April 18, 2016

Dear Health Law Section Members:

The Section website has been updated with the February and March 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 or its Health Law Section. 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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COMPLIANCE

Post-Market Management of Cybersecurity in Medical Devices. Draft Guidance for Industry and Food and Drug Administration Staff.

On January 22, 2016 the FDA's Center for Devices and Radiological Health issued a new guidance that addresses the agency's expectations for the effective post-market management of cybersecurity in networked medical devices. This new guidance comes on the heels of a 2014 FDA guidance that addressed the content of premarket submissions for the management of cybersecurity risks in networked medical devices (http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM356190.pdf).

Under the new guidance, device manufacturers' obligations would not be limited to meeting security standards at the time of pre-market submission but rather throughout the entire product lifecycle up to obsolescence. Accordingly, device manufacturers are now expected to implement comprehensive cybersecurity risk management programs to be able to handle complaints, conduct quality audits, implement preventive and corrective actions, conduct software validation and risk analysis and servicing (*see* 21 CFR Part 820). The draft guidance even goes as far as identifying the elements of an effective post-market cybersecurity program using the same elements of the 2014 guidance (Identify, Protect, Detect, Respond and Recover) but elaborating much more on what is expected. However, while the draft guidance recognizes that strengthening cybersecurity should be a joint effort and that device manufacturers are but only one link in the chain, it does not elaborate much on the role of healthcare delivery organizations (HDOs) whose IT departments may act as cyber gatekeepers from outside threats.

The draft guidance also encourages device manufacturers to participate in Information Sharing Analysis Organizations (ISAOs) as part of their comprehensive proactive approach to managing post-market security threats. ISAOs are groups created to gather, analyze, and disseminate critical infrastructure information and which are not directly tied to any specific infrastructure sector (see Executive Order 13691 – *Promoting Private Sector Cybersecurity Information Sharing* dated February 13, 2015). In fact, the draft guidance even states that for companies that voluntarily participate in ISAOs and also follow the guidance, the FDA would not intend to enforce certain reporting requirements contained in the Food, Drug and Cosmetic Act.

The complete text of the draft guidance is available at: http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM482022.pdf and is open for comments for a period of ninety (90) days following publication in the Federal Register of the notice announcing availability of the draft guidance.

Reported by: Christian Perez Font, Esq.

Florida-based Olympus Latin America, Inc. to pay $22.8MM to settle FCPA investigation.

As of March 1, 2016, Florida-based Olympus Latin America, Inc. has entered into a deferred prosecution agreement in connection with the Department of Justice's investigation on possible Foreign Corrupt Practices Act (FCPA) violations stemming from the activities in Latin America from 2006 through 2011. Olympus is the biggest distributor of endoscopes and related medical equipment in the United States and sells the devices worldwide.

The deferred prosecution agreement requires the company to, among others, pay a $22.8 million fine, adopt a robust compliance program and submit to monitorship for a period of thirty-six months. Concurrently with this settlement, its parent company, Olympus Corporation of the Americas, entered into a corporate integrity agreement with the Department of Health and Human Services' Office of the Inspector General and a separate deferred prosecution agreement with the Department of Justice to settle claims of violations of the Federal Anti-Kickback Statute. Under the terms of the second deferred prosecution agreement Olympus Corporation of the Americas will be required to make payments of $ 612MM plus interest, cooperate in other ongoing investigations, implement a robust compliance program and submit to monitorship for a period of thirty-six months.

Reported by: Christian Perez Font, Esq.

FACILITY AND PROFESSIONAL LICENSURE

License by Default.

In Chilito, M.D., v. Department of Health, DOAH Case No. 15-3568 (February 29, 2016), an Administrative Law Judge from the Division of Administrative Hearings recently ruled that a physician's medical license was renewed by default despite Medicare and Medicaid revoking the physician's license. The physician timely submitted a license renewal application to the Department of Health. The Department did not notify the physician of any errors or omissions in the application or request any additional information from the physician.

