October 2020

Dear Health Law Section Members:

The Health Law Section ("HLS") website has been updated with August through September 2020 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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Thank you,

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TABLE OF CONTENTS

UPDATES			
General Topic	**Sub-Topic**	**Article Title**	**Page No.**
Fraud and Abuse	COVID-19	**OIG Accepting Inquiries Regarding the Application of Its Administrative Enforcement Authorities During COVID-19**	3
Legislative Updates	Pelvic Examination Consent	**Florida Approves Automated Pharmacy for Outpatient Dispending**	5
Legislative Updates	Pharmaceutical Dispensing	**Florida Board of Medicine Provides Guidance on Written Consent for Pelvic Examinations**	7
Regulatory Updates	VALID Act	**Regulatory Uncertainty: HHS Announcement on Regulation of Laboratory Developed Tests**	8
Privacy Updates	COVID-19	**OCR issues Updated Guidance on HIPAA and Contacting Former COVID-19 Patients about Plasma**	10
CITATIONS			11

FRAUD AND ABUSE UPDATES

OIG Accepting Inquiries Regarding the Application of Its Administrative Enforcement Authorities During COVID-19

The Office of Inspector General ("OIG") is accepting inquiries regarding its enforcement authority for arrangements arising out of the COVID-19 public health emergency ("PHE") that implicate the Federal Antikickback Statute ("AKS") and civil monetary penalty ("CMP") law. Though OIG is actively providing feedback on such arrangements, requestors should beware that OIG's feedback does not bind the U.S. Department of Health and Human Services, U.S. Department of Justice, or any other federal or state agency. Accordingly, unlike the OIG Advisory Opinion process, a favorable response from OIG does not result in prospective immunity or protection from administrative sanctions, federal criminal law, or any other federal, state or local rule, regulation or ordinance, including the liability for violations of the False Claims Act, Stark Law, or other legal authorities for improper billing, claims submission, cost reporting, or related conduct by any party.[1]

To date, OIG has received numerous inquiries.[2] Below is a sampling of notable inquiries:

(1) OIG indicated that providing free COVID-19 antibody testing to patients who contemporaneously have a medically necessary blood test(s) implicates the AKS and the Beneficiary Inducement CMP, however this scenario poses a low risk of fraud and abuse.

OIG reasoned that free testing promotes increased patient awareness, donations of COVID-19 blood plasma, and offers "valuable public health information and data."[3]

OIG noted the arrangement should include the following safeguards: (1) the ordering physician would not receive any payments/anything of value from the lab; (2) the patient would not receive payment; (3) the antibody tests were only offered when receiving medically necessary blood tests; (4) neither the patient, commercial insurance company, or federal health care program would be billed for any costs; and (5) the antibody test used is approved by the FDA.

(2) OIG indicated there was a low risk of fraud or abuse if an oncology practice offers free or discounted lodging to financially needy patients who received free or discounted lodging at a non-profit lodging facility prior to COVID-19 while receiving chemotherapy or radiation treatment.[4]

Though OIG noted that the arrangement implicates the AKS and Beneficiary Inducement CMP, OIG reasoned that the arrangements presented low risk of fraud and abuse if they include the following conditions: (1) patient resides at least 50 miles from treatment site; (2) the patient was established with the oncology practice prior to the

PHE; (3) the physician determines that the lodging would facilitate access to care; (4) the patient would have received free or discounted lodging at a non-profit lodging facility; (5) the remuneration is in-kind (direct payment to hotel); (6) the hotel is in close proximity to the treatment site; (7) the practice does not advertise free housing for patient recruitment; and (8) the lodging is provided during the PHE.

(3) OIG also found that while the AKS was implicated, there was a low risk of fraud in an arrangement in which a physician group provides face masks to a nursing home with which it contracts to provide services when the nursing home faces supply shortages.

OIG noted that providing face masks would protect the health of the physicians and nursing home staff and residents. OIG noted the following conditions of the arrangement: (1) furnishing masks is directly related to the COVID-19 PHE; (2) masks are furnished only during the COVID-19 PHE; (3) furnishing of masks was not marketed by the physician practice; and (4) furnishing masks is not contingent on referrals from the nursing home to the physician group.

