June 15, 2015

Dear Health Law Section Members:

The Section website has been updated with the April/May 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:

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Thank you.

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

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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.

# April/May- Health Law Updates

# Fraud and Abuse

**OIG Releases *Practical Guidance (or Healthcare Boards on Compliance Oversight)***

In April, the Office of Inspector General, U.S. Department of Health and Human Services, in conjunction with several trade associations, published *Practical Guidance for Healthcare Boards on Compliance Oversight.* That guidance provides practical tips concerning five issues relating to a board's compliance oversight:

(1) Expectations for board oversight of compliance functions;
(2) The roles of, and relationships between, the organization's audit, compliance, and legal departments;
(3) The mechanism and process for issue-reporting within an organization;
(4) The approach to identifying regulatory risk; and
(5) The methods of encouraging enterprise-wide accountability for achievement of compliance goals and objectives.

The practical tips urge a board to consider, among other things:

- Benchmarking according to widely-recognized compliance resources, such as CIAs and government guidance, and approaches employed by similar companies.
- Regularly assessing the adequacy of their company's compliance systems and functions, especially in light of changes in law, the company's size, or business practices since the board's last assessment,
- Developing a plan for staying informed of business and regulatory changes that affect their company's risk, such as attending educational programs or creating an in-house education plan,
- Whether they need to increase their compliance and legal expertise by consulting regularly with outside counsel or appointing to the board a professional with sufficient compliance or legal experience,
- How to define the board's expectations of compliance legal, audit, human resources, and quality improvement functions in their organization,
- Setting and enforcing expectations for the kinds of information management provides to the board and the regularity with which management reports to the board, and
- How transparency inforn1ation can assist the board with monitoring compliance.

*Practical Guidance for Healthcare Boards on Compliance Oversight* IS available at http://oig.hhs.gov/compliance/compliance-guidance/docs/Practical-Guidance-for-Health-Care-Boards-on-Compliance-Oversight.pdf

***Reported by Timothy M. Moore, Esq.***

**First Circuit Reaffirms in False Claims Act Case That Courts Should Use Fact-Intensive and Context-Specific Inquiry When Analyzing Whether a Requirement is a Precondition for Payment**

A recent First Circuit opinion may make it more difficult to dismiss False Claims Act *qui tam* cases on grounds that the relator cannot prove that the defendant violated a material precondition of payment.

In *United States ex rei. Escobar v. Universal Health Services*, the relator alleged that several employees of a mental health service provider held themselves out as licensed professionals even though they were unlicensed. 780 F.3d 504, 508 (1st Cir. 2015). The relator asserted that the provider violated the False Claims Act by submitting bills to Medicaid while fraudulently misrepresenting those staff members as properly licensed. The district court dismissed the suit, holding that the preamble to the relevant regulations established that the regulations were conditions of the provider's participation in Medicaid rather than payment of its claims.

In reversing, the First Circuit held that the lower court improperly applied a formalistic distinction between regulations establishing a condition of participation versus those setting a condition of payment. The court rejected an interpretation premised solely on placement in a regulatory scheme or the labeling of a regulation. Instead, the court explained that "the question whether a given requirement constitutes a precondition to payment is a 'fact-intensive and context-specific inquiry,' involving a close reading of the foundational documents, or statutes and regulations, at issue." (citation omitted). Applying that rule, the court concluded that the supervision and licensure requirements at issue imposed conditions of payment.

***Reported by Ian Kennedy, Esq.***

# Licensure

**The Board has Final Authority to Determine Violation of Laws and Rules Regulating Profession**

The Florida Board of Medicine recently rejected an interpretation of the Medical Practice Act by an Administrative Law Judge from the Division of Administrative Hearings. *DOH v. Goldberg, MD.*, Case No. 14-3507PL (DOAH March 4, 2015). One of the allegations against the physician was prescribing, dispensing, administering, mixing, or otherwise preparing a legend drug, including any controlled substance, other than in the course of the physician's professional practice in violation of Section 458.331(1)(q), Florida Statutes. The Administrative Law Judge found the physician was practicing medicine in the treatment of the patient, and therefore rebutted the presumption that the treatment was not within the course of the physician's professional practice. The Board rejected that finding by the Administrative Law Judge. The Board clarified that all that is required to establish a violation of Section 458.331(1)(q), Florida Statutes, is a showing that the physician inappropriately or excessively prescribed drugs to a patient. According to the Board, the fact that the physician was treating the patient when the

over prescribing took place did not excuse the physician from the violation. The Board is authorized by statute (Section 456.073(5) of the Florida Statute) to make the final determination on violations of the laws and rules regulating the profession.

