Summer 2021

Dear Health Law Section Members:

The Florida Bar Health Law Section ("HLS") website has been updated with Summer 2021 articles on significant developments in the health law arena that may be of interest to you in your practice.

These summaries are presented to HLS members for general information only and do not constitute legal advice from the Florida Bar or the HLS. HLS thanks the following volunteers who have generously donated their time to prepare these summaries for our members:

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- **Nicole Perez, Esq., *Blue Cross Blue Shield of Florida***
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FRAUD AND ABUSE UPDATES

DOJ Announces Coordinated Enforcement Action to Combat COVID-19-related Healthcare Fraud and Abuse

On May 26, 2021 the Department of Justice announced 14 different criminal enforcement actions against defendants located throughout the United States, including Florida, and who allegedly participated in various healthcare fraud schemes related to COVID-19 that resulted in over $143MM in false billings. The Center for Program Integrity, Centers for Medicare and Medicaid Services also announced administrative actions against more than 50 medical professionals for their alleged involvement in healthcare fraud schemes in connection with COVID-19.

According to the DOJ press release, the schemes included, among others, the offering of COVID-19 testing to senior citizens in order to obtain their personal information and samples which were subsequently used to bill Medicare for unrelated and unnecessary tests such as cancer genetic testing, allergies testing and respiratory pathogen panel tests; as well as charges for sham telehealth encounters that never occurred.

These indictments highlight the DOJs continued effort and focus on COVID-19-related healthcare fraud and abuse and it is expected that more cases will continue to follow. The entire DOJ press release can be found at https://www.justice.gov/opa/pr/doj-announces-coordinated-law-enforcement-action-combat-health-care-fraud-related-covid-19.

Submitted by: **Christian Perez Font, Esq., *Thinkeen Legal PA***

Drug Manufacturer Teva Reaches Settlement in Price Fixing Case

In June 2021, Teva Pharmaceuticals (Teva) the world's leading provider of generic drugs reached a $925K settlement with the State of Mississippi on a lawsuit brought by the United States and 44 States alleging that Teva and other generic manufacturers had engaged in a sophisticated price-fixing scheme. [1] Teva is a United States subsidiary of the parent company headquartered in Israel. [2] One in ten of the 3.66 billion generic prescriptions written in the United States is filled with a Teva product.

According to former Connecticut Attorney General William Tong, Teva's alleged drug price hikes reached over 1,000%. However, throughout the trial, Teva claimed that it "helped to contribute to the $42 billions in savings in the United States healthcare by providing affordable generic drugs in 2018." [3] However, several states, 44 to be exact, including Florida disagree. Florida Attorney General Ashley Moody has stated in the past that, "*Inflating and manipulating the pricing of essential drugs prescribed to those with chronic conditions is shameful. Routine health care can already be a burdensome cost for individuals, not to mention those suffering with life-altering and critical illnesses, and patients should not have to further worry about rising prescription drug costs of medicine they may desperately need. I am proud of my office for being one of the lead states in this ongoing investigation, and I hope this new complaint will help restore faith that drug pricing, and our marketplace are both legal and fair*." [4]

The $925K settlement with the State of Mississippi seems to indicate that more settlements, including possibly Florida, are on the way in the near future

Submitted by: **Nicole Perez, Esq.** ***Florida Blue Cross Blue Shield.***

REGULATORY AND LEGISLATIVE UPDATES:

In Vitro Clinical Tests (IVCTs), In Vitro Diagnostics (IVDs) and Laboratory Developed Tests (LDTs)

On May 18, 2021, U.S. Senator Rand Paul (R-KY) reintroduced the Verified Innovative Testing in American Laboratories ("VITAL") Act, a comprehensive bill seeking to inject clarity and resolution into historical disputes regarding federal administrative jurisdiction and the appropriate legal and regulatory frameworks for governing In Vitro Clinical Tests ("IVCTs"), In Vitro Diagnostics ("IVDs") and Laboratory Developed Tests ("LDTs").[5]

First introduced on March 17, 2020, the VITAL Act seeks to explicitly exclude the Food and Drug Administration ("FDA") from the regulatory oversight and governance of LDTs. Instead, under the VITAL Act, the Clinical Laboratory Improvement Amendments ("CLIA"), a department of the Centers for Medicare and Medicaid Services ("CMS"), would have exclusive jurisdiction and regulatory authority over IVCTs, IVDs, and LDTs.[6]

