Dear Health Law Section Members:

The Health Law Section ("HLS") website has been updated with April - July 2023 articles on significant developments in health law 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 its Health Law Section. HLS thanks these volunteers who have generously donated their time to prepare these summaries for our members.

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COVID-19 PUBLIC HEALTH EMERGENCY

All Good Things Must Come to an End: The Expiration of OCR's Enforcement Discretion

On April 11, 2023, the Department of Health and Human Services' Office for Civil Rights (OCR) confirmed that four notifications of enforcement discretion regarding enforcement of the HIPAA Privacy, Security, and Breach Notification Rules (the HIPAA rules) during the COVID-19 public health emergency (PHE) will expire at the end of the PHE.[1] The notifications, which address (i) telehealth services, (ii) COVID-19 community-based testing sites, (iii) business associate disclosures of COVID-19 data to public health and health oversight agencies, and (iv) web-based scheduling applications for vaccinations, will expire at 11:59 pm on May 11, 2023.[2] After that date, OCR will no longer rely on the notifications to exercise enforcement discretion with respect to the HIPAA violations addressed in each notification.

To soften the transition, OCR is providing a 90-calendar-day period (ending on August 9, 2023, at 11:59 pm) to give covered entities and business associates relying on the telehealth services notification additional time to come into full compliance with the HIPAA rules. There is not a similar transition period for the other notifications. OCR will continue to exercise enforcement discretion for violations of the HIPAA rules which occurred during the PHE and are covered by the notifications.

Background

OCR issued the notifications during the PHE to assist covered entities and their business associates (collectively, regulated entities) in addressing the nation's healthcare needs during the COVID-19 pandemic. Because of the speed and scale with which regulated entities had to provide healthcare services, particularly in the early days of the PHE, such entities sometimes used technology or otherwise delivered healthcare services in a manner that did not fully comply with the HIPAA rules. Pursuant to the notifications, OCR exercised enforcement discretion and refrained from penalizing certain violations of the HIPAA Rules during the PHE. However, OCR also encouraged regulated entities to implement safeguards to minimize the risk to the privacy and security of protected health information (PHI).
The four notifications set to expire at the end of the PHE are described below, though given developments over the past three years, the telehealth services notification is likely to be most relevant to regulated entities.

Enforcement Discretion for Telehealth Remote Communications During the COVID–19 Nationwide Public Health Emergency:

This notification provides that OCR will not impose penalties for noncompliance with the HIPAA rules in connection with the good faith provision of telehealth during the PHE.[3] OCR's exercise of enforcement discretion with respect to telehealth services was crucial during the COVID-19 pandemic, allowing providers to treat patients virtually, thereby limiting the risk of exposure for providers, their staffs, and other patients. Under this notification, a covered healthcare provider could use any non-public facing remote communication product for audio or video communication (e.g., Apple FaceTime, Zoom, and Skype) with a patient for the good-faith

provision of telehealth services. For example, OCR stated that it would not impose penalties against covered entity healthcare providers for lack of a HIPAA business associate agreement (BAA) with a video communications vendor. OCR also issued FAQs explaining what it may consider to be the bad faith provision of telehealth services that could trigger enforcement action by the agency.

In the April 2023 notice, OCR encourages regulated entities to use the 90-day transition period to modify their telehealth practices to come into compliance with the HIPAA rules by, among other things, selecting a telehealth vendor that will sign a BAA and comply with the applicable HIPAA rules. The transition period will give regulated entities until 11:59 pm on August 9, 2023, to bring their telehealth services into compliance with the HIPAA rules.

Enforcement Discretion Regarding COVID-19 Community-Based Testing Sites During the COVID-19 Nationwide Public Health Emergency:

This notification provides that OCR will exercise enforcement discretion with respect to noncompliance by regulated entities with the HIPAA rules related to good faith participation in the operation of COVID-19 community-based testing sites (CBTS).[4] OCR recognized that during the COVID-19 pandemic, covered healthcare providers, including large pharmacy chains, and business associates may participate in CBTS, including mobile, drive-through, or walk-up sites providing COVID–19 specimen collection or testing services to the public. OCR issued this notification to prevent the fear of technical HIPAA violations from impeding the rapid rollout of CBTS during the pandemic. Those covered healthcare providers and business associates still operating CBTS must comply with the HIPAA rules after 11:59 pm on May 11, 2023.