***Reported by Michael L. Smith***

**New Florida Assisted Living Facility Legislation**

For a number of years the Florida Legislature has considered bills aimed at strengthening assisted living facility (ALF) regulation. This effort was sparked by a series of Miami Herald articles published in 2011 that detailed horrific conditions in particular facilities. This session new legislation passed (HB 1001) that if it becomes law, strengthens ALF regulation and improves quality in a number of ways. For example the bill increases penalties for ALFs. The Agency for Health Care Administration (AHCA) must deny or revoke an ALF license if the facility has two moratoria imposed within a two year period. The license must also be revoked if AHCA cites the facility for two or more class I violations arising from unrelated circun1stances during the same survey or investigation, or if the facility is cited for two or more class I violations arising from separate surveys or investigations within a two year period. AHCA must impose an immediate moratorium if the ALF fails to provide AHCA with access to the facility or prohibits AHCA from conducting an inspection. The ALF must permit AHCA staff to access and copy records and conduct confidential interviews with staff or residents.

The bill expands the types of services that trained staff may provide relating to assisting residents who self-administer medications. Specifically, staff may perform additional functions such as assisting with insulin syringes, nebulizers, and blood-glucose level checks.

One change will allow consumers to go online and find ALF information more easily. The bill requires AHCA to create content that is easily accessible on a searchable website that enables the public to find out information regarding ALFs more easily. The website must be up and running by November 1, 2015.

The bill also includes a number of other changes, including revisions relating to personal property of residents, notification of resident rights, staffing levels and staff training. For example, upon admission, the facility must provide information to the resident or the resident's representative indicating that the resident may not be retaliated against for presenting grievances or for exercising any other right. Assuming the bill becomes law, ALFs will need to update their policies and procedures to ensure that they comply with the new requirements.

***Reported by Shannon H. Salimone, Esq.***

# Life Sciences

## House Bill to Repeal Medical Device Tax on the Fast Track Through Congress

In March 2015, Florida Members of the U.S. House of Representatives, along with other members, sent a letter urging the leaders of the House to fast track a vote for H.R. 160, the Protect Medical Innovation Act of2015, a House Bill that was introduced in January 2015. This law aims to amend the Internal Revenue Code to repeal the 2.3% excise tax on medical devices, which was introduced in 2013 by the Affordable Care Act. If passed, H.R. 160 will also allow medical device companies to receive refunds for taxes already paid under the law.

***Shantal Henriquez, Student, Stetson University College of Law***

## Senate Introduces Bill to Legalize Marijuana under Federal Law

On March 10, 2015, the Senate introduced S. 683, the Compassionate Access, Research Expansion, and Respect States Act of 2015 ("CARERS Act"), to reschedule Marijuana from a Schedule I to a Schedule II drug under the Controlled Substances Act ("CSA"), 21 U.S.C. 812(c). The CARERS Act also aims to make medical marijuana legal at the federal level in those states that have already passed medical marijuana laws. Florida passed the Compassionate Medical Cannabis Act, F.S. 381.986, which authorized the production and use of the low THC high CBD drug Charlotte's Web. The Act will prevent health care providers and patients from being subjected to federal prosecution for prescribing and taking the drug for medical treatment. The Act will also remove Cannabidiol (CBD) from the definition of "marijuana" under the CSA. CBD is the compound in marijuana that provides for its medicinal effects.

The CARERS Act also allows banks to accept funds from the sale and distribution of both medical and recreational marijuana. It provides for a number of federal protections and safeguards for banks that receive and lend money to legitimate marijuana-related businesses.

The CARERS Act further authorizes the Drug Enforcement Agency ("DEA") to issue at least 3 licenses under the CSA for the FDA-approved manufacturing of marijuana and marijuana-derivatives for research purposes. Additionally, the Act authorizes physicians and other health care providers employed by the Department of Veterans Affairs to make recommendations for the treatment of veterans with medical marijuana in the states where its use for treatment is already legal.

For more information, please visit: https://www.congress.gov/bill/114th-congress/sentate-bill/683.text

***Shantal Henriquez, Student, Stetson University College of Law***

**FDA Releases Proposed Rule to Address Safety, Effectiveness of Healthcare Antiseptics**

Based on new scientific information and concerns expressed by outside scientific and medical communities, the U.S. Food and Drug Administration (FDA) is asking manufacturers to provide additional scientific data showing that the ingredients in antiseptic products used in healthcare settings are safe and effective for health care providers and patients. Healthcare antiseptics are used most commonly by healthcare professionals in hospitals, clinics, medical offices, and nursing homes and are different from consumer antiseptics, which include antibacterial soaps and hand sanitizer rubs. Consumer antiseptics are not included in this proposed rule. The most common ingredients in healthcare antiseptics affected by this proposed rule are alcohol and iodines.