Under Section 120.60(1), Florida Statutes, the Department must grant or deny a complete application within 90-days or the application is granted by default. The application is complete when the Department receives all the requested information. The Department employee processing the physician's application verbally advised the physician that the application was being denied because the physician was terminated for cause from Medicaid. But, that Department sent written denial more than 90 days after the physician submitted the renewal application.

The Department argued that a DOH staff member verbally notified the physician of the Department's intent to deny the application within the 90-day time period. However, the ALJ found that the verbal notice was not provided by the person at the Department authorized to make a final decision on the application, and that the Department had not made a final decision on the application at the time of that verbal notice.

The ALJ found the physician's renewal application was complete as of date the Department received it because the Department failed to notify the physician of any errors or omissions in the application within 30-days of receipt. The ALJ also found that the Department failed to grant or deny the application within 90-days of the application being complete, so the license was granted by default. The Board of Medicine still must consider the ALJ's recommended order.

Reported by: Michael L. Smith, Esq.

Zika Reporting Requirements for physicians and other healthcare providers.

The Department issued guidance on the Zika virus for physicians and other healthcare providers on February 9, 2016. Physicians are required to report suspected cases of Zika virus to their County Health Department immediately upon suspicion. Providers must provide health status updates every 24-hours to the County Health Department for every hospitalized patient with suspected or confirmed Zika. Physicians and healthcare providers are required to provide updates to the County Health Department every 72-hours for patients with suspected or confirmed Zika who are not hospitalized. The Department of Health website also includes a link to a free CDC continuing education program on the Zika virus.

Reported by: Michael L. Smith, Esq.

FRAUD & ABUSE

CMS Final Rule on 60-day Reporting Period.

The Centers for Medicare & Medicaid Services (CMS) published the final "60-day rule" for reporting and returning Medicare Part A and B overpayments in February. 81 Fed. Reg. 7654-7684 (Feb. 12, 2016). For many years now, lawyers, regulators and courts debated the requirements, scope and impact of Social Security Act section 1128J(d). "Section 1128J(d) of the Act requires a person or entity who has received a Medicare overpayment to report and return the overpayment to the appropriate entity by the later of: (1) 60 days after the date on which the overpayment was "identified"; or (2) the date any corresponding cost report is due (if applicable). It also made the failure to report or repay overpayments within 60 days an "obligation" under the False Claims Act (FCA), and therefore subject to FCA liability. Proof of specific intent to defraud the government is not required for a person or entity to be liable under the FCA."

Initially, the Proposed Rule did not define what it means to "identify" an overpayment and set the look-back period as far as ten years, (received with significant disapproval in the legal community). However, the final rule addressed these issues by (1) defining the meaning of overpayment "identification," and (2) setting the required look-back period to six years. Regarding identification of an overpayment, the final rule states "that a person has identified an overpayment when the person has, or should have through the exercise of reasonable diligence, determined that the person has received an overpayment and quantified the amount of the overpayment." In addition, the final rule clarifies that "the quantification of the amount of the overpayment may be determined using statistical sampling, extrapolation methodologies, and other methodologies as

appropriate. According to CMS, this definition is broad enough to include both actual and constructive knowledge." See 81 Fed. Reg. 7661.

Moreover, the rule clarifies that providers have an obligation to conduct timely, good faith investigations of credible investigations and according to the final rule, which means both proactive and retroactive reviews of Medicare billing. This suggests that auditing based on compliance hotline calls or issues raised by staff are no longer sufficient under the rule and proactive reviews of Medicare billing are mandatory. As such, the final rule suggests that overpayment liability may also be subject to False Claims Act liability under 31 U.S.C. § 3729(a)(1)(G) as "reverse" false claims.

For a detailed summary on the final rule, see HLA's Executive Summary: CMS Publishes the 60-Day Reporting and Returning of Overpayments Final Rule, March 2016: https://www.healthlawyers.org/Members/PracticeGroups/PGCSSummaries/Documents/FA/60-Day_Final_Rule_ES.pdf.

