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Dear Health Law Section Members:

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

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Thank you.

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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.

COMPLIANCE

Healthcare Compliance in Florida is not just Florida anymore.

Lawyers tend to be quasi-obsessed with having defined terms when writing an article or memo or drafting a pleading or contract. We strive for certainty, a desire for everyone to be “on the same page”, and share an agreed upon position. Yet, trying to reach a single definition or understanding of what is “compliance” or what Compliance departments do remains a daunting task, particularly when we look at how compliance programs are structured across industries, companies or even countries. Despite the lack of a common definition, it is safe to say Compliance is here to stay, particularly in the healthcare industry.

This article will focus only on the anti-corruption side of Healthcare Compliance; laws, programs and efforts aimed at eradicating or preventing dishonest or fraudulent practices in business transactions.

U.S. authorities (and therefore U.S practitioners) have devoted most of their efforts to the enforcement of U.S. healthcare fraud and abuse laws, specially the False Claims Act (31 U.S.C. §§ 3729–3733), the Anti-Kickback Statute (42 U.S.C. § 1320a–7b(b)), the Physician Self-Referral Law (42 U.S.C. § 1395nn), and the Criminal Healthcare Fraud Statute (18 U.S.C. §§ 1347, 1349), and Florida has been at the spotlight of these efforts.

This enforcement push is recently being reinforced through an often forgotten piece of legislation: the Foreign Corrupt Practices Act of 1977 (FCPA). Although not aimed specifically at the healthcare sector, the FCPA has become a powerful collateral tool to enforce healthcare compliance laws. U.S. Government officials have expressed that healthcare corporations and their executives are and will continue to be the focus of FCPA enforcement actions, and they have remained true to that commitment by imposing multi-million dollar fines and entering into deferred prosecution agreements with some of the biggest names in healthcare. By example, on July 28, 2015 Mead Johnson agreed to pay \$12 million to the Securities Exchange Commission (SEC) to settle FCPA violation claims (see <http://www.sec.gov/news/pressrelease/2015-154.html>).

Healthcare fraud and abuse enforcement has now become a significant and relatively steady source of revenue for the federal government. According to the U.S. Departments of Health and Human Services and Justice Annual Report on the Health Care Fraud and Abuse Control Program for FY 2014, the return on investment for the program over the last three years (2012-2014) has been of \$7.70 returned for every \$1.00 expended. With such financial returns on enforcement penalties, healthcare compliance enforcement will not go away. This is the new normal.

Why is this relevant to Florida? Aside from being a huge healthcare market by itself with almost 20 million people (see <http://quickfacts.census.gov/qfd/states/12000.html>), South Florida serves as the gateway to the Americas and the healthcare market in Latin America is quite significant. According to the World Bank, the average healthcare expenditure per capita in the

Latin America region during 2013 was approximately \$590. If we consider that the region has an approximate population of 586 million people and that government expenditures represent approximately 50% of the total healthcare expenditure that represents a potential market of \$173 billion per year. Major multi-national corporations operating in Latin America often have a Florida regional office so the FCPA applies to how such businesses conduct themselves.

But these days, the FCPA is not the only anti-corruption statute that a multinational company needs to consider in its daily operations. Other countries are increasingly enacting and enforcing international anti-corruption statutes. In a landmark FCPA enforcement action, U.S. and German authorities imposed combined penalties in the amount of \$1.6 billion (\$800M US & \$800M Germany) to global giant Siemens for violating both the FCPA and German anticorruption laws.

Most Latin American governments also have joined the worldwide fight against corruption and have enacted comprehensive statutes to prevent and punish corrupt activities. While these statutes share the same principles contained in the FCPA, there are significant nuances that must be considered by multi-national corporations. For example, the recently enacted Regulations to the Brazilian Clean Company Act which specifically establish the elements of an effective compliance program in Brazil exceeds the U.S. Sentencing Commission's seven elements of an effective compliance program, by requiring compliance programs to have specific controls for public procurement activities, third party due diligence and political contribution transparency (See Decreto No 8.420 de 18 de Março de 2015 que Regulamenta a Lei No. 12.846, de 1º de Agosto de 2013, que Dispõe Sobre a Responsabilização Administrativa de Pessoas Jurídicas Pela Prática de Atos Contra a Administração Pública, Nacional ou Estrangeira e dá Outras Providências (Brazil)).

As Compliance continues to evolve and practitioners become more globalized, we need to look beyond our own borders. Healthcare compliance in Florida is most certainly not just in or for Florida anymore.

Reported by: Christian Perez Font, Esq.

FACILITY AND PROFESSIONAL LICENSURE

Board Cannot Conditionally Suspend License Pending Appeal & Retain Jurisdiction to Impose Revocation.