The proposed rule does not mean that these products are ineffective or unsafe, and does not require any healthcare antiseptic products to be removed from the market at this time. The proposed rule has a 180-day period for the public to submit comments and other information to the FDA.

The proposed rule can be accessed at the following website:
https://www.federalregister.gov/articles/2015/05/01/2015-10174/safety-and-effectiveness-of-health-care-antiseptics-topical-antimicrobial-drug-products-for

***Reported by Kevin Dewar, Esq.***

# Privacy and HIT

**House Committee Issues Updated Discussion Draft of 21st Century Cures Act, Proposing Revisions to Federal Privacy Regulations**

On April 29, 2015, the *House Energy and Commerce Committee* released a revised discussion draft of the proposed medical reform legislation known as the 21st Century Cures Act ("Cures Act"), which aims to "accelerate the discovery, development, and delivery of 21st century cures" for patients in the United States. Among other things, the revised Cures Act would implement certain revisions to existing federal privacy regulations under the Health Insurance Portability and Accountability Act (HIPAA) and the *Health Information Technology for Economic and Clinical Health Act (HITECH).*

These revisions would include permitting the use and disclosure of protected health information (PHI) for "research purposes" without patient authorization, provided that the PHI is used for such purposes by covered entities and their business associates, as defined under HIPAA. The Cures Act would also permit patients to authorize all "future research purposes" involving their PHI using a single authorization form, provided that the form "sufficiently describes the purposes" of the future research, and permits the patient to revoke the authorization at any time. Additionally, the Cures Act would permit researchers to remotely access PHI maintained by a covered entity if "appropriate security and privacy safeguards" are maintained by the covered entity and researcher, and the PHI is not copied or otherwise retained by the researcher. The text of the revised discussion draft of the Cures Act can be found here:

http://energycommerce.house.gov/sites/republicans.energycommerce.house.gov/files/114/20150429DiscussionDraft.pdf

***Reported by Michael L. Ehren, Esq.***

## HHS Office for Civil Rights Issues HIPAA Guidance on Workplace Wellness Programs

In April of 2015, the Department of Health and Human Services' Office for Civil Rights (OCR) issued two "frequently asked questions" providing guidance on workplace wellness programs under the HIPAA Privacy, Security, and Breach Notification rules. The guidance is available here:
http://www.hhs.gov/ocr/privacy/hipaa/understanding/coveredentities/wellness/index.html
OCR reiterated that employers, as such, are not covered entities. Therefore, whether HIPAA applies to an employer's wellness program will depend on how the program is structured. The program will be subject to the HIPAA privacy and security rules if it is part of the employee group health plan. Offering incentives or rewards related to plan benefits in exchange for wellness program participation would suggest that the wellness program is part of the group health plan. Individually identifiable health information obtained in connection with the wellness program will be protected by HIPAA if the program is part of the plan. OCR stated that "HIPAA also protects [protected health information (PHI)] that is held by the employer as plan sponsor on the plan's behalf when the plan sponsor is administering aspects of the plan including wellness program benefits offered through the plan." HIPAA will not protect wellness program information when the program "is offered by an employer directly and not as part of a group health plan."

If the wellness program is offered through a group health plan HIPAA protects the PHI in a number of ways. When the employer is the plan sponsor and is involved in administering aspects of the group health plan the employer may access PHI as necessary to perform its plan administration functions even without employee authorization, provided that the plan documents have been amended as required by HIPAA. Additionally the plan sponsor must certify to the group health plan that it has established adequate firewalls to separate employees who perform plan administration functions from those who do not. The certification must also provide among other things, that the PHI will not be used for employment-related actions or other purposes not permitted by HIPAA. Electronic PHI must also be safeguarded and required notices must be provided if there is a breach of unsecured plan PHI at the plan sponsor. If the plan sponsor does not administer the plan its access to information of a plans wellness program information will be much more limited absent the patient's written authorization.

***Reported by Shannon Hartsfield Salimone, Esq.***

# Public Health

**Issue Brief and Presentation on Federally Qualified Health Centers (FQHC)**

The following link includes resources that summarize the role of the FQHC in the delivery of healthcare services for the expanding Medicaid population – http://www.cdc.gov/phlp/publications/topic/transformation.html

***Reported by Rodney Johnson, Esq.***

**Webinar Series on the Intersection of Public Health and Health Care – The Role of the 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 first webinar in the series, Part I: Legal Issues Impacting Federally Qualified Health Centers and Rural Health Clinics, too place Friday, June 5, 2015. Other upcoming seminars are scheduled for July 17, 2015 from 1:00 pm – 2:30 pm Easter (Part 2: Health Care Quality: What's Law Got to Do with It?)

