Fall 2021

Dear Health Law Section Members:

The Health Law Section ("HLS") website has been updated with Fall 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:

- **Alé Dalton, Esq.,** ***Arant, Boult Cummings, LLP***
- **Amy S. Leopard, Esq.,** ***Bradley, Arant, Boult Cummings, LLP***
- **Kevin C. Michael, Esq.,** ***Bradley, Arant, Boult Cummings, LLP***
- **Christian Perez-Font, Esq, Managing Partner,** ***Thinkeen Legal PA***
- **Gray W. Rifkin, Esq.,** ***Chief Legal Officer and Chief Operating Officer, Commonwealth Diagnostics International, Inc.***

Thank you,

Elizabeth Scarola, Esq., ***Epstein Becker & Green, P.C.*****, HLS Editor in Chief**

Ashley Brevda, Esq., Corp Counsel/Chief Compliance Officer, ***Oncology Analytics, Inc.*****, HLS Team Editor**

Trish Huie, Esq., ***Patricia A. Huie, PLLC*****, HLS Team Editor**

Christian Perez-Font, Esq., Managing Partner, ***Thinkeen Legal PA*****, HLS Team Editor**

FRAUD AND ABUSE UPDATES

PhRMA Updates its Code on Interactions with Health Care Professionals

Pharmaceutical Research and Manufacturers of America, one of the biggest trade groups representing companies in the pharmaceutical industry in the United States, recently introduced changes to its Code on Interactions with Health Care Professionals, which will take effect on January 1, 2022.

The changes which largely come on the heels of increased scrutiny by government officials over speaker programs as set forth in the November 16, 2020 special fraud alert from the Department of Health and Human Services Inspector General, introduce the following changes, among others:

- The code reiterates that the purpose of speaker programs must only be to present substantive educational information designed to help address a bona fide educational need among attendees, in light of recent substantive changes in relevant information (e.g., new medical or scientific information or a new FDA-approved indication for the product). Hence, speaker programs that do not address recent changes are subject to scrutiny.

- The code reiterates the need for modest locations which are conducive to a *bona fide* exchange of information. Accordingly, the provision of alcoholic beverages and the selection of high-end restaurants or venues for speaker programs are not allowed.

- The code now expressly states that repeat attendance by healthcare providers at speaker program on the same or substantially the same topic where a meal is provided is generally not appropriate, unless the attendee has a bona fide educational need to receive the information presented. The code also clarifies that attendance by speakers as participants at programs after they have spoken on the same or substantially the same topic is redundant and, therefore, generally not appropriate.

You can read more about these changes in the following link: https://www.phrma.org/resource-center/Pages/Statement-on-Revisions-to-the-PhRMA-Code-on-Interactions-with-Health-Care-Professionals

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

Two South Florida Addiction Treatment Facilities Operators Convicted in $112 MM Fraud Scheme

On November 4, 2021, a federal jury convicted the operators of two South Florida addiction treatment facilities for engaging in a fraudulent scheme that involved, among others, the billing of approximately $112 MM for services that were never provided or were medically unnecessary, and for paying and receiving unlawful kickbacks.

According to the Department of Justice press release, the two defendants obtained patients through patient recruiters who offered illegal kickbacks to patients in the form of free airline tickets, cash and most shockingly, illegal drugs. Under the scheme, the two operators would shuffle patients between the two facilities (one was inpatient and the other was outpatient) to fraudulently bill for as much as possible. To justify admission into the inpatient facility, patient recruiters procured drugs for the patients to justify admission and thereafter to keep patients docile and complying with their instructions. The two operators also billed for therapy sessions that were never provided and also engaged in medically unnecessary urinalysis drug tests for which they received illegal kickbacks.

The two defendants are scheduled to be sentenced on Jan. 13, 2022 and they face a maximum of 20 years for the health care fraud and wire fraud conspiracy count, 10 years for each substantive count of health care fraud and paying and receiving kickbacks, and five years for the kickbacks conspiracy. One of the defendants has also been convicted on money laundering and bank fraud charges associated with the fraud scheme for which he could receive additional maximum sentences of 20 years for conspiracy to commit money laundering, 20 years for each substantive count of concealment money laundering, 10 years for each additional count of money laundering, and 30 years for each substantive count of bank fraud.

The entire DOJ press release can be found at https://www.justice.gov/opa/pr/south-florida-addiction-treatment-facility-operators-convicted-112-million-addiction .

