June 2020

Dear Health Law Section Members:

The Health Law Section ("HLS") website has been updated with April through May 2020 articles on significant developments in the health law arena that may be of interest to you in your practice. This edition contains articles that are specific to COVID-19 in addition to non-COVID-19 updates. As a result, we have divided this edition into COVID-19-related articles versus non-COVID-19 related articles, with the former appearing at the beginning of this publication. Please note that the laws are changing on an almost-daily basis. As such, some of these Updates may no longer be entirely accurate by the time these Updates are published or reviewed. We recommend that our readers consult applicable legal authorities to evaluate whether the information summarized herein is still accurate upon reading these Updates.

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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Effective Compliance Testing in the Times of COVID-19

The arrival of the COVID-19 pandemic has created incredible disruption in all aspects of our lives, from our basic ability to interact socially to the functioning of our economy. In the world of compliance, it is particularly affecting our ability to conduct effective monitoring (1 of the 7 elements of an effective compliance program)[1] since many companies are either closed or working remotely and many employees have been terminated, are furloughed or are working remotely.[2] All of this makes it particularly challenging to conduct effective compliance monitoring, particularly for companies that rely on traditional monitoring methods.

In the past, we have explained the distinction between structured and unstructured data.[3] Put simply, structured data is data that is organized in a specific uniform format that allows for better organization and extraction with the aid of electronic tools (i.e., data that resides in an ERP or T&E system). In contrast, unstructured data is data that is not organized based on common parameters and consequently requires significant efforts to collect it (i.e., documents whose contents are not in searchable form such as physical documents in a company archive or data that is visually or personally collected, such as a monitor's personal observations during a field ride). COVID-19 has undoubtedly impacted our ability to collect both types of data, but more so unstructured data. Therefore, compliance programs that rely heavily on face-to-face interactions and unstructured data for their monitoring efforts will be at a disadvantage vis-à-vis those that incorporate more structured data analytics since less data = less monitoring = less effectiveness.

Of course, this by no means is meant to convey the idea that compliance programs should rely solely on structured data. Unstructured data is still an important element of a compliance program, especially in the context of complex internal investigations but compliance programs should always be highly adaptable and use every resource in the toolbox in order to be effective, particularly in these changing times. Even compliance programs that already incorporate structured data analytics should adapt to meet the challenges of situations like COVID-19. This adaptability should come not only from the type of data that is collected (new data points, i.e. how many calls a rep is placing to a particular practice during social distancing times) but also from the actual amount of data collected (i.e., sample size) from an existing data point (i.e., increasing the number of phone monitoring events to compensate for missed live monitoring events). Another important element to consider is a re-definition of what are acceptable benchmarks as the pandemic has affected everyone in a different manner and information collected during these times could end up being considered statistical anomalies (i.e., less compliance hotline calls in March, April and May doesn't necessarily mean that your compliance efforts have improved.).

In sum, compliance programs need to adapt to challenges like COVID-19, especially in light of this "new normal," and incorporating/improving the use of data analytics will go great lengths in

these efforts. After all, compliance is not a process with a set beginning and an end but rather a cycle more similar to a four-stroke engine and in that cycle, data is the fuel.

Submitted by: **Christian Perez Font, Esq.,** ***ThinkeenLegal, P.A.***

COVID-19:
REGULATORY UPDATES
Labor and Employment

EEOC Updates Guidance on Employer Rights in the Workplace for COVID-19 Pandemic

As employers contemplate sending employees back to work, questions arise as to how to safely operate their businesses and prevent the spread of COVID-19 among employees and customers. Common questions include whether employers can screen employees for COVID-19, require employees to take COVID-19 tests, send employees home who exhibit COVID-19 symptoms, or whether an employer may take (and maintain records of) an employee's temperature without violating privacy and employment laws.