(4) OIG determined that the following arrangements also implicated the AKS and Beneficiary Inducement CMP, but determined if various safeguards were implemented, there was a low risk of fraud and abuse:

- A clinical laboratory could bill a payor and pay fair market value to a retail pharmacy for costs associated with COVID-19 collection testing sites. The costs are related to items/services such as PPE, processing, sending specimens and scheduling services.
- A hospital could assist a Federally Qualified Health Center Look-Alike (FQHCLA) by suspending rental charges and forgoing the accrual of interest during the PHE. This would allow the FQHCLA to continue to serve the medical needs of some of the country's most vulnerable individuals.
- A mental health or substance use provider could provide a cell phone and/or data plan for patients who are financially needed and do not own a cell phone, service or data plan to provide medically necessary care while in-person care is disrupted during the PHE.
- Health care providers could furnish services (within their scope of practice) for free or at a reduced rate to a skilled nursing facility ("SNF") or other long-term care provider facility that face staffing shortages due to the PHE.
- A hospital could provide free access to its telehealth platform to physicians on its medical staff during the PHE.

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

LEGISLATIVE UPDATES

Florida Approves Automated Pharmacy for Outpatient Dispensing

When it comes to healthcare, one of the main concerns for many Americans – particularly those suffering from chronic conditions – is access to medication. In addition to prescription drug costs, pharmacy hours of operation and location often impede access to medication. In an effort to address the foregoing impediments and to increase individual access to prescription drugs, Florida legislators passed House Bill 59 ("HB 59") in the 2020 legislative session. The bill, which went into effect on July 1, 2020, addresses the above-mentioned obstacles by allowing pharmacies to dispense certain prescription drugs through automated pharmacy systems.

While the concept of vendor or kiosk-like dispensing may be novel to some, automated pharmacy systems have been in use for several years throughout Florida in long term-care facilities, hospices, and correctional institutions pursuant to Section 465.0235, Florida Statutes. HB 59 merely amended existing state law to extend the use of automated pharmacy systems to outpatient dispensing in locations other than that of a community pharmacy. Of course, given the heightened concerns around the establishment of automated pharmacy systems for outpatient dispensing, practitioners will find that HB 59 includes a number of safeguards – the most critical one being that any automated pharmacy system must have "a mechanism in place that provides live, real-time patient counseling by a [Florida-licensed] pharmacist."[5] The foregoing requirement ensures that the patient is educated about the drug prior to the drug being dispensed, which is a critical component of medication adherence and ultimately patient health.

Other requirements for operating a kiosk-like pharmacy include:

1. That the automated pharmacy system be under the supervision and control of the community pharmacy;[6]
2. That the automated pharmacy system be located in an indoor environment and in a location that will increase patients' access to their prescriptions;
3. That the community pharmacy notifies the Board of Pharmacy of the location of the automated pharmacy system and any changes to such location;
4. That the automated pharmacy system not contain or dispense controlled substances listed under state or federal law;[7]
5. That the community pharmacy system maintains a record of all drugs dispensed, including the identity of the pharmacist responsible for verifying the accuracy of the dosage and providing patient counseling;
6. That the automated pharmacy system maintains confidentiality of personal health information; and
7. That the community pharmacy maintain written policies and procedures to ensure the proper, safe, and secure functioning of the automated pharmacy system with an annual review.[8]

In short, HB 59 removes the barriers of time and location with respect to prescription drug access. Automated pharmacies can operate 24 hours a day, 7 days a week, allowing individuals to access their medications at any time that is convenient to them and they are not limited to being located in the same location as the supervisory community or retail pharmacy.

Submitted by: **Tadena Simpson, Esq., *Envision Pharmaceutical Holdings***

LEGISLATIVE UPDATES

Florida Board of Medicine Provides Guidance on Written Consent for Pelvic Examinations

As reported in the August 2020 HLS Updates, on August 7, 2020, the Florida Board of Medicine (the "Board") considered a Petition for a Declaratory Statement (the "Petition") seeking clarity on several matters regarding implementation of Senate Bill 698, which requires Florida health care providers, and providers in training, to obtain written consent from their patients (or their legal representatives) before performing a pelvic examination. The Petition was submitted by several of Florida's largest health care organizations, including the Florida Medical Association, the Florida Chapter of the American Academy of Pediatrics, Inc., and the Florida Chapter of the American College of Physicians.

Specifically, the Petition sought clarity on whether: (i) Senate Bill 698 was gender neutral and accordingly applied to men; (ii) the legislation applies to pelvic examinations performed for non-diagnostic purposes (i.e., surgical procedures involving organs such as the vulva, vagina, ovaries, uterus and rectum); (iii) the mere touching or looking at the listed parts of the pelvic area constituted a pelvic examination; and (iv) written consent for an initial pelvic examination is sufficient for any additional pelvic examinations needed during treatment. As an initial matter, the Board noted that it lacked the statutory authority to change the language of Senate Bill 698; however, the Board still issued several position statements that provide guidance and clarify the breadth of the Bill.