Reported by: Anu Sagi-Nakkana, Esq.

HEALTH INFORMATION TECHNOLOGY & PRIVACY

HIPAA Modification Allows Increased Disclosure of Patient Information to Screen Potential Firearm Purchasers.

Recently, the Department of Health and Human Services ("HHS") announced a final rule which modifies the Health Insurance Portability and Accountability Act ("HIPAA") Privacy Rule ("Privacy Rule") to further the Obama Administration's desire to allow certain covered entities to disclose to the National Instant Criminal Background Check System ("NICS") the personal information of a limited number of individuals who suffer from mental health conditions. The disclosure of such information is intended to help prevent the sale of firearms to individuals deemed ineligible to own guns. HHS alleges that this modification should help curb gun violence while simultaneously protecting individuals' privacy rights.

Specifically, "[t]he information that can be disclosed is the minimum necessary identifying information about individuals who have been involuntarily committed to a mental institution or otherwise have been determined by a lawful authority to be a danger to themselves or others or to lack the mental capacity to manage their own affairs." HHS has noted that the new rule only pertains to a limited number of covered entities that make mental health decisions which can lead to the disqualification of individuals from owning firearms. The rule does not allow diagnostic, clinical, or other mental health treatment information to be reported.

Critics of the modification argue that this change to HIPAA erodes the relationship between patients and their doctors, while discouraging individuals with mental health conditions from seeking medical treatment. In addition, veterans' organizations, such as the American Legion have voiced concerns that this rule will disproportionately affect veterans who often suffer from post-traumatic stress disorder. Dale Barnett, the American Legion's national commander, stated, "the American Legion strongly believes that treatment for post-traumatic stress disorder…which a

number of wartime veterans experience, should not be the sole factor in denying a veteran the right to purchase a firearm." However, HHS has made clear that individuals who seek treatment for mental health conditions are not automatically precluded from owning a firearm and this modification to HIPAA does not change that maxim.

With the adoption of this rule, questions abound regarding whether the abovementioned covered entities will violate the privacy rights of individuals with mental health conditions by disclosing patient information without their consent.

The final rule can be found at: https://www.federalregister.gov/articles/2016/01/06/2015-33181/health-insurance-portability-and-accountability-act-hipaa-privacy-rule-and-the-national-instant.

Reported by: Zachary Merson, Esq.

LIFE SCIENCES

New Florida Medical Marijuana Legislation Passed.

On March 25, 2016, HB 307, the "Medical use of Cannabis" bill was enacted into law and will expand Fla. Stat. § 381.986, the so-called Compassionate Medical Cannabis Act that originally allowed for the cultivation and use of the high-CBD, low-THC marijuana strain known as Charlotte's Web. HB 307 was proposed as a result of last year's passing of Fla. Stat. § 499.0295, Florida's "Right to Try Act," which allows cancer and terminally ill patients who are given less than one year to live the right to try experimental medical treatments.

In expanding the Compassionate Medical Cannabis Act, HB 307 provides for the regulation, cultivation, dispensing, and compassionate use of "medical cannabis," in addition to Charlotte's Web. Here, medical cannabis is defined as every portion of any cannabis plant, but the new law specifically denotes that possession, use, or administration of cannabis by smoking is *not* a medical use. HB 307 will also authorize the licensure of three additional dispensaries once the compassionate use registry reaches 250,000 patients; this is in addition to the five dispensary licenses that were awarded last fall.
This new law may see a short future as Florida Constitutional Amendment 2, known as the "Florida Right to Medical Marijuana Initiative," will still appear on the ballot in November. If passed, Amendment 2 will supersede Fla. Stat. § 381.986 to allow the medical use of marijuana by a larger number of patients, not just those who are terminally ill or suffering from epileptic seizures. The amendment authorizes the use of medical marijuana by patients suffering from epilepsy, glaucoma, HIV, AIDS, PTSD, ALS, Crohn's disease, Parkinson's disease, MS, or other debilitating medical conditions, and does not prohibit smoking as a means of administration.

