

Dear Health Law Section Members:

The Section website has been updated with 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, I extend my deepest appreciation to the following volunteers who have generously donated their time to prepare these summaries for your review:

Martin Dix

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Thank you,

Malinda R. Lugo, Esq.

You can download a copy of this month's update using this [link](#) or read the updates in this [article](#) on the Section website.

MISCELLANEOUS

Medical Malpractice Caps – Declared Unconstitutional

The Florida Supreme Court, Lewis, J., held that the statutory cap on wrongful death noneconomic damages recoverable in medical malpractice actions violates the right to equal protection under state constitution. *Estate of McCall v. United States*, SC11-1148, 2014 WL 959180 (Fla. Mar. 13, 2014).

The case stemmed from a lawsuit first heard by the court in February 2012, wherein a jury initially awarded a total of \$2 million in pain and suffering damages to the decedent's family, but pursuant to the statutory caps under Fla. Stat. § 766.118, the total amount for the multiple claimants was reduced to \$1 million.

Reported by Joy Easterwood, Esq.

Obama Administration Extends Pre-Existing Condition Plan Again

The Obama Administration is extending the Pre-Existing Condition Insurance Plan until April 30 to give individuals more time to sign up for a standard health plan through the insurance exchanges. This is the third extension that has been given and open enrollment ends March 31. In the extension notice, HHS urged members to sign up for an exchange plan before the end of open enrollment.

Reported by Joy Easterwood, Esq.

COMPLIANCE

U.S. v. Halifax Hospital Medical Center –\$85,000,000.00 Settlement

A settlement in the amount of \$85,000,000.00 was announced in United States et al. v. Halifax Hospital Medical Center et al., Case No. 6:09-cv-Orl-31TBS, Fla. Middle Dist. This qui tam action was filed by a whistleblower and long standing employee of Halifax. Her primary allegation was that Halifax violated the Stark Law by rewarding bonuses to employed physicians that were tied to their referrals of Medicare patients to the hospital. In November, the court entered summary judgment against Halifax on the Stark Law claim. Now, Halifax has agreed to pay \$85,000,000.00 to resolve the allegations that they violated the False Claims Act by submitting claims to Medicare that violated the Stark Law. The tentative settlement is not yet finalized and is pending court approval. As part of the settlement, Halifax agreed to enter into a Corporate Integrity Agreement with the Department of Health and Human Services Office of Inspector General.

Reported by Joy Easterwood, Esq.

HEALTH INFORMATION TECHNOLOGY & PRIVACY

HHS Announces New Round of HIPAA Audits

On February 24, 2014, HHS announced a plan to survey a total of 1,200 organizations, consisting of 800 covered entities and 400 business associates, as a first step in selecting organizations for a new round of HIPAA audits. Not all organizations that are chosen to participate in the survey will be audited, as the survey is intended to allow OCR to collect data regarding the number of patient visits, use of electronic information, revenue, and business locations of survey participants in order to assess whether the organizations should be audited.

The forthcoming round of HIPAA audits are intended to supplement OCR's regular compliance efforts through routine complaint and investigation measures, and will likely focus on security risk assessments, breach notification procedures, encryption, staff training, policies and procedures, and compliance program implementation. OCR will revise its existing audit protocols to reflect modifications introduced by the HIPAA Omnibus Rule. See <http://www.gpo.gov/fdsys/pkg/FR-2014-02-24/pdf/2014-03830.pdf> for additional information.

County Government Agrees to Settle Potential HIPAA Violations

On March 7, 2014, HHS announced the first-ever county government settlement of potential HIPAA violations. Skagit County, Washington, agreed to a \$ 215,000.00 monetary settlement and to correct deficiencies in its compliance program. OCR investigated Skagit County after receiving a breach report that money receipts containing ePHI for seven individuals were accessed by unknown parties after the data had been moved to a publicly accessible County server. The investigation revealed a much broader exposure of ePHI (up to 1,581 individuals were impacted), as well as disclosure regarding testing and treatment for infectious diseases. OCR also discovered general and widespread non-compliance of the HIPAA Privacy, Security and Breach Notification Rules by the County.

Under the corrective action plan, Skagit County will ensure HIPAA compliance by confirming that it has in place written policies and procedures, documentation requirements, and training, as well as providing regular status reports to OCR. In announcing the settlement, HHS emphasized that the settlement is intended to send a strong message about the importance of HIPAA compliance to local and county governments, regardless of size.

See <http://www.hhs.gov/news/press/2014pres/03/20140307a.html> for additional information.

OCR Director Leon Rodriguez Nominated by President Obama to Serve as New Director of the United States Citizenship and Immigration Services

OCR Director Leon Rodriguez has been nominated by President Barack Obama to serve as the new director of the United States Citizenship and Immigration Services, and is likely to be confirmed for the new position by Summer 2014, subject to Congressional approval. Mr.

Rodriguez has led OCR since 2011 and has served as the primary spokesperson of OCR on clarification of HIPAA compliance strategies and audit preparation. Although the leadership change comes at a crucial time for OCR, as long-awaited HIPAA audits of both covered entities and business associates are anticipated to commence in 2014, it is unlikely to delay or otherwise impact the audits. Mr. Rodriguez's successor is likely to be appointed by Kathleen Sebelius, Secretary of HHS.