The First District Court of Appeal recently affirmed a decision of the Board of Psychology revoking the license of a psychologist that had been convicted of health care fraud. Kale v. Department of Health, No. 1D14-4273 (Fla. 1st DCA June 4, 2015). The practitioner's criminal conviction is on appeal in the United States Court of Appeals for the Eleventh Circuit. The practitioner urged the Board to impose a conditional suspension of his license pending the outcome of the criminal appeal at which time the Board could remove the suspension or impose other discipline. The Board concluded, on the advice of its counsel, that the Board could not impose a conditional suspension and retain jurisdiction to reconsider the penalty at the

conclusion of the criminal appeal. The First District Court of Appeal agreed with the Board's decision that neither the statute nor the Board's rules permitted the Board to conditionally suspend the practitioner's license while allowing the Board to retain jurisdiction to revisit the penalty and later impose revocation. The Court also noted that the practitioner was free to petition the Board to vacate the final order if the criminal conviction is overturned on appeal.

Reported by: Michael L. Smith, Esq.

HEALTH INFORMATION AND PRIVACY

21st Century Cures Bill Passes House.

On July 10, 2015, the U.S. House of Representatives passed the 21st Century Cures Bill that aims to change HIPAA regulations as they relate to the use and disclosure of protected health information (PHI) used for research. Currently, HIPAA permits covered entities using or disclosing PHI in the treatment, payment, and healthcare operations without patient authorization. If this bill is ultimately signed into law, PHI use or disclosure would not require patient authorization for research purposes if the PHI is exchanged with covered entities or business associates as defined by HIPAA. Proponents argue this will reduce barriers and speed up research because obtaining consent is too complex. Opponents argue that allowing researchers to use PHI without patient authorization increases the risks of data breaches in a healthcare system that already has weak links in protecting privacy.

Other provisions of the bill provide for penalties to vendors of health IT systems who fail to meet standards for interoperable and secure information exchange and “patient empowerment,” giving patients the right to the entirety of their health information. The bill currently is in the Senate’s Committee on Health, Education, Labor, and Pensions.

The legislation can be located at: <https://www.congress.gov/bill/114th-congress/house-bill/6/text?q=%7B%22search%22%3A%5B%22hipaa%22%5D%7D&resultIndex=24> and <http://www.healthcareinfosecurity.com/bill-that-changes-hipaa-passes-house-a-8394>

Reported by: Ray Chamy, Esq.

LIFE SCIENCES

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>

FDA Issues Draft Guidance on Acceptance of Medical Device Clinical Data from Studies Conducted Outside the United States.

On April 22, 2015, the U.S. Food and Drug Administration (FDA) released a draft guidance document which clarifies the FDA's position of accepting medical device data from clinical studies conducted outside of the United States ("OUS"). This draft guidance is in response to the 2012 Food and Drug Administration Safety and Innovation Act § 1123, amending Food, Drug & Cosmetic Act § 569B, which codified FDA's position of accepting scientifically-valid clinical data obtained from clinical studies conducted OUS.

The draft guidance outlines special considerations that apply when using data from clinical investigations conducted OUS, including applicability of the data to certain patient populations within the United States, and also provides recommendations to help sponsors in developing data that is adequate under applicable FDA standards to promote approval or clearance of the device in the United States. The FDA pays special attention to considerations that sponsors of device submissions should take into account when initiating, or relying on previously collected data from, an OUS clinical study to support an Investigation Device Exemption, Premarket Notification (501(k)), De Novo Petition, Humanitarian Device Exemption (HAD), or Premarket Approval Application. The draft guidance also includes several hypothetical examples to highlight special considerations that must be taken into account when relying on clinical data resulting from OUS studies.

Comments on the draft guidance are due to the FDA by July 20, 2015. The draft guidance can be found at the following website:
<http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm443133.pdf>

FDA Issues Final Guidance on Biosimilars.

The U.S. Food and Drug Administration (FDA) recently issued three long-sought guidance documents which outline its expectations for near-exact copies of existing biological drugs called biosimilars. The three guidance documents were released in draft form for comment in February 2012, and were the first policy documents released by the FDA after the passage of the 2010 Biologics Price Competition and Innovation Act (BPCI). A biosimilar product is a biological product that is approved based on a showing that it is highly similar to an FDA-approved biological product, known as a reference product, and has no clinically meaningful difference in terms of safety and effectiveness from the reference product.

Questions and Answers

The first guidance document, titled “Biosimilars: Questions and Answers Regarding Implementation of the Biologics Price Innovation Act of 2009,” answers questions posed to the FDA about the FDA’s interpretation of certain statutory requirements, including its provisions on exclusivity, biosimilarity and interchangeability. The guidance document addresses three broad categories: (1) Biosimilarity and interchangeability; (2) Provisions related to the requirement to submit a BLA for a biological product; and (3) Exclusivity.

Quality Considerations

A second guidance document, titled “Quality Considerations in Demonstrating Biosimilarity of a Therapeutic Protein Product to a Reference Product,” discusses technical aspects of chemistry, manufacturing, and controls (CMC) information for a proposed biosimilar application. This guidance outlines factors that are relevant in determining whether proposed products and the reference product are highly similar to one another.