See more at: https://www.healthlawyers.org/Pages/Events-and-Education

**Association Public Health Emergency Preparedness Professionals (AHEPP)**

A new professional association dedicated to advancing the field of disaster preparedness and response, AHEPP, is accepting members and announces their first national conference. The conference with take place November 17-18, 2015 in Omaha, Nebraska, and will help guide participants through the most important disaster concerns in various types of healthcare facilities. See AHEPP's website for early bird rates, the complete conference agenda and more information.

***Reported by Rodney Johnson***

# Third Party Payors

**CMS Changes Requirements for Part D Prescribers**

On May 6, 2015, the Centers for Medicare and Medicaid Services published an interim final rule changing the requirements for Part D claims when prescribed by health care professionals other than physicians or other eligible professionals. This rule change is designed to remedy an issue that arose under the previous version of the rule that specifically affected pharmacists. The previous version of section 6405 of the Affordable Care Act and the Final Rule published May 23, 2014 required all pharmacy claims and beneficiary requests for reimbursement for Medicare Part D prescriptions be written by physicians and eligible professionals who are enrolled in Medicare and in approved status or who have opted out. However, pharmacists are not permitted to enroll in Medicare or opt-out because they do not fall under the definition of physician or other eligible

professional under the rules. This resulted in denied claims which affected beneficiaries' access to care because pharmacists in many states are permitted to enter into collaborative practice agreements and prescribe Part D medications. The revised rule permits "other authorized prescribers" to bill Medicare Part D using a "valid and active National Provider Identification (NPI) number when submitting the Part D prescription claim." For more please see the following Federal Register page:

https://www.federalregister.gove/articles/2015/05/06/2015-10545/medicare-program-changes-to-the-requirements-for-part-d-prescribers?utm_campain=subscription+mailing+list&utm_medium=email&utm_source=federal register.gov

***Reported by Ray Chamy, Esq.***

## Governor Rick Scott to File Suit Against the Federal Government

Governor Rick Scott has stated that he will take legal action against the federal government for what he cites as the federal government's attempt to strong-arm Florida into implementing the Medicaid expansion program pursuant to the Patient Protection and Affordable Care Act ("PPACA"). Governor Scott claims that the federal government has refused to fund Florida's Low Income Pool ("LIP") program unless Florida agrees to expand Medicaid pursuant to PPACA. The LIP program is administered by the Agency for Health Care Administration and manages funding distributions for the following programs:

- Disproportionate Share Hospital program (DSH);
- Hospital Rate Enhancements program; and
- Graduate Medical Education (GME) Statewide Residency program.

The LIP program consists of $2.167 billion and is used to give government support to providers that care for the Medicaid, underinsured and uninsured populations. Unless an agreement is reached, the LIP program will expire in June. If no LIP funds are awarded, Florida would lose $1.3 billion in program funds. Governor Scott cites the Supreme Court ruling in *NFIB v. Sebelius* in which the Court held the President cannot force Medicaid expansion upon the states.

***Reported by Maria T. Santi, 3L Nova Southeastern Law School***

## SGR Updates

In May, the Senate repealed the Medicare Sustainable Growth Rate (SGR) formula and replaced it with automatic payment increases for all doctors from 2015-2019. Beginning in 2020, automatic increases cease, and Medicare transitions into the new Merit Based Payment Incentive System (MIPS). MIPS incentivizes quality, value and accountability, as physicians' respective rates will be based on performance (i.e., MIPS composite performance score). MIPS scores (0-100) will be assessed in four categories (1) quality; (2) efficiency; (3) meaningful use of EMRs and (4) clinical practice improvement.

Physicians who participate in advanced payment models (APMs) such as ACOs, medical homes, and bundled payment models, are not eligible for MIPS. However, the SGR deal incentivizes APM development. In the years 2019-2025, physicians participating in APMs will receive 5% more than their non-participating peers. Additionally, Medicare will provide payment for patients with ongoing health needs in chronic care management programs.

CMS published a quality measure plan earlier this month. This plan provides information on the metrics by which MIPS scores are calculated. Of note, poorest performing doctors (those with the lowest combined MIPS score) will see their payments cut by 9%. Providers who score above established CMS MIPS scores will receive additional bonuses from an allocated $500 million annual pool, with the best performers receiving the largest bonuses. The legislation goes beyond financial incentives for high MIPS scores, as score results will be posted on Physician Compare for all to see.

***Reported by Elizabeth Scarola, Esq.***