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

Laboratory Owner Sentenced to 82 Months in Prison for COVID-19 Kickback Scheme

On November 9, 2021, a Florida man who owned multiple diagnostic testing laboratories was sentenced to 82 months in prison for engaging in a fraudulent scheme that involved the payment and receipt of illegal kickbacks by exploiting regulatory waivers put in place during the COVID-19 pandemic.

Under the scheme, the defendants exploited temporary amendments to telehealth restrictions enacted during the pandemic, which were aimed at expanding access to care for Medicare recipients by making it easier for beneficiaries to receive needed medical care from home instead of going to the providers facilities. In this regard, the defendants arranged for telemedicine providers to authorize thousands of medically unnecessary cancer and cardiovascular genetic testing orders at the defendant-owned laboratories. In exchange, the defendant gave these telemedicine providers access to beneficiary information and the opportunity to bill for purported telehealth consultations, which in many cases never took place.

The entire DOJ press release can be found at https://www.justice.gov/opa/pr/laboratory-owner-sentenced-82-months-prison-covid-19-kickback-scheme .

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

COMPLIANCE UPDATES

Alexa, Are You Allowed to Be Here? Considerations for Drafting Virtual Assistant Policies for Long Term Care Facilities

Virtual assistants such as Amazon's Alexa, Facebook's Portal, Google's Nest Hub, and countless others continue growing in popularity as families navigate safely remaining connected with their loved ones receiving long-term care during a continuing pandemic. In some instances, use of virtual assistants has been encouraged directly by facilities hoping to improve isolation, boost morale, and promote independence.

At their core, virtual assistants are passive listening and recording devices. This raises significant compliance concerns not just around the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Law and analogous state laws, but also laws governing the recording of in-person conversations and disability discrimination and accommodations. Further, Virginia recently adopted HB 2154 directing the Virginia Department of Health to establish regulations requiring hospitals, nursing homes, and certified nursing facilities to implement policies that ensure patient access to intelligent personal assistants while protecting their HIPAA privacy rights.

There are many considerations in drafting a virtual assistant policy that supports the positive outcomes of allowing this technology in a long-term care facility, but that also comports with applicable state and federals laws and regulations.

1. **Where is the facility located?** Consider whether this policy will only apply to a particular location or perhaps a group of facilities in a single state? If the policy will be used across states, the strictest set of state rules should govern the limits of the policy, though it is important to consider whether any overlap in state laws could trigger an internal conflict in the policy. Will a single policy govern different types of long-term care facilities (long-term acute care, skilled nursing, or assisted living) or even different types of healthcare facilities across a health system? For example, certain states have laws regulating the use of video cameras that record both video and audio in nursing homes (among other healthcare facilities). These laws could be tripped by virtual assistants with cameras, such as Facebook's Portal or Amazon's Echo Show, but may be a non-issue in another residential facility in the same state. States also may have restrictive recording laws that prevent virtual assistants from being used in shared spaces. Note that federal privacy laws, such as the HIPAA Privacy Rule, will apply regardless of location and should be the cornerstone of these considerations for covered entities.

2. **What is a virtual assistant?** In defining "virtual assistant," the facility should first consider any relevant state law definitions. Different states may also use different terms for these devices, such as "digital assistants" or "intelligent personal assistant." For example, Virginia defines an "intelligent personal assistant" as "a combination of an electronic device and a specialized software application designed to assist users with basic tasks using a combination of natural language processing and artificial

intelligence."[1] It is also important to consider any exclusions from the definition that make sense for the type of facility and its patient population (e.g., "virtual assistants shall not include any video devices"), as well as exceptions for medical devices that arguably could be classified as virtual assistants (depending on how broad the definition of "virtual assistant" may be).

3. **Who provides the device and who gets to use one?** It is important to consider how antidiscrimination laws, such as the federal Americans with Disabilities Act (ADA), may be tripped by situations in which the facility is providing the virtual assistant and may be required to provide adaptive access to the virtual assistant. Facilities can streamline the ADA and HIPAA Security Rule requirements by requiring patients to bring their own device rather than provisioning a personal device to the patient. The facility should set forth the eligibility requirements for patients to use these devices at the facility. This policy may include rules regarding whether patients' devices may connect to a facility's wireless network (e.g., a family member may need to connect to the patient's personal network to install the device vs. the facility undertaking maintenance within the context of its network security policies); limitations of use in public or shared spaces; and a requirement to sign the appropriate authorization and consent forms. If patients are unwilling or unable to meet these requirements, the policy may prevent them from having a virtual assistant.