For additional information or to read HB 307, see https://www.flsenate.gov/Session/Bill/2016/0307.

Reported by: Shantal L. Henriquez, 3L, Stetson University College of Law

FDA Seeks Comments on Refurbished Medical Devices.

The Food and Drug Administration ("FDA") has issued a call for comments concerning medical devices that are refurbished, reconditioned, rebuilt, remarketed, remanufactured, or serviced by third-party entities or original equipment manufacturers ("OEM"). This request comes due to the suspected use of unqualified personnel in performing service, maintenance, refurbishment, and alterations on medical devices. The work of these unqualified personnel may not be adequately documented, resulting in ineffective recalls, disabled device safety features, and improper or unexpected device operation.

The FDA is seeking comments from the widest range of interested persons, including those who engage in the business of the above-listed activities and those who utilize said medical devices. Specifically, the FDA has posed a series of questions to gain insight on the challenges that third-party entities face in maintaining or restoring devices to their original or current specifications. The comment period closes on May 3, 2016.

For details about the specific questions posed or to submit comments to the FDA, see: https://www.federalregister.gov/articles/2016/03/04/2016-04700/refurbishing-reconditioning-rebuilding-remarketing-remanufacturing-and-servicing-of-medical-devices.

Reported by: Shantal L. Henriquez, 3L, Stetson University College of Law

PUBLIC HEALTH

Travel Notices and the Spread of Zika Virus.

The Zika virus, a mosquito-transmitted infection, is "spreading explosively" across Caribbean, South and Central American countries since an initial outbreak occurred last May in Brazil. Due to the serious health consequences of Zika virus to pregnant women and their unborn babies, the Centers for Disease Control and Prevention has issued a travel notice covering over 25 countries in the Caribbean, North, South, and Central America, and Africa.

Reported by: Rodney M. Johnson, Esq.

Biting Back: Controlling the Spread of Zika Virus Through Mosquito Abatement.

Mosquito infested jurisdictions in the U.S. have been exploring multiple approaches to control the two species of Aedes mosquitos that spread not only the Zika virus, but also dengue, chikungunya and yellow fever viruses. Implementation of mosquito abatement efforts depends in part on legal authority and the definition of this authority varies in different localities.

Reported by: Rodney M. Johnson, Esq.

Updated Primer: Public Health Legal Preparedness and Response to Zika.

Since mid-2015, Brazil has reported over 4,100 cases of the birth defect microcephaly in babies – a drastic increase from previous years. The rise in microcephaly is suspected to be linked to pregnant mothers infected with the Zika virus, transmitted through mosquitos. The Centers for Disease Control and Prevention identified 30 countries in the Americas with active transmissions of the virus and advised people, especially pregnant women, to avoid traveling to those countries. Our updated primer outlines the public health concerns related to the Zika virus, and lays out current and anticipated legal preparedness and response issues.

Reported by: Rodney M. Johnson, Esq.

Video Directly Observed Therapy for Tuberculosis in Minnesota.

Video Directly Observed Therapy (VDOT) appears to be a promising alternative to traditional DOT practices and has the potential to improve tuberculosis control efforts. However, there are legal, regulatory, and practical challenges relating to the use of VDOT and the implementation of VDOT will not be immediate or simple. Our new fact sheet [https://www.networkforphl.org/resources_collection/2016/02/17/742/fact_sheet_video_directly_observed_therapy_for_tuberculosis_in_mn/?utm_source=Network+Report+3-3-16&utm_campaign=Network+Report+3-3-16&utm_medium=email&utm_content=198] examines the legal issues faced by health service providers in Minnesota, and can provide a starting point for local health departments in other states to discuss with their legal counsel when considering the integration of a VDOT program into their TB control program efforts.

Reported by: Rodney M. Johnson, Esq.

The Child Nicotine Poisoning Prevention Act.