First, the Board voted unanimously that Senate Bill 698 is not gender neutral and therefore does *not* apply to males. The Board reviewed the legislative history of Senate Bill 698, which refers exclusively to female patients and concluded that male patients were not intended to be covered under the legislation. Second, the Board found that written consent is *not* needed when a pelvic examination is performed for non-diagnostic purposes. Third, the Board determined written consent is *not* needed when there is a visual inspection without physical contact of the pelvic area by a practitioner. Finally, the Board did not issue a position on whether written consent, when required, could be for one or more pelvic examinations as may be necessary during a course of treatment.

Please be aware that the above-described position statements were provided orally by the Board at their August 7, 2020 meeting. Counsel for the Board is drafting a final order memorializing the orally issued position statements. The final order is tentatively scheduled to be presented and finalized at the next Board meeting on October 2, 2020.

Submitted by: **Jeff Mustari, Esq., *Southern Health Lawyers, LLC***

REGULATORY UPDATES

HHS Announcement on Regulation of Laboratory Developed Tests

Earlier this year, the HLS Updates [9] provided an overview of the introduction of bipartisan legislation in the U.S. House and Senate: the Verifying Accurate Leading-edge IVCT Development Act of 2020 (the "VALID Act"), a comprehensive bill that would provide regulation of in vitro clinical tests ("IVCTs") and, more specifically, Laboratory Developed Tests ("LDTs") – two areas of regulatory oversight that have remained muddled for decades.[2]

Adding further complexity to the unresolved paradigm for regulating IVCTs and LDTs, on August 19, 2020, as the FDA and other federal agencies continue to adapt to the burdens and complications of COVID-19, the Department of Health and Human Services ("HHS") for the United States issued an unanticipated announcement regarding the regulation of LDTs. In a post titled "Rescission of Guidances and Other Informal Issuances Concerning Premarket Review of Laboratory Developed Tests" (the "Announcement"), HHS proclaimed:

> The Trump Administration is committed to combating COVID-19, to ensuring that the American people are protected against future pandemics, and to keeping duplicative regulations and unnecessary policies from interfering with those efforts. Consistent with the President's [prior Executive Orders], and as part of HHS's ongoing department wide review of regulatory flexibilities enacted since the start of COVID-19, the department has determined that the Food and Drug Administration ('FDA') will not require premarket review of laboratory developed tests ('LDT') absent notice-and-comment rulemaking, as opposed to through guidance documents, compliance manuals, website statements, or other informal issuances. Those seeking approval or clearance of, or an emergency use authorization ('EUA') for an LDT may nonetheless voluntarily submit a premarket approval application, premarket notification or an EUA request, respectively, but are not required to do so, and FDA will adjudicate those submissions. Those opting to use LDTs in their laboratories without FDA premarket review or authorization may do so with the understanding that they would not be eligible for PREP Act coverage absent approval, clearance, or authorization and would remain subject to regulation by the Centers for Medicare and Medicaid Services under the Clinical Laboratory Improvement Amendments and its implementing regulations. Those with active EUA to use an LDT to detect the virus causing COVID-19 or its antibodies are unaffected by this announcement.[10]

By its text, the Announcement does not remove the FDA's jurisdiction over LDTs, but instead requires "notice and comment rulemaking" – a considerably more arduous process – in lieu of the FDA's historically favored means of attempting to regulate LDTs via guidance documents and formal statements. In the days following the Announcement, the FDA did not formally respond to

any questions during town hall meetings, but instead directed all questions regarding the Announcement to HHS.[11]

A multitude of industry experts, trade associations, and other stakeholders from the healthcare industry immediately dissected the Announcement. Opinions are divided. Some subject matter experts have criticized the Announcement for being "terse and ambiguous," arguing that it will lead to more questions than answers and ensuing "scrambling" for a variety of industry stakeholders—particularly clinical laboratories.[12] Other industry groups, such as the American Clinical Laboratory Association and the Association for Molecular Pathology, released statements praising HHS's actions taken in the Announcement.[13] As a presidential election looms on the horizon, it is increasingly unlikely that Congress will convene on the VALID Act in the near future. It is also unclear how a potential change in the White House in November could impact or nullify the recent Announcement.

With historically rapid advancements in new health technology platforms and diagnostic testing methodologies – advancements that are increasingly characterized by the integration of highly advanced computer algorithms, leading-edge scientific instruments, and sophisticated software – a the ultimate resolutions to these areas of regulatory uncertainty hold significant implications for state and federal officials tasked with overseeing the delivery of healthcare, commercial and non-profit health care providers, patients, and the public health at large.