Under ordinary circumstances, the Americans with Disabilities Act ("ADA") prohibits medical examinations unless they are job-related and consistent with business necessity.[4] Generally, measuring an employee's body temperature or administering a medical test constitutes a medical examination. Recognizing the need for greater flexibility and protection in the present pandemic, the Equal Employment Opportunity Commission ("EEOC") has issued and continues to update guidance on what employers can do in the workplace regarding COVID-19.[5] A summary of some of the relevant guidance follows:

- **Can an ADA-covered employer take the body temperature of employees during the COVID-19 pandemic?** Employers may measure an employee's body temperature during the pandemic because COVID-19 is widespread in the community. The U.S. Centers for Disease Control and Prevention ("CDC") recommends that temperature checks should happen before the individual enters the facility. Any temperature readings should be kept confidential. Temperature readings and any medical records must be kept in confidential files that are separate from personnel files.
- **Can an employer send an employee home if they have symptoms of COVID-19?** EEOC guidance states that: "Yes. The CDC states that employees who become ill with symptoms of COVID-19 should leave the workplace. The ADA does not interfere with employers following this advice."
- **May an employer administer a COVID-19 test before permitting employees to enter the workplace?** Because an individual with COVID-19 poses a direct threat to the health of others, an employer may choose to administer COVID-19 testing to employees before they enter the workplace to determine if they have it. Employers, however, should ensure that the tests are accurate and reliable.
- **May an employer screen applicants for symptoms of COVID-19?** An employer may screen job applicants for symptoms of COVID-19 after making a conditional job offer if it does so for all entering employees in the same type of job.
- **Can an employer withdraw a job offer when it needs the applicant to start immediately but the individual has COVID-19 or symptoms of it?** Yes, because the individual cannot safely enter the workplace per CDC guidance.

- **Can an employer require returning workers to wear personal protective gear and engage in infection control practices?** Yes, an employer may require employees to wear protective gear and observe infection control practices. But if an employee with a disability needs an accommodation to wear the gear or observe the practices, then the employer should discuss the request and provide the accommodation if feasible and not an undue hardship.

The EEOC's guidance covers a variety of topics related to the workplace and the COVID-19 pandemic and should be consulted by employers when bringing employees back to work especially those in the healthcare industry.

Submitted by: **Colby J. Ellis, Esq., *Johnson Jackson PLLC***

COVID-19:
REGULATORY UPDATES
Stark Law

COVID-19 Prompts HHS to Issue Blanket Waivers of Federal Stark Law

On March 30, 2020, the Department of Health and Human Services ("HHS") issued nationwide blanket waivers ("Blanket Waivers") of the federal Anti-Kickback Statute ("AKS") and physician self-referral law ('Stark"). The Blanket Waivers are retroactive to March 1, 2020.

On April 3, 2020, HHS Office of Inspector General ("OIG") issued a statement relating to these Blanket Waivers, specifically advising that it will "exercise its enforcement discretion not to impose administrative sanctions under AKS for certain remuneration related to COVID-19" for conduct occurring on or after April 3, 2020 through the end of the Blanket Waivers.

The Blanket Waivers are designed to provide relief to the healthcare industry as it navigates a never-before-seen healthcare crisis, giving providers flexibility and allowing them to be able to meet patient needs.

The Blanket Waivers focus on fair market value requirements for certain instances related to COVID-19, including remuneration for services performed by a physician; rental charges for office space or equipment; interest rates on loans; the temporary expansion of facility capacity above the number of operating rooms, procedure rooms, and beds for which the hospital was licensed, among others. (A complete list of these arrangements can be found at: https://www.cms.gov/files/document/covid-19-blanket-waivers-section-1877g.pdf).