Scientific Considerations

Finally, the third guidance document intends to help sponsors in demonstrating biosimilarity between the proposed product and a reference product by using scientific data. The FDA recommends that sponsors use a “stepwise approach” to develop data and information needed to demonstrate biosimilarity. According to the FDA, the stepwise approach will help the sponsor evaluate residual uncertainty about the biosimilarity of the proposed product to the reference product. Further, the FDA said it is committed to the “totality of the evidence” approach when considering the data and information contained in a biosimilar application.

The three final guidance documents can be found here:

1. Biosimilars: Questions and Answers Regarding Implementation of the Biologics Price Competition and Innovation Act of 2009 (“Q & A”): <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM444661.pdf>
2. Quality Considerations in Demonstrating Biosimilarity of a Therapeutic Protein Product to a Reference Product (“Quality Considerations”):

<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM291134.pdf>

3. Scientific Considerations in Demonstrating Biosimilarity to a Reference Product (“Scientific Considerations”):

<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM291128.pdf>

Reported by: Kevin Dewar, Esq.

Public Health

Webinar: [Telehealth: A Game-Changer for Health Care – Are Laws Keeping Pace?](#)

Telehealth services allow patients to consult with doctors through videoconferencing and other technologies. Many in public view telehealth services as an opportunity to improve access to health services for patients in rural areas, reduce health care costs and ensure disease control surveillance through video directly observed therapy (VDOT). This webinar will examine the various ways telehealth can be used and the laws currently regulating telehealth practices in each state. This webinar takes place on **Thursday, August 20 at 1 p.m. ET**, and there is no cost to attend.

Public Health Legal Resources:

Model Medicaid Managed Care Contract Provisions: EPSDT Vision and Hearing Services.

Children enrolled in Medicaid are entitled to a comprehensive array of preventive and ameliorative care through the Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefit. As states have increasingly turned to managed care entities to fulfill their Medicaid administrative obligations, these companies are charged with ensuring that children receive EPSDT benefits. This resource suggests model contract provisions for coverage of vision and hearing services in Medicaid managed care.

The resource can be located at https://www.networkforphl.org/resources_collection/2015/07/08/662/model_medicare_managed_care_contract_provisions_epsdt_vision_and_hearing_services/?utm_source=Network+Report+8-20-15&utm_campaign=Network+Report+8-20-15&utm_medium=email&utm_content=170

MOU Template for Cross-Jurisdictional Sharing of Immunization Data.

The Network and the Partnership for Public Health Law, in consultation with the Association of State and Territorial Health Officials, have developed a template for a Memorandum of

Understanding (MOU) for secure, electronic exchange of immunization information among governmental entities that operate Immunization Information Systems. Data exchange allows immunization providers to work more efficiently and supports public health's mission to protect the public from vaccine-preventable diseases through timely and appropriate vaccination of individuals, and reduces instances of over vaccination due to the lack of vaccination records.

The template can be located at <http://www.astho.org/Public-Policy/Public-Health-Law/Resources/Partnership-for-Public-Health-Law/>

Reported by: Rodney Johnson, Esq.

THIRD PARTY PAYERS

Additional Guidance for ICD 10 Implementation

ICD 10 implementation begins October 1, 2015. Medicare claims with a date of service on or after this date will be rejected without a valid ICD-10 code (a [complete list](#) of valid 2016 ICD-10-CM codes and code titles is posted on the CMS website). The Centers for Medicare and Medicaid Services (CMS) and the American Medical Association (AMA) released a joint [letter](#) this July addressing ICD-10 implementation.

In the letter, CMS announced additional support for ICD-10 transitioning including a CMS ICD-10 Ombudsman (in place by October 1, 2015), and added flexibility in claims audits and the quality reporting process (through October, 2016 Medicare review contractors will not deny claims billed under the Part B physician fee schedule based solely on the specificity of the ICD-10 diagnosis code as long as the code used was from the right ICD-10 family).

For additional guidance, CMS offers the "[Road to 10](#)" program for smaller physician practices. "Road to 10" provides free in-person training with primers for clinical documentation and specialty-specific resources for implementation.

Note: as part of the pending transition, the Medicare claims processing system will not have the capability to accept ICD-9 codes after September 30, 2015, or the capability to accept both ICD-9 and ICD-10 codes.

Reported by: Elizabeth A. Scarola, Esq.

TRANSACTIONS

Mega Mergers: Anthem-Cigna and Aetna-Humana.

The flurry of announced mergers in the last few months, namely the Anthem-Cigna and Aetna Humana mergers, raise several interesting health law questions. Anthem announced it will buy insurance goliath Cigna for over \$54 billion, and would serve more than 53 million members. Weeks earlier, Aetna announced its \$37 billion deal to buy Humana, growing its market share to more than 33 million members. These mergers leave only three major players in the health insurance industry. Consolidations of this magnitude could cause concerns in the industry

regarding cost control, loss of competition, and highly concentrated political influence. Although the insurance companies see this as a way to improve efficiency and reduce cost for consumers, the reduction in competition and choice of insurance carriers will have to answer to antitrust concerns and pass a very hard look from the Department of Justice (“DOJ”) and Federal Trade Commission (“FTC”).

Reported by: Morgan Means Harber, JD, CHC