Enforcement Discretion under HIPAA to Allow Uses and Disclosures of Protected Health Information by Business Associates for Public Health and Health Oversight Activities in Response to COVID-19:

This notification provides that OCR will exercise enforcement discretion with respect to business associates providing PHI, such as COVID-19 data, to federal, state, and local public health and health oversight agencies to assist with ensuring the public health and safety during the PHE.[5] During the pandemic, federal public health authorities and health oversight agencies like the Centers for Disease Control and Prevention and Centers for Medicare & Medicaid Services, state and local health departments, and state emergency operations centers requested COVID-19 data, including PHI, from business associates. However, under the HIPAA Rules, business associates could not disclose such PHI unless expressly permitted by a BAA. This notification permitted business associates to make good faith disclosures of the needed COVID-19 data to federal, state, and local public health and health oversight agencies. To the extent that business associates are providing PHI under this notification, that provision of data must end or otherwise come into compliance with the HIPAA rules on May 12, 2023.

Enforcement Discretion Regarding Online or Web-Based Scheduling Applications for the Scheduling of Individual Appointments for COVID-19 Vaccination During the COVID-19 Nationwide Public Health Emergency:

This notification provides that OCR will not impose penalties for noncompliance in connection with the good faith use of online or web-based scheduling applications (WBSAs) for scheduling individual appointments for COVID–19 vaccinations during the PHE.[6] OCR recognized that covered healthcare providers may use WBSAs to quickly schedule large numbers of people for COVID-19 vaccinations. However, some WBSAs, and the ways in which they are used, may not fully comply with the HIPAA rules. To the extent regulated entities are using or providing WBSAs, they must fully comply with the HIPAA rules beginning May 12, 2023.

Coming into Compliance

Regulated entities should prepare for the expiration of the notifications by assessing whether they are still relying on any of the notifications in providing services. If so, they should consider how to provide the services in a way that fully complies with the HIPAA rules. For example, while there were relatively few telehealth applications that complied with the HIPAA Security Rule at the beginning of the COVID-19 pandemic, there are now many more telehealth vendors offering products that comply with the HIPAA Rules. Regulated entities should also update their HIPAA policies and procedures once they identify how they will provide services after May 11, 2023, and train their workforce members accordingly.

End Of Continuous Medicaid Coverage Requirement In Florida May Have Substantial Impact On Patients, Advocates, Legal Aid, And The Healthcare System.

Background and Recent Data

In 2020, in response to the COVID-19 pandemic, federal legislation provided states with significant federal funding to provide continuous Medicaid coverage for individuals enrolled in the program, even those who were no longer technically eligible. In late December 2022, federal legislation was passed requiring the continuous Medicaid coverage requirement to end on March 31, 2023. In this regard, each state was required to develop a plan to review the eligibility of all of its Medicaid enrollees, which would renew those who remain eligible or terminate Medicaid coverage for those who no longer meet eligibility requirements. Florida's plan called for reviewing eligibility for its approximately 4.9 million Medicaid enrollees over 12 months, beginning in March 2023. The first terminations for those no longer eligible or who did not renew timely began April 30, 2023.

Data Reported

According to recent data available from the Florida Department of Children and Families (DCF) regarding Medicaid redeterminations 461,322 redeterminations have been completed as of June 13, 2023. Of these, 211,895 or 46% were found to be still eligible and their Medicaid was renewed; 44,305 or 10% were terminated due to being found ineligible, and 205,122 or 44% were terminated for procedural reasons, i.e., failing to provide the information necessary to complete the redetermination. Additional data is in the full "unwinding" data report from DCF for April (filed with the federal government) which is linked here, and prior DCF reports, beginning with the baseline data report submitted in March, 2023. All the Florida Unwinding Monthly Reports can be found here.

The Consolidated Appropriations Act of 2023 now requires states to report their data to CMS and to provide it for public view.[i] Already, states have experienced difficulties conforming with these requirements and CMS has yet to post the unwinding data. Although states, under this same legislation, must submit their data to CMS, there will likely be a delay between when states submit and CMS posts their data. Professionals and advocates wishing to obtain data in states that had not published their data may need to file a public record request for this data for the report.

Effect on the Legal Sector

Health law lawyers and pro bono health rights organizations will likely see an increase in the number of clients seeking assistance with their Medicaid termination or re-application. A significant number of applicants are not computer literate, do not have access to technology, or do not understand the intricacies of the Medicaid application. Additionally, the state's notices are often confusing and difficult to understand. These clients will require additional assistance. Lawyers, advocates, and patients can make use of existing resources created by health rights organizations, such as videos, guides, fact sheets, Q&As, and flyers. Find examples of Florida Health Justice Project's resources here.