HHS provided examples of activities that may fall within the scope of the Blanket Waivers, for example:

- Hospitals paying above previously contracted rates for services in particularly hazardous or challenging environments.
- Hospitals providing free medical office space to physicians whose patients do not need inpatient care.
- Hospitals renting office space or equipment from an independent physician practice at below fair market value or at no charge to accommodate patient surge.
- An entity providing free telehealth equipment to a physician practice to care for patients who are in isolation.
- Hospitals providing meals, comfort items (a change of clothing), or on-site child care with a value greater than $36.00 per instance to medical staff physicians who spend long hours at the hospital during the COVID-19 outbreak.

The Center for Medicare & Medicaid Services ("CMS") provided additional examples of activities that may fall within the scope of the Blanket Waivers. These examples may be found at: https://www.mwe.com/insights/cms-issues-nationwide-blanket-waivers-of-stark-law/.

The Blanket Waivers were issued for arrangements related to COVID-19 only, and have no impact on arrangements that otherwise implicate the AKS and are not covered by the Blanket Waivers (e.g., the Blanket Waivers would not apply to direct financial relationships between pharmaceutical or device manufacturers and physicians or between providers where there is no physician involved).

Submitted by: **Amy Morse, Esq.,** ***Morse & Morse, LLC***

GENERAL UPDATES:
LEGISLATIVE UPDATES

Florida Permits Consultant Pharmacists to Enter into Collaborative Practice Agreements with Certain Healthcare Providers

On March 11, 2020, Florida enacted House Bill 599 ("HB 599" or the "Bill") which expands the scope of practice for consultant pharmacists by permitting them to enter into written collaborative practice agreements with health care facility medical directors, licensed allopathic, osteopathic and podiatric physicians, and dentists authorized to prescribe medicinal drugs.

Under HB 599, which goes into effect July 1, 2020, a consultant pharmacist with a written collaborative practice agreement may:

- Provide medication management services;
- Order and evaluate laboratory or clinical testing;
- Conduct patient assessments to evaluate and monitor drug therapy; and
- Modify, discontinue or administer medicinal drugs.

To that end, and as required by HB 599, counsel must ensure that a collaborative practice agreement details the situations for which a consultant pharmacist can engage in the conduct outlined above.

Other critical points of note regarding HB 599:

- The Bill does not give consultant pharmacists permission to diagnose diseases or conditions.
- The Bill requires both consultant pharmacists and applicable healthcare providers to maintain, and make available upon request, written collaborative agreements.
- The Bill mandates additional training for a pharmacist to become a licensed consultant pharmacist.
- The Bill requires consultant pharmacists to maintain patient care and quality assurance records in addition to drug records.

HB 599 should help improve access to care, which is of particular importance right now given the existing COVID-19 pandemic.

Submitted by: Tadena Simpson, Esq., Assistant General Counsel, *Envision Rx Options*

GENERAL UPDATES:
LEGISLATIVE UPDATES

VALID Act:
Regulation of In Vitro Clinical Diagnostic Tests

A "Laboratory Developed Test" or "LDT" was historically defined by the U.S. Food and Drug Administration ("FDA") as "a type of in vitro diagnostic test that is designed, manufactured and used within a single laboratory."[6] Although the FDA started regulating "devices" in the 1970s, the agency historically afforded "enforcement discretion" to LDTs, leaving the regulation and oversight of clinical laboratories and the LDTs developed and validated in those laboratories to the Centers for Medicare and Medicaid Services' ("CMS") Clinical Laboratory Improvement Amendments ("CLIA").[7] In 2014, however, attempting to address concerns emanating from unprecedented technology improvements and new scientific platform developments that have steadily arrived since the turn of the century, the FDA announced its intention to formally regulate LDTs via the issuance of a guidance document titled "*Draft Guidance for Industry, Food and Drug Administration Staff, and Clinical Laboratories: Framework for Regulatory Oversight of Laboratory Developed Tests (LDTs)*"[8] (the "2014 Guidance"). During the comment period for the FDA's 2014 Guidance, however, many industry groups and stakeholders vigorously contested the FDA's authority to regulate LDTs given CLIA's already robust system of governance and oversight. After encountering stakeholder opposition and threat of legal proceedings, the FDA did not effectuate the 2014 Guidance, leaving a perceived lack of resolution to the regulatory framework for LDTs.