With the rise in popularity of electronic smoking devices came increased calls to poison control centers around the country and at least one reported death of a young child due to ingestion of liquid nicotine. On January 11, Congress passed the Child Nicotine Poisoning Prevention Act, requiring that containers of liquid nicotine - typically used to refill electronic smoking devices - meet the Consumer Product Safety Commission standards established to prevent children under age five from opening the container.

Reported by: Rodney M. Johnson, Esq.

THIRD PARTY PAYORS

Medicare Proposes Testing of New Models for Part B Prescription Drugs.

On March 8, 2016 CMS announced its intention of testing six alternative approaches to pricing and payment for Part B drugs with the goal of disincentivizing physicians from prescribing higher cost drugs when less costly, evidence based medicines are available to meet the unique needs of patients.

Currently Medicare Part B pays physicians and hospital outpatient departments a drug's average sales price plus a 6 percent add-on to cover costs. By virtue of how Medicare pays for Part B drugs, physicians and hospitals are naturally encouraged to select the more expensive of equivalent drugs to maximize revenues for their practice.

Commencing in late 2016, CMS proposes to test how prescribing patterns are affected by implementing a new model whereby the physician will receive an add-on payment of only 2.5% plus a flat fee payment of $16.80 per drug per day. Critics of the proposed payment reform argue that CMS is inappropriately attempting to manipulate a physician's choice of appropriate treatment for patients with reimbursement techniques.

CMS is ultimately attempting to improve quality of care while significantly reducing costs. CMS reports that in 2015 prescription drug spending was approximately $457 billion or 16.7% of overall health spending. Medicare Part B alone spent $20 billion on outpatient drugs administered by physicians and hospital outpatient departments.

Other alternatives to be tested for Part B include:

- Decreasing or eliminating cost sharing to improve beneficiaries' access and appropriate use of effective drugs
- Creation of evidence-based, clinical decision support tools as a resource for providers and suppliers focused on safe and appropriate use for selected drugs and indications
- Varying payment for a drug based on its clinical effectiveness for different indications
- Reference pricing, i.e. setting a standard, benchmark payment rate for a group of similar drugs
- Allowing CMS to enter into voluntary agreements with drug manufacturer to link patient outcomes with price adjustments

The deadline for comments on the proposed rule is May 9, 2016.

Reported by: Ashely Brevda, Esq.

Governor Scott Signs PPO Balance-Billing, Out-of-Network Reimbursement Bill.

On April 14, 2016, Governor Rick Scott signed into law HB 221, which prohibits healthcare providers from directly billing PPO members for the remaining balance not reimbursed by the member's insurance company for out-of-network services. The statute applies to emergency services by an out-of-network provider, and nonemergency services by an out-of-network provider when the facility where the services are provided has a contract with the insurer and the insured does not have an opportunity to choose a participating provider at the facility. A similar balance-billing prohibition is already in effect for HMO members. § 641.3154, Fla. Stat.

The law, which expands Florida Statutes Chapter 627, also implements a reimbursement structure for healthcare services provided to PPO members by out-of-network providers. The newly created § 627.64194 will adopt the reimbursement scheme already in place for HMO out-of-network emergency services. Under the statute, reimbursement for services by a provider who

does not have a contract with the member's PPO plan "shall be the lesser of: (a) the provider's charges; (b) the usual and customary provider charges for similar services in the community where the services were provided; or (c) the charge mutually agreed to by the health maintenance organization and the provider within 60 days of the submittal of the claim." Like the balance-billing provision, the reimbursement structure applies to emergency services by an out-of-network provider, and nonemergency services by an out-of-network provider at in-network facility.

The law also prohibits health insurers from requiring health care providers to obtain a prior authorization before furnishing emergency services to PPO members, another provision already applicable to HMO members. The new law becomes effective July 1, 2016.

Reported by Monica M. McNulty, Esq.

TRANSACTIONS

Florida Regulators Conditionally Approve Aetna-Humana Transaction: What it Means.