Legal professionals and advocates should also be aware of other avenues in which patients may access care.[ii] According to Fla. Stat. 154.011, all 67 Florida counties must provide free primary care and prenatal services to Medicaid and other qualified low-income persons. Eligibility for free primary care and prenatal services is 100% below the poverty level. Counties have the discretion to decide which entity will provide care.

Conclusion:

The end of the continuous Medicaid coverage requirement is having substantial impacts on patients, advocates, legal aid, and the healthcare system. As such, it is important for practitioners to monitor the status of Medicaid redeterminations and make use of factual resources in order to navigate the legal and public health ramifications of loss of coverage.

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REGULATORY AND COMPLIANCE

Chief Compliance Officer of Pharmacy Holding Company Convicted in $50MM Medicare Fraud Scheme

A federal jury has convicted a Florida man, who acted as the Chief Compliance Officer for a pharmacy holding company, for conspiracy to commit healthcare and wire fraud to the tune of over $50MM. According to court documents, the pharmacy fraudulently billed Medicare for unnecessary and unwanted lidocaine and diabetic testing supplies. In addition to improper billing, the company took additional steps to avoid scrutiny including mischaracterizing mail order pharmacies as brick-and-mortar locations, concealing the ultimate ownership of the company and transferring patients between different pharmacies within their group without obtaining appropriate patient consent. These violations were particularly egregious considering that the person in charge of preventing and reporting the fraudulent scheme was a participant in the scheme. Sentencing, which may include up to 20 years in prison, is scheduled for September 14, 2023.

You can find more information about this case in the Department of Justice's press release which is available at https://www.justice.gov/opa/pr/chief-compliance-officer-convicted-50m-medicare-fraud-scheme

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

DOJ's Lisa Miller's Remarks Reinforce that Florida Will continue to be a focus of Healthcare Fraud and Abuse Investigations in the Future.

On May 4, 2023, Deputy Assistant Attorney General Lisa Miller, delivered some remarks at the American Bar Association's 33rd Annual national Institute on Healthcare Fraud held in Chicago IL. During these remarks Ms. Miller indicated that *the Health Care Fraud Unit and its partners will be prioritizing the investigation and prosecution of schemes that involve sober homes fraud, illegal prescribing of controlled substances, and hospice fraud*. These remarks reflect a growing concern in the government for the protection of particularly vulnerable populations and in segments where medical expenses have increased dramatically over the last couple of years.

For instance, according to data from the National Hospice and Palliative Care Organization (NHPCO) Medicare spending in hospice care increased from $15.1 billion in 2014 to $19.2 Billion in 2018. [iiiiv]Considering that Florida's proportion of Medicare decedents enrolled in hospice at the time of death usually ranks in the nation's top 5,[v] it is easy to understand why the government would be particularly interested in scrutinizing hospice and home care providers in our state. Sober home and controlled substance fraud is also on the rise nationally and Florida has also recently seen a number of important prosecutions, including the January 2023 sentencing of a Florida doctor who made $127 million by billing insurance companies for fraudulent tests and treatment for addiction patients.[vi]

In sum, even though Florida has in the past been at the forefront of the DOJ's healthcare fraud and abuse enforcement efforts in general, the statement should provide some guidance to practitioners on where specifically these efforts will focus in the near future.

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

Reforms to the Florida Patient Self-Referral Act: A Closer Look at the Impact of SB 768

Florida Senate Bill 768 ("SB 768"), which became effective July 1, 2023, amends the Florida Patient Self-Referral Act of 1992 (the "PSRA"),[vii] which regulates financial arrangements between referring health care providers and providers of health care services. This amendment to the PSRA has important implications for the state's health care providers subject to it by making the physician supervision requirements less onerous.

The PSRA was established to minimize potential conflicts of interest in patient referrals. The PSRA primarily restricts health care providers[viii] from referring patients to an entity in which they hold a financial interest for the provision of certain designated health services ("DHS")[ix] or any other health care item or service unless an exception applies.

Specifically, the PSRA sets forth a number of scenarios that are excluded from the definition of a "referral" and thus are not implicated by the PSRA. In relevant part, the PSRA excludes from the definition of a "referral" an order, recommendation, or plan of