On March 5, 2020, bipartisan lawmakers from the U.S. House of Representative and Senate simultaneously introduced the *Verifying Accurate Leading-edge IVCT Development Act of 2020* (the "VALID Act"), a comprehensive piece of legislation that's stated purpose is "[t]o amend the Federal Food, Drug, and Cosmetic Act to provide for the regulation of in vitro clinical tests, and for other purposes."[9] The VALID Act introduces a regulatory paradigm that expressly defines a new category of products—*in vitro clinical tests* ("IVCTs")—and sets forth new regulations and pathways that govern IVCTs.

> Pursuant to the VALID Act, an *in vitro clinical test*:
>
> (A) means a test intended by its developer (as defined in section 587) to be used in the collection, preparation, analysis, or in vitro clinical examination of specimens taken or derived from the human body for the purpose of:
>
> (i) identifying or diagnosing a disease or condition;
> (ii) providing information for diagnosing, screening, measuring, detecting, predicting, prognosing, analyzing, or monitoring a disease or condition, including by making a determination of an individual's state of health; or
> (iii) selecting, monitoring, or informing therapy or treatment for a disease or condition;

and
(B) may include:

(i) a test protocol or laboratory test protocol;
(ii) an instrument (as defined in section 587(11));
(iii) an article for taking, deriving, holding, or transporting specimens from the human body (as defined in section 587(16)); software, excluding software that is excluded by section 520(o) from the definition of a device under section 201(h), and excluding modifications that are exempt in accordance with section 587A(l)(2)(A); and
(v) subject to subparagraph (2), a component or part of a test, a test protocol, an instrument, an article, or software described in any of clauses (A) through (D) of such subparagraph, whether alone or in combination, including re8 agents, calibrators, and controls.[10]

While expressly including IVCTs (and LDTs) within the FDA's regulatory oversight, the VALID Act adopts many aspects of previous legislation and recommendations included in the 2014 Guidance and prior legislation, including affording multiple approval pathways utilizing risk-based regulatory classifications for IVCTs. At the same time, the VALID Act calls for the establishment of new committees, platforms, and programs to effectuate its purpose.

Some key concepts addressed in the VALID Act include:

1. *Breakthrough In Vitro Clinical Tests (Breakthrough IVCTs)* – The VALID Act expressly encourages the Secretary of the Department of Health and Human Services (the "Secretary") to "apply efficient and flexible approaches to expedite the development of, and prioritize the review of, in vitro clinical tests that represent breakthrough technologies" and also calls for the establishment of a program "to expedite the development of and provide for the priority review of" Breakthrough IVCTs.[11]

2. *Technology Certification* - The VALID Act establishes a "Technology Certification" program for IVCT developers.[12] The Secretary is charged with establishing a public docket to receive comments and recommendations concerning the implementation of this section and convening a public meeting to "discuss components of the technology certification process including application requirements, inspections, alignment with third-party accreditors, and the definition of 'technology' under Section 587(17)."[13] The Technology Certification program would allow IVCT developers to submit detailed data relating to the resources, processes, and procedures for a "representative" IVCT and, if approved by the FDA, subsequent tests from the same IVCT manufacturer would not have to undergoes individual review if within the same scope of the "Technology Certification".[14]

3. *Registration and Listing* – The VALID Act calls for a new comprehensive registration and listing system for IVCTs. Though listing requirements will vary depending on the nature of the IVCT (i.e., Grandfathered IVCT, Exempt IVCT, Low Risk IVCT, etc.), the requirements generally include: name of the establishment; contact information; name of

the IVCT and its test listing number (when available); CLIA certificate number (for any CLIA-certified laboratory performing high complexity testing that the developer of the IVCT); whether the test is offered as a test approved under Section 587B or Section 587D, or whether the test is offered as an IVCT under Section 587A; summary of analytical and clinical performance; description of conformance with any mitigation measures, representative labeling for the IVCT; and a statement that the information is truthful and accurate.[15]