See <http://www.himss.org/News/NewsDetail.aspx?ItemNumber=27166&navItemNumber=17425> for additional information.

LIFE SCIENCES

DEA

Hydrocodone combination products to be rescheduled as a Schedule II controlled substance.

On February 27, 2014 the U. S. Drug Enforcement Administration (DEA) published in the *Federal Register* a Notice of Proposed Rulemaking (NPRM) to move hydrocodone combination products (HCPs) from Schedule III to Schedule II. This NPRM proposes to impose the regulatory controls and sanctions applicable to Schedule II substances on those who handle or propose to handle HCPs. It could become law as early as May 2014. This means that these products:

- Will have to be ordered with DEA 222s
- Will need written prescriptions
- Can't be refilled
- Must be Reported through ARCOS

Board of Pharmacy

Board of Pharmacy Moving forward with adoption of USP 797 for Sterile Compounding

The Board of Pharmacy continues to move toward adoption of USP 797 as the standard for sterile compounding. This will amend and replace the current sterile compounding Rule 64B16-27.797, FAC. The Board is also moving toward adopting USP 795 for non-sterile compounding. Florida pharmacies performing sterile compounding after March 21, 2014, must have the new Sterile Compounding permit. There are exceptions.

The Board has also begun amendment of the rules to implement the requirement that pharmacy records be maintained for 4 years. It is also reviewing rules related to supervision of pharmacy technicians.

Rules amended in February 2014

Rule 64B16-28.450, FAC

The central fill rule was amended to allow hospitals to engage in central fill processing.

Rule 64B16-28.301, FAC

The rule addressing destruction of controlled substances at a long term care pharmacy was amended to allow a law enforcement officer as the second signatory.

Rule 64B16-28.810, FAC

The list of drugs dispensed by a special limited community permit was expanded to include multi-dose medicinal drugs such as inhalers that are not manufactured in a 3 day supply dosage form.

Rule 64B16-30.001, FAC

The disciplinary guidelines were finalized.

Reported By Martin R. Dix, Esq.

Drug Wholesale Distributors Advisory Council Meeting.

The Drug Wholesale Distributor Advisory Council held its February in-person meeting in Tallahassee on February 27, 2014. Reginald Dixon indicated that because the Drug Quality and Security Act ("DQSA") was made law so late in the year (November 27, 2013), DBPR did not have time to prepare and vet comprehensive legislation to address the changes wrought by the DQSA. Thus, Florida will not have legislation addressing the DQSA this year. He did ask persons with questions about how the DQSA impacts Florida licensing and regulatory issues make their inquiries through the declaratory statement process.

The Council also reviewed information on how product registration is not economically feasible for hospital repackagers.

Recent Declaratory Statement Petitions

Publix Supermarkets, Inc. – Asking for an interpretation of Chapter 499, Florida Statutes' requirement that a retail pharmacy obtain a retail pharmacy wholesale distributor permit for distributions among pharmacies under common ownership considering the DQSA's preemption clause.

Safecor Health LLC- Asking whether a non-resident drug repackager may receive drugs purchased by a hospital and distribute them to Florida hospital locations under common control considering the DQSA's preemption clause.

Reported By Martin R. Dix, Esq.

PUBLIC HEALTH

CDC Public Health Law Program Externship. The CDC Externship in Public Health Law consists of 9–14 weeks of professional work experience, for academic credit, with CDC’s Public Health Law Program in Atlanta, Georgia. The program features rolling start and completion dates throughout the academic year. It exposes law students to the public health field, allowing for exploration of the critical role law plays in advancing public health goals. The unpaid externship is open to second and third year law students who are interested in exploring careers in public health law. Participants must receive academic credit. **Applications for the summer 2014 program must be submitted by February 28, 2014; fall 2014 applications must be submitted by May 31, 2014; and spring 2014 applications must be submitted by November 1, 2014. Find more information and apply for the [externship program](#).**

ERISA issue brief. This issue brief is a summary of responses to technical assistance requests received by the CDC Public Health Law Program regarding the Employee Retirement Income Security Act of 1974 (ERISA) and its relationship to health benefit plans and state laws that address health system transformation. **Find more information and read the [ERISA Issue Brief](#)  [\[PDF - 272KB\]](#).**

LawAtlas maps. LawAtlas, part of Public Health Law Research, a national program of the Robert Wood Johnson Foundation based at Temple University, has published four new interactive LawAtlas maps: [Medical Marijuana Laws for Patients](#); [Communicable Disease Intervention Protocol](#); [Insurance Billing Practices for Sensitive Health Services: Provider Immunity](#); and [Insurance Billing for Sensitive Health Services: Limits on 3rd Party Billing](#). Find more information about [LawAtlas](#) and access other Public Health Law Research publications.

2014 Public Health Law Conference. The 2014 Public Health Law Conference will take place October 16–17, 2014, in Atlanta, Georgia. The conference will gather public health and legal experts from across the country to examine and discuss today's critical challenges in public health law. [Find more information about the conference and learn how to get the early bird registration rate](#).