While the regulatory governance framework for LDTs has been unclear and debated for nearly a decade without resolution, the critical role of laboratory developed testing in combating the COVID19 public health crises occasioned renewed vigor to settle historical debates. In reintroducing the VITAL Act, Senator Paul noted the bill is designed "to help make tests quickly and widely available in health emergencies by removing unnecessary government barriers that have drastically slowed the response to the novel coronavirus pandemic."[7] Noting that "[l]ab-developed testing procedures ("LDPs"), which are developed validated, and performed in the same laboratory, are regulated under the Clinical Laboratory Improvement Amendments," Senator Paul's office further opined that the FDA's involvement in the testing process, and its multiple policy changes in the early stages of the coronavirus pandemic, resulted in unacceptable delays in administering public health. The Association of Molecular Pathology and the Association of Pathology Chairs issued a joint statement in support of the VITAL Act: "[i]n the earliest and most frightening days of the pandemic, CLIA accredited academic clinical laboratories could have used their valuable expertise and resources to expand SARS-CoV-2 diagnostic testing in their communities, but were unable to due to inappropriate FDA restrictions. Priceless weeks were lost, making the urgency to address these issues now even more clear."[8]

The VITAL Act offers an antithetical regulatory framework for governing LDTs to the that of the Verifying Accurate Leading-Edge IVCT Development ("VALID") Act of 2020, a competitive bill that was introduced into the US House of Representatives and Senate on March 5, 2020.[9] Unlike the VITAL Act, the VALID Act "would explicitly grant the FDA authority to regulate LDTs through a risk-based framework that categorizes LDTs as high risk or low risk, with high-risk tests facing approval requirements that are comparable to existing medical device regulations."[10] For more information on the VITAL ACT, VALID Act, and recent HHS Announcements on LDTs, please see the HLS Updates from June 2020, October 2021, and March 2021[11]

Submitted by: Gray W. Rifkin, Esq., EMBA – Chief Legal Officer and Chief Operating Officer, Commonwealth Diagnostics International, Inc.

Florida Joins a Growing Number of States Requiring Licensure of Genetic Counselors

On June 21, 2021, Florida Governor Ron DeSantis signed into law a bill requiring genetic counselors to be licensed by the Florida Department of Health ("FLDOH"). The new law, known as the Genetic Counseling Workforce Act ("GCWA"), became effective on July 1, 2021. FLDOH has announced a 90 day enforcement moratorium to allow counselors time to become appropriately licensed in the State. Florida now joins a growing number of states that regulate the work of genetic counselors.

The new law was added to Part III of Chapter 483, Florida Statutes (FLA. STATS §§ 483.11-483.919). The GCWA generally defines genetic counseling as "the process of advising an individual or a family affected by or at risk of genetic disorders" including by:

- Obtaining and evaluating individual, family, and medical histories to determine genetic risk for genetic or medical conditions and diseases in a patient, his or her offspring, and other family members;
- Discussing the features, natural history, means of diagnosis, genetic and environmental factors, and management of risk for genetic or medical conditions and diseases;
- Identifying, ordering, and coordinating genetic laboratory tests and other diagnostic studies as appropriate for a genetic assessment;
- Integrating genetic laboratory test results and other diagnostic studies with personal and family medical history to assess and communicate risk factors for genetic or medical conditions and diseases;
- Explaining the clinical implications of genetic laboratory tests and other diagnostic studies and their results;
- Evaluating the client's or family's responses to the condition or risk of recurrence and providing client-centered counseling and anticipatory guidance;
- Identifying and using community resources that provide medical, educational, financial, and psychosocial support and advocacy;
- Providing written documentation of medical, genetic, and counseling information for families and health care professionals; and
- Referring patients to a physician for diagnosis and treatment.

Interestingly, the Act's definition of genetic counseling appears to cover counseling relating to laboratory tests that are not necessarily genetic in nature, including "explaining clinical implications of . . . other diagnostic studies and their results" so long as the counseling pertains to a "genetic condition", which is an undefined term. The law may also cover business development and promotional activities, in that it purports to regulate the act of "providing written documentation of medical, genetic and counseling information for families and health care professionals."

The GCWA includes only limited exemptions to licensure. Specifically, active-duty commissioned medical officers acting within the scope of their military service and licensed professionals included in the definition of "health care practitioners" under Section 456.0001, Florida Statutes (doctors, nurses and midwives, for example) are exempt from licensure.[12] The GCWA also contains a "conscience clause", which explains that the law does not require licensed genetic counselors to participate in counseling that offends their deeply held religious or moral beliefs.[13]

Who is eligible to obtain a license and how do you get one?

The educational criteria for obtaining a license is similar to that of other jurisdictions. The applicant must provide FLDOH with satisfactory documentation of having earned either a master's degree from a genetic counseling training program or its equivalent as determined by the Accreditation Council of Genetic Counseling or its successor or an equivalent entity *or* a doctoral degree from a medical genetics training program accredited by the American Board of Medical Genetics and Genomics or the Canadian College of Medical Geneticists. Additionally, the applicant must pass the examination for certification as a genetic counselor given by the American Board of Genetic Counseling, Inc., the American Board of Medical Genetics and Genomics, or the Canadian Association of Genetic Counsellors or as a medical or clinical geneticist from the American Board of Medical Genetics and Genomics or the Canadian College of Medical Geneticists.[14] Applicants who meet the educational criteria for licensure but who have not passed a certification examination are eligible for two-year temporary license.[15] Standard licenses are also given for a two-year term.[1]

Are genetic counselors who are located outside of Florida but who counsel patients within the State impacted?