In July 2015, Aetna signed an agreement to purchase rival Humana for $37 billion in cash and stock, which was a transaction involving two of the nation's four largest health insurers, and, at the time, the largest deal ever in the health insurance industry. Since then, the acquisition has been bombarded by regulatory scrutiny from many states, including Florida, to determine whether the proposed combination is hazardous to the public, would substantially lessen competition in insurance, and/or would create a monopoly. On February 15, 2016, The Florida Office of Insurance Regulation gave conditional approval to the acquisition, clearing a major regulatory hurdle for Aetna to have access to the several million Medicare Advantage and exchange patients covered by these insurers in Florida.

The Consent Order imposed by The Florida Office of Insurance Regulation found that moving policyholders to an unaffiliated company is not in the best interests of Florida policyholders because of its potential to disrupt quality of services, benefits, networks, and cost-sharing provisions. The Consent Order also states certain conditions of approval of the proposed acquisition, including, among others that: (1) by January 1, 2018, through Florida affiliates, Aetna will enter into five new counties not in its 2016 Florida Individual Health Insurance Exchange portfolio, (2) by January 1, 2020, Aetna will provide the Office of Insurance Regulation with a market analysis of exchange counties not in its 2018 Florida Individual Health Insurance Exchange portfolio and use it to develop a plan to enter into these markets, (3) Aetna and all of its companies agree to maintain fair treatment of individuals living with HIV, and (4) Aetna's Florida-based HMOs are required to comply with Risk-Based Capital standards.

The Aetna-Humana transaction is a signal of the growing consolidation in the insurance industry, along with other major transactions including Anthem's $54 billion purchase of Cigna. The Anthem-Cigna transaction is also undergoing similar regulatory scrutiny as these transactions would reduce the number of nationwide health insurers from five to three along with United Healthcare. While the conditional approval granted by The Florida Office of Insurance Regulation is certainly a positive development for Aetna's and Humana's prospects for closing the transaction,

the U.S. Department of Justice and the Florida Attorney General (as well as other state regulatory bodies) still need to approve the proposed acquisition.

The full consent order is located at:
http://www.floir.com/siteDocuments/AetnaHumanaAcquisition185926-16-CO.pdf

Reported by: Matthew J. Friendly, Esq.

MISCELLANEOUS

Non-Discrimination in Health Care: §1557 of the Affordable Care Act.

Section 1557 of the Affordable Care Act (ACA) codifies the antidiscrimination provisions of ACA. This section prohibits discrimination based on race, color, national origin, incorporating the grounds under Title VI of the Civil Rights Act of 1964 (Title VI), 42 U.S.C. 2000d et seq. It prohibits discrimination based on sex incorporating the grounds under Title IX of the Education

Amendments of 1972 (Title IX), 20 U.S.C. 1681 et seq. It also prohibits discrimination based on age, incorporating the Age Discrimination Act of 1975 (Age Act), 42 U.S.C. 6101 et seq., and disability based discrimination by incorporating Section 504 of the Rehabilitation Act of 1973, 29 U.S.C. 794.

In a nutshell, this ACA provision insures no one is denied health services or health coverage or discriminated against in other way in health services or coverage because of their race, color, national origin, sex, age, or disability. Section1557 applies to any health program or activity, any part of which receives funding from Department of Health and Human Services (HHS). Section 1557 is the first civil rights law to prohibit sex discrimination in the provision of health care.

HHS recently released proposed regulations for § 1557 "Nondiscrimination in Health Programs and Activities." https://www.federalregister.gov/articles/2015/09/08/2015-22043 /nondiscrimination-in-health-programs-and-activities. The most sweeping change in the proposed regulations is the acknowledgement that sex discrimination now includes discrimination based on gender identity. This means that health care providers cannot refuse to provide services to a person based on their gender identity or their stage in gender transition, and they cannot refuse treatment for a medical condition related to their previous gender, where treatment is medically indicated. The comment period for the proposed regulations has closed and the final regulations should be released before the end of the year. Though the regulations are not yet final, HHS' Office on Civil Rights accepts complaints under §1557.

Reported by: Barbara L. Kornblau, J.D., OTR/L