4. **Setting ground rules (ownership, use, misuse, and damage).** The policy should set "ground rules" governing ownership of the device and any waivers to facility liability if the virtual assistant is not owned by the facility (or recovering damages if a facility-owned virtual assistant is damaged), as well as what may be considered proper "use" and "misuse" (partly informed by the facility's general policies, but also by applicable laws and regulations). Facilities may choose to handle some of the thornier issues by adopting some broader ground rules, such as limiting use of virtual assistants solely to private rooms.

5. **Preparing necessary consent forms and notices.** The facility should consider preparing a virtual assistant-specific consent form, which may include HIPAA authorization language and patient consent to any preconditions to be met or acknowledgements to be made in connection with receiving or being allowed to use a virtual assistant in the facility. The facility should confirm whether posting any "recording" warnings in spaces in which virtual assistants are used is required by state law and, if not, whether it is still advisable to consider requiring such signage to prevent inadvertent privacy disclosures.

6. **Always allow for facility discretion and professional judgment.** The policy should give the facility ultimate discretion (and protect providers' professional judgment) in connection with the use of a virtual assistant. In particular, consider actions such as disabling a device when appropriate, whether it is due to misuse or to protect a patient's privacy (e.g., muting an Alexa device when a provider is examining a patient or discussing protected health information), so that patients' care is not compromised by access or use of virtual assistants in the facility.

There is no one-size-fits-all virtual assistant policy and the complexities of these considerations will continue to evolve as more states begin to regulate the use of virtual assistants in healthcare spaces, not just for long-term care facilities. Ultimately, the most important goal in preparing these policies is to protect the well-being and privacy of all patients receiving care at the facility.

Special thanks to Adriante Carter (3L University of Florida), a Bradley summer associate, for her thorough research and contributions to this update.

Submitted by: Alé Dalton, Esq. and Amy S. Leopard, Esq. *Bradley, Arant, Boult Cummings, LLP*

Newly Issued Vaccine Guidance Brings Increased Uncertainty for Nursing Home Operators and Staff

Among additional measures announced by the Biden administration on August 18 in response to the proliferation of the Delta variant of COVID-19, the Department of Health and Human Services is directed to implement guidelines in effect requiring, as a condition to participation in the Medicare and/or Medicaid programs, that nursing homes require all staff to be fully vaccinated against COVID-19. The administration did not include periodic testing as an alternative for the vaccine-hesitant. According to the corresponding White House announcement, this new requirement will impact nearly 15,000 facilities employing approximately 1.6 million workers; the Centers for Medicare & Medicaid Services (CMS) separately reported that as of August 8, about 62% of staff at nursing home facilities were fully vaccinated across the nation, leaving a significant portion of skilled nursing facility staff that will soon need to decide whether to get vaccinated or leave their positions. According to a related August 18 press release, CMS is currently developing an emergency regulation in collaboration with the Centers for Disease Control and Prevention (CDC) to implement the new policy and expects to complete rule-making within a matter of weeks for issuance of the new rules in September. CMS has otherwise provided limited indication of the mechanics of implementation and monitoring, including deadlines for compliance. Regulations published by CMS in May imposed requirements that long term care facilities report, on a weekly basis, resident and staff vaccination data to the CDC's National Healthcare Safety Network (NHSN). CMS has indicated it will utilize NHSN data as one form of compliance monitoring and will deploy Quality Improvement Organizations in connection with the policy.

These new measures project to add further staffing strain for an industry already struggling with a labor shortage, as operators will grapple with both implementation and compliance monitoring costs and some inevitable loss of employees that refuse to comply. Given the current tightening of margins due to lower occupancy rates, wage pressure in light of the existing labor shortage, higher insurance costs, capital expenditures and other variables, prudent operators will attempt to get ahead of the announced guidelines as much as possible, both from a messaging and a compliance perspective, in order to minimize potential downside impact. This might be accomplished by further incentivizing (and facilitating) staff vaccination, providing a period within which vaccination must be commenced as an internal policy, or otherwise.