Counselors who are located outside the boundaries of the State, but who counsel patients located in Florida using remote or telemedicine technologies, likely are subject to GCWA licensure requirements. The Act's prohibition against unlicensed practice is broadly worded and is easily interpreted to cover interstate counseling activities.[16] Unlicensed practice is punishable as a misdemeanor under Florida law.[17]

In what appears to be a legislative oversight, the GCWA did not amend Section 456.47(1)(b), Florida Statutes to add genetic counselors to the definition of "telehealth provider". This means that genetic counselors who are physically located outside of Florida and not licensed in the State cannot counsel patients located in Florida via telehealth by simply registering as an out-of-state telehealth provider under Section 456.47(4), Florida Statues. The telehealth registration pathway is just not available to out-of-state genetic counselors at this time. Nevertheless, there appears to be no prohibition against out-of-state counselors who obtain a Florida genetic counselor license from providing services to patients located in Florida from a remote location. Likewise, the criteria for licensure do not preclude the licensure of out-of-state applicants.

What is the application process?

[1] *Id.* at § 483.914(2).

The good news is that the application process is relatively easy. It appears no application fee has been set by rule at this time, and the application can be completed online. FLDOH's website on genetic counselor licensing, including a link to access the application, can be found at: http://www.floridahealth.gov/licensing-and-regulation/genetic-counseling/index.html.

Submitted by: **Robert Hearn, Esq., *Epstein Becker & Green, P.C.***

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[1] https://www.tevagenerics.com/about-teva-generics/who-we-are/
[2] Id.
[3] Id.
[4] https://myfloridalegal.com/newsrel.nsf/newsreleases/25544B6CAD3C1A6D852583F9004B25C3
[5] S. 3512, 116th Congress: VITAL Act of 2020. www. GovTrack.us. 2020. June 3, 2021 <https://www.govtrack.us/congress/bills/116/s3512.
[6] Id. *See also*, Dr. Rand Paul Reintroduces the VITAL Act to Cut Red Tape and Speed Availability of Testing in Health Emergencies (2021). June 3, 2021 <https://www.paul.senate.gov/news/dr-rand-paul-reintroduces-vital-act-cut-red-tape-and-speed-availability-testing-health.
[7] Id.
[8] Genomeweb: 360DX (2021). Rand Paul Reintroduces Bill Aimed at Blocking FDA Regulations of LDTs. June 3, 2021 > https://www.360dx.com/policy-legislation/rand-paul-reintroduces-bill-aimed-blocking-fda-regulation-ldts
[9] S. 3404, 116th Congress: VALID Act of 2020. www. GovTrack.us. 2020. April 30, 2020 <https://www.govtrack.us/congress/bills/116/s3404.
[10] Boston Healthcare Associates (2020). The VALID and VITAL Acts: What do they Mean for Diagnostic Innovators. February 21, 2021 > https://www.bostonhealthcare.com/what-the-valid-and-vital-acts-mean-for-diagnostic-innovators/#:~:text=The%20VITAL%20Act%20is%20intended,during%20a%20public%20health%20emergency.
[11] Rifkin, Gray W. (2020). Florida Bar: Health Law Section Updates, June 2020. Legislative Updates: Regulation of In Vitro Clinical Diagnostic Tests. June 3, 2021 < https://flabarhls.org/wp-content/uploads/2020/11/HLS-Monthly-Updates-2020-June.pdf; Rifkin, Gray W. (2020). Florida Bar: Health Law Section Updates, October 2020. Regulatory Updates. Regulatory Uncertainty: HHS Announcement on Regulation of Laboratory Developed Tests. June 3, 2021< https://flabarhls.org/wp-content/uploads/2020/11/HLS-Monthly-Updates-2020-October.pdf; Rifkin, Gray W. (2021). Florida Bar: Health Law Section Updates, March 2021. Regulatory Updates: In Vitro Clinical Tests (IVCTs), Invitro Diagnostic (IVDs) and Laboratory Developed Tests (LDTs). June 3, 2021 < https://flabarhls.org/wp-content/uploads/2021/03/HLS-Monthly-Updates-2020-2021-December-February-Updated.pdf
[12] FLA. STATS. § 483.919.
[13] *Id.* at § 483.918.
[14] FLA. STATS. §§ 483.914(2)(c)-(d).
[15] *Id.* at § 483.914(3).
[16] *See*, FLA. STATS. §§ 483.916(1)(b)-(c).
[17] *Id.* at § 483.916(2).