public health agencies collect and use identifiable health information for surveillance, disease investigation and other public health purposes. The Veterans Health Administration (VHA) is an important source of data for public health activities. Health care facilities under the jurisdiction of the VHA are a significant component of health care services delivered to the United States population and should be included in public health related reporting and surveillance activities. This Issue Brief provides an overview of the statutes and requirements that permit, and in some cases require, VHA health facilities to release identifiable data, without the patient's authorization, to public health agencies. Link: https://www.networkforphl.org/resources_collection/2016/06/07/351/issue_brief_data_sharing_and_the_veterans_health_administrationc/?utm_source=Network+Report+6-9-16&utm_campaign=Network+Report+6-9-16&utm_medium=email&utm_content=216

Reported by: Rodney M. Johnson, Esq.

Updated Youth Sports Concussion Laws Table

The Centers for Disease Control and Prevention estimates 248,418 children aged 19 or younger were treated in U.S. emergency departments for sports and recreation related injuries that included a diagnosis of concussion or traumatic brain injury. This Table contains important updates to state concussion laws, and includes information on return-to-play protocols for student athletes, as well as the types of care providers that can issue return-to-play clearances. Link: https://www.networkforphl.org/resources_collection/2014/07/16/472/table_youth_sports_concussion_laws/?utm_source=Network+Report+6-9-16&utm_campaign=Network+Report+6-9-16&utm_medium=email&utm_content=216

Reported by: Rodney M. Johnson, Esq.

Webinars

Pursuing Health Equity: Promising Practices in Policy and Law: According to Healthy People 2020, health equity can be defined as the "attainment of the highest level of health for all people," regardless of one's race, gender, nationality, age, ethnicity, religion, and socioeconomic status. Legal approaches and tools are increasingly becoming a means for maximizing equity. This webinar, co-sponsored by CDC's Public Health Law Program and the Network, will focus on

promising practices, based in law, to address health equity issues through drug abuse treatment and overdose prevention, Medical-Legal Partnerships, and interventions in domestic violence and homelessness. The webinar will take place on Thursday, June 23 at 1:00 p.m. ET. Link: https://www.networkforphl.org/webinars/2016/05/23/780/pursuing_health_equity_promising_practices_in_policy_and_law/?utm_source=Network+Report+6-9-16&utm_campaign=Network+Report+6-9-16&utm_medium=email&utm_content=216

Reported by: Rodney M. Johnson, Esq.

Ask the Experts

States' Laws and Regulations Related to Body Art: As the popularity of tattoos, piercings and other forms of body art grows, states and localities must continue to adjust their regulations to address associated health risks. The Network was recently contacted by a county health department for information about regulations in different jurisdictions that define, prohibit or allow more unusual forms of body art. The Network provided a number of resources on laws and regulations. Link: https://www.networkforphl.org/resources_collection/2016/06/07/786/states_laws_and_regulations_related_to_body_art/?utm_source=Network+Report+6-9-16&utm_campaign=Network+Report+6-9-16&utm_medium=email&utm_content=216

Reported by: Rodney M. Johnson, Esq.

THIRD PARTY PAYORS

Physician Payment Reform: A New Proposed Rule Under Medicare Access and CHIP Reauthorization Act of 2015 ("MACRA")

A new rule was proposed under the Medicare Access and CHIP Reauthorization Act of 2015 ("MACRA"). This new rule proposes a two-track "Quality Payment Program" where clinicians could elect to participate in either the Merit-Based Incentive Payment System ("MIPS") or Advanced Alternative Payment Models ("Advanced APMs"). Some clinicians who participate in Advanced APMs may be exempt from MIPS reporting and qualify for a five percent Medicare Part B incentive payment. The list of qualifying Advanced APMs will be posted by CMS by January 1, 2017. And, comments on the Proposed Rule must be submitted by June 27, 2016.

MIPS would be a hybrid of three existing programs – the Physician Quality Reporting System, Physician Value-Based Payment Modifier and the Medicare Electronic Health Record ("EHR") Incentive Program for Eligible Professionals. In the single program, Eligible Professionals ("EPs") will be measured on:

- Quality (50% of the total score in year one; evaluated on six chosen measures from a range of options and replaces the "Physician Quality Reporting System")
- Cost (10% of total score in year one; based on claims using 40 episode-specific measures and replaces the Value Modifier Program)

- Clinical Practice Improvement (15% of the total score in year one; based on selected activities from a list of 90 options with a focus on rewarding clinical practice improvements such as care coordination, patient safety, etc.)
- Advancing Care Information (25% of total score in year one; customizable measures that reflect how clinicians use technology, also known as "meaningful use")

For more information on the Proposed Rule, including a fact sheet, please visit: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/Quality-Payment-Program.html

Link for Proposed Rule: https://www.gpo.gov/fdsys/pkg/FR-2016-05-09/pdf/2016-10032.pdf

Reported by: Anu Sagi-Nakkana, Esq.