The implementation of express guidelines by the federal government will likely be welcomed by at least some skilled nursing operators that have been struggling with the decision of whether to impose a vaccine mandate, since in effect it takes the decision out of their hands (at least in state and local jurisdictions that have not separately enacted a ban on vaccine mandates). A new, broader mandate, announced on September 9, will require that any healthcare provider receiving Medicare or Medicaid funds mandate vaccination of its employees, which should to some degree mitigate the staffing impact on skilled nursing operators by reducing the alternative employment options in the healthcare industry to which vaccine-hesitant skilled nursing staff might otherwise pivot. Larger long-term care operators will also need to consider the impact of forthcoming rulemaking by the Occupational Safety and Health Administration, also announced on September 9, which will mandate that private employers with 100 or more employees require either vaccination or weekly testing for their employees.

If a facility loses its Medicare or Medicaid funding due to unvaccinated staff, it would have a significant impact on cash flow. Lenders in the industry should also monitor these new requirements and consider working with counsel to, on a going-forward basis, build express references to such mandates into their loan documents and covenants to specifically require compliance with such guidelines when they become effective. With respect to existing relationships, lenders should consider proactively discussing implementation measures, timing, and labor and cost impacts with their borrowers to avoid surprises. The newly announced vaccination requirements are projected to increase uncertainty in an industry already struggling with labor and cost challenges, and operators and their lenders will need to keep a close watch on the specific requirements that will be issued later this month and consider the interplay between these new federal requirements and any competing or complementary state or local laws and regulations.

Submitted by: Kevin C. Michael, Esq., *Bradley, Arant, Boult Cummings, LLP*

REGULATORY AND LEGISLATIVE UPDATES:

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

Reintroduction of the VALID Act

On June 24, 2021, bipartisan members of the United States House of Representatives and Congress reintroduced the Verifying Accurate Leading-Edge IVCT Development (VALID) Act of 2021, a comprehensive bill that would clearly establish the United States Food and Drug Administration's (FDA) jurisdiction and authority over In Vitro Clinical Tests (IVCTs), In Vitro Diagnostics (IVDs), and more specifically Laboratory Developed Tests (LDTs).[2] At its core, the VALID Act would establish a "new risk-based oversight framework for so-called *in vitro* clinical tests, a category comprising [LDTs] and test kits, and would give the FDA authority to regulate these tests."[3]

The VALID Act has a nemesis in the form of a competing bill, the Verified Innovative Testing in American Laboratories (VITAL) Act, which was reintroduced on May 18, 2021.[4] Unlike the VALID Act, the VITAL Act seeks to explicitly remove the FDA from any claim to jurisdiction or oversight over 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.[5]

This is not the first time that the VALID Act and VITAL Act have been positioned for battle against each other. The opposing bills were first introduced in March of 2020 during the emergence of the COVID19 pandemic. Both bills have been referred to the Senate Health, Education, Labor, and Pensions Committee. The emergence of a clear legislative victor will have a resounding impact on diagnostic healthcare delivery in the United States and will end a protracted political and industry dispute that has lasted a decade.

For more information on the VITAL ACT, VALID Act, and recent HHS Announcements on LDTs, please see the HLS Updates from June 2020 – Summer 2021.[6]

---

[1] Va. Code Ann. § 32.1-127(B)(29).

[2] H.R.4128 - 117th Congress (2021-2022): VALID Act of 2021, H.R.4128, 117th Cong. (2021), https://www.congress.gov/bill/117th-congress/house-bill/4128/text.

[3] Genomeweb: 360DX (2021). US House and Senate Reintroduce Bill That Would Give FDA Authority to Regulate LDTs. June 24, 2021 < https://www.360dx.com/policy-legislation/us-house-and-senate-reintroduce-bill-would-give-fda-authority-regulate-ldts.

[4] S.1666 - 117th Congress (2021-2022): VITAL Act of 2021, S.1666, 117th Cong. (2021), https://www.congress.gov/bill/117th-congress/senate-bill/1666/committees.

[5] 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.

[6] 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; Rifkin, Gray W. (2021). Florida Bar: Health Law Section Updates, Summer 2021. Regulatory Updates: In Vitro Clinical Tests (IVCTs), In Vitro Diagnostics (IVDs), and Laboratory Developed Tests (LDTs). < https://flabarhls.org/wp-content/uploads/2021/08/HLS-Monthly-Updates-2021-Summer.pdf.