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

PRIVACY UPDATES

OCR Issues Updated Guidance on HIPAA and Contacting Former COVID-19 Patients about Plasma Donation

In August 2020, the Department of Health and Human Services' Office for Civil Rights ("OCR") updated its Guidance on HIPAA and Contacting COVID-19 Patients About Plasma Donation.[14] In this regard, OCR noted that covered entities (including health plans)[15] may use protected health information ("PHI") to identify individuals who have recovered from COVID-19 and provide them with information about how they can donate their plasma for use in the treatment of other patients with COVID-19. OCR's reasoning is that such use of PHI is permitted under HIPAA as it could amount to "health care operations activities"[16] to the extent that facilitating the supply of donated plasma would be expected to improve the covered entity's ability to conduct case management for its own patients or beneficiaries that have or may become infected with COVID-19.[17] The updated guidance also includes a warning on the use of this type of calls as marketing opportunities. In this regard, OCR warned that recommending patients to use a specific center or site for plasma donation could be viewed as a marketing activity if the covered entity making the recommendation receives a direct or indirect payment or benefit from, or on behalf of, the plasma donation center.

The full text of the updated guidance can be found in the following link: https://www.hhs.gov/sites/default/files/guidance-on-hipaa-and-contacting-former-covid-19-patients-about-plasma-donation.pdf

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

[1] Note that the OIG's Advisory Opinion process, which does bind HHS and other agencies, remains available during this time.
[2] *Available at* https://oig.hhs.gov/coronavirus/authorities-faq.asp.
[3] *Id.*
[4] Many of the non-profit lodging facilities closed due to COVID-19 and some practices had to be consolidated.
[5] *See* HB 59.
[6] *See* FLA. STAT. § 465.003(11)(a) ("Community pharmacy" includes every location where medicinal drugs are compounded, dispensed, stored, or sold or where prescriptions are filled or dispensed on an outpatient basis).
[7] *See id.* § 893.03; 21 U.S.C. § 812.
[8] *See* HB 59.
[9] Rifkin, Gray W. (2020), Legislative Updates: Regulation of In Vitro Clinical Diagnostic Tests, https://www.flabarhls.org/resources-menu/document-library/health-law-updates/349-hls-monthly-updates-2020-june/file
[10] HHS.gov. Rescission of Guidances and Other Informal Issuances Concerning Premarket Review of Laboratory Developed Tests. August 19, 2020. September 17, 2020, https://www.hhs.gov/coronavirus/testing/recission-guidances-informal-issuances-premarket-review-lab-tests/index.html (emphasis added).
[11] Ray, Turna (2020), Stakeholder Scramble to Predict Impact of HHS Move Limiting FDA Ability to Regulate LDTs. September 19, 2020, https://www.genomeweb.com/molecular-diagnostics/stakeholders-scramble-predict-impact-hhs-move-limiting-fda-ability-regulate#.X2Nm3mhKiUk
[12] *Id*.
[13] *Id.*; *see also* ACLA (2020). ACLA Statement on Recent HHS Announcement Regarding Regulation of Laboratory Developed Tests. September 17, 2020, https://www.acla.com/acla-statement-on-recent-hhs-announcement-regarding-regulation-of-laboratory-developed-tests/; AMP (2020). Association for Molecular Pathology Commends Department of Health and Human Services on Decision to Lessen Regulatory Burden on Laboratory Professionals. September 17, 2020, https://www.amp.org/AMP/assets/File/pressreleases/2020/HHS_Press_Release_082120.pdf?pass=75
[14] *See* U.S Department of Health and Human Services Office for Civil Rights' Updated Guidance on HIPAA and Contacting Former COVID-19 Patients about Plasma Donation < https://www.hhs.gov/sites/default/files/guidance-on-hipaa-and-contacting-former-covid-19-patients-about-plasma-donation.pdf>
[15] Note that the original guidance issued in June 2020, only referred to health care providers but the updated one has been expanded to also include health plans.
[16] *See* definition of "healthcare operations" at 45 C.F.R. § 164.501(i).
[17] The updated guidance reiterates specifically that while the HIPAA Privacy Rule permits covered entities to use PHI to identify and contact its own patients or beneficiaries who have recovered from COVID-19, they generally cannot disclose PHI to third parties, including other covered entities, without the individuals' authorization. *See* U.S. Department of Health and Human Services Office for Civil Rights, *supra* note 14.