AHCA Reaches Settlement Requiring Improved Access to Medicaid Services

In April 2016, the Agency for Health Care Administration ("ACHA") and groups representing pediatricians and dentists settled a class action regarding children's access to healthcare services under Florida's Medicaid program. After over a decade of litigation and three months of mediation, the parties entered into a settlement agreement on April 5, 2016, which was preliminarily approved by the United States District Court for the Southern District of Florida on April 28, 2016.

The settlement agreement requires AHCA to improve children's access to Medicaid services. As a result of Florida's transition to Medicaid managed care in 2014, many of the settlement terms are implemented through Managed Medical Assistance ("MMA") plans. Among other things, AHCA agreed to require MMA plans to adopt "Incentive Plans" under which Board-certified pediatricians treating children on Medicaid, obstetricians and other providers will have the opportunity to earn Medicare-equivalent reimbursement if they meet criteria for patient outcomes and access to care. The Incentive Plans are to be funded by savings generated from increased efficiencies associated with the transition to the MMA program. The performance of the Incentive Plans will be evaluated by a set of participation-related benchmarks. MMA plans that do not meet the benchmarks will be required to take corrective action.

The settlement agreement also includes measures designed to increase access to and utilization of pediatric dental services. AHCA agreed to undertake a study of network adequacy standards for pediatric dental providers to determine enhancements to MMA plan contracts for the 2016 contract year. The agreement sets forth annual interim benchmarks for individual MMA plans and the statewide MMA program.

The case is *Florida Pediatric Society/The Florida Chapter of the American Academy of Pediatrics, et al. v. Liz Dudek, et al.,* case number 05-23037, in the United States District Court for the Southern District of Florida.

Reported by: Monica McNulty, Esq.

TRANSACTIONS

First District Court of Appeal comments on Referral Sources in Healthcare

On May 31, 2016, the First District Court of Appeal reversed a trial court order denying a motion for a temporary injunction against a marketing representative who formerly worked for Smart Pharmacy and went to work for a competitor. The compounding pharmacy argued that it is dependent upon physicians prescribing medications to patients and as a result, considers its physician referral sources and their prescribing patterns to be *trade secrets.*

Viccari, a sales representative for Smart Pharmacy, had a restrictive covenant that precluded him from competing with Smart Pharmacy in the Jacksonville FL market for two years post-employment. Viccari resigned and three months later, went to work for another pharmacy and called on some of the same physicians he contacted when he was working for Smart Pharmacy in the Jacksonville market. Smart Pharmacy filed suit and requested a temporary injunction. The trial court denied the request for the injunction, reasoning that although the non-compete validly protected Smart Pharmacy's legitimate business interests in its relationships with referring physicians, Smart Pharmacy had an adequate remedy at law. Smart Pharmacy appealed and the 1st DCA reversed the order and remanded for entry of a temporary injunction.

This decision is notable in the North Florida community because there is currently a split of authority in the District Courts of Appeal regarding whether an employer can protect a "referral resource". Florida Statute §542.331 requires that any restrictive covenant, to be enforced, must be supported by one or more legitimate business interests. In *Southernmost Foot and Ankle Specialists, P.A v. Torregrosa*, 891 So. 2d 591 (Fla. 3d DCA 2004), Florida's Third District Court of Appeal held that the employer's relationships with "referral doctors" who referred patients to a South Florida podiatry practice were included among the legitimate business interests the court would protect. Yet, in *Florida Hematology & Oncology v. Tummala,* 927 So.2d 135 (Fla. 5th DCA 2006), the Fifth District Court of Appeal held to the contrary that the statute only protects substantial relationships with specific, identifiable existing or prospective patients. Referral sources supply a stream of unidentified prospective patients with whom the plaintiff had no prior relationship. As such, referral sources do not constitute a legitimate business interest under 542.335. The split in authorities has poised this issue to come before the Florida Supreme Court. However, in the meantime, the Smart Pharmacy case provides some indication that referral sources are protected in the First District Court of Appeal.

For more information please see: **Smart Pharmacy, Inc. v. Viccari, --- So.3d ---- (2016)** 2016 WL 3057379. Only the Westlaw citation is currently available.

Reported by: John F. MacLennan, Esq.