4. *Collaborative Communities* – The VALID Act introduces the concept of "Collaborative Communities" for IVCTs, which the Act describes as a group of "public and private participants that may provide recommendations and other advice to the Secretary on the development and regulation of in vitro clinical tests."[16] Specifically, Collaborative Communities will make recommendations on matters including: (1) mitigating measures for IVCTs, (2) standards development for IVCTs, (3) scientific and clinical evidence to support new claims for IVCTs, (4) new technologies and methodologies related to IVCTs, (5) stakeholder communications and engagement, and (6) development of policies and processes to develop and/or regulate tests in accordance with the least burdensome principles under the VALID Act.[17] The Secretary is charged with issuing draft guidance on Collaborative Communities within 180 days of enactment of the VALID Act.[18]

5. *Grandfathered Tests* – The VALID Act contains provisions to "grandfather in" tests that are already offered clinically prior to the enactment of the VALID Act.[19]

With the VALID Act now pending before Congress and the Senate, it is anticipated that congressional committees with oversight over the FDA will commence stakeholder discussions and hold hearings on the VALID Act this summer.[20]

Submitted by: **Gray W. Rifkin, Esq., *Commonwealth Diagnostics International, Inc.***

[1] *See* U.S.S.G. § 8B2.1(b)(5), *available at* https://guidelines.ussc.gov/gl/%C2%A78B2.1.
[2] Effective monitoring is also a key element of the Department of Justice's Guidance on the Evaluation of Corporate Compliance Programs, released in April of 2019, which states: "Prosecutors should likewise look to whether a company has taken 'reasonable steps' to 'ensure that the organization's compliance and ethics program is followed, including monitoring and auditing to detect criminal conduct,' and 'evaluate periodically the effectiveness of the organization's' program." *See* https://www.justice.gov/criminal-fraud/page/file/937501/download.
[3] *See* https://www.linkedin.com/pulse/enter-matrix-seriously-please-do-come-christian-perez-font/.
[4] U.S. Equal Emp. Opportunity Comm'n, EEOC-NVTA-2009-3, Pandemic Preparedness in the Workplace and the Americans with Disabilities Act (2009).
[5] U.S. Equal Emp. Opportunity Comm'n, Technical Assistance Questions and Answers – What You Should Know About COVID-19 and the ADA, the Rehabilitation Act, and Other EEO Laws (2020).
[6] *See id.* at "High Complexity Molecular-Based Laboratory Developed Tests."
[7] U.S. Food and Drug Administration (2014). Draft Guidance for Industry, Food and Drug Administration Staff, and Clinical Laboratories: Framework for Regulatory Oversight of Laboratory Developed Tests (LDTs) (2014). April 30, 2020, https://www.fda.gov/regulatory-information/search-fda-guidance-documents/framework-regulatory-oversight-laboratory-developed-tests-ldts; *see also* Josephson, Aaron L (2020). The National Law Review. The VALID Act, Aiming to Reform the Regulation of Diagnostic Products, is Finally Introduced in Congress. April 30, 2020, https://www.natlawreview.com/article/valid-act-aiming-to-reform-regulation-diagnostic-products-finally-introduced
[8] U.S. Food and Drug Administration (2014). Draft Guidance. Framework for Regulatory Oversight of Laboratory Developed Tests.
[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] *Id.* § S3403(2)(a)(1)(1)(A)-(B).
[11] *Id.* § 587C(a).
[12] *Id.* § 587D.
[13] *Id.*
[14] *Id.*
[15] *Id.* § 587I.
[16] *Id.* § 587S.
[17] *Id.*
[18] *Id.*
[19] *Id.*§ 587A(c).
[20] Josephson, *supra* note 7.