Reported By Rodney Johnson, Esq.

PROFESSIONAL AND FACILITY LICENSURE

Florida Medicaid Updates Provider General Handbook

The Florida Agency for Health Care Administration (AHCA) recently announced that Florida Medicaid will be updating the Provider General Handbook to requiring newly enrolling providers to have either a health care clinic license, or a certificate of exemption from licensure as a health care clinic. After the new changes are implemented, AHCA will announce its plan for existing health care providers to submit either the license or certificate of exemption. *See http://www.fdhc.state.fl.us/MCHQ/Health_Facility_Regulation/HealthCareClinic/Index.shtml.*

AHCA recommends that existing health care providers who require a license and presently do not hold one immediately obtain their health care clinic license. Information on health care clinic licensure and applicable exemptions are contained in Florida Statute §408.801 et seq. and Chapter 59A-33, FL. Administrative Code.

Florida Department of Health (DOH) Professional License Renewal Process Now Includes Continued Education Review

Physicians and other providers will find a new feature when renewing their professional license. DOH, Division of Medical Quality Assurance, will now automatically review their continuing education records in the electronic tracking system at the time of renewal to ensure compliance. If the records are current in the electronic system, physicians and other providers will be able to renew their license as usual. However, if records are not current, they will have to report their continuing education hours prior to renewing their license. Additional information is available at <http://www.ceat renewal.com/>.

Reported By: Maria D. Garcia, Esq.

1Revocation and \$10,000 Fine for Stealing Patient Identities

An Administrative Law Judge with the Division of Administrative Hearings recently issued a Recommended Order with a recommended penalty of revocation and a fine of \$10,000 against a licensed practical nurse. The Respondent was employed by Armor Correctional Health Services, Inc. as a licensed practical nurse providing services to inmates incarcerated by the Hillsborough County Sheriff's Office. The Respondent was stealing the personal information of inmates and selling the information for the filing of fraudulent federal tax returns. The Respondent agreed to provide the personal information of 20 to 30 inmates per week for the filing of fraudulent tax returns in exchange for half of the proceeds of the fraudulently obtained tax refunds.

The Administrative Law Judge found the Respondent engaged in unprofessional conduct in violation of Section 464.0181(h), Florida Statutes. The Administrative Law Judge also found the Respondent had employed a trick or scheme in or related to the practice of a profession in violation of Section 456.072(1)(m), Florida Statutes. The penalty guidelines provide for a fine of \$10,000 for any offense involving fraud.

The licensed practical nurse has also been criminally charged with multiple counts of fraudulent use of personal information.

Reported by Michael L. Smith, Esq.

TRANSACTIONS

Boise Hospital System Acquisition of Physician Group Successfully Challenged

The US District Court for the District of Idaho has ruled that a hospital system's proposed acquisition of a multi-specialty group would increase the bargaining leverage for primary care physician services resulting in the potential to increase prices for those services. St. Luke's Health System is based in Boise, Idaho. It includes a 400 bed hospital in Boise, and a 167 bed facility in Meridian. Meridian is approximately 13 miles east of Nampa, which is the home of Saltzer Medical Group, a 41 member multi-specialty group that includes 16 adult primary care physicians. Nampa is also the home of St. Alphonsus Health System and Treasure Valley Hospital. Those two facilities filed a motion for a preliminary injunction claiming that St. Luke's acquisition of Saltzer would impact admissions to their facilities and ultimately reduce access to health care services in Nampa. Their motion was denied, but the Federal Trade Commission (FTC) and the Idaho Attorney General subsequently filed a complaint for permanent injunctive relief claiming that the combination of 7 primary care physicians already employed by St. Luke's with Saltzer's 16 primary care physicians would provide sufficient leverage to allow them to increase prices for their services, and would also increase costs of ancillary services by shifting them from office based to hospital based reimbursement levels.

This is the first litigated challenge by the FTC of a hospital's acquisition of a physician group. The court noted that this was an extremely complex and difficult case. St. Luke's argued that the acquisition would increase efficiencies and was consistent with the evolution of health care delivery systems. The court recognized those benefits, but determined that they were outweighed by the anti-competitive effects of the transaction.

Tremendous amounts of evidence and documentation were submitted to the court during the four week trial. Among them were business documents cited by the court as supporting its decision that the transaction was motivated at least in part by the opportunity to increase reimbursement rates. Those documents were not, however, the type of 'smoking gun' that might have been anticipated. They contained what could have otherwise been innocuous statements as to a healthcare system's desire to increase its revenues. The court nonetheless found them to support the government's position.

This transaction was not reportable to the FTC under the Hart-Scott Rodino Act, which obligates entities to notify the government of proposed acquisitions involving over \$75.9 million. The government's involvement demonstrates that they, and private plaintiffs, may pursue matters even though those thresholds are not met.

The court noted that even though patient outcomes might be improved through the transaction, the potential increase in bargaining power outweighed those benefits. The court further noted that the same benefits in healthcare delivery might be accomplished through affiliations and relationships that were short of a full merger. St. Luke's intends to appeal the current ruling.

Reported by Chip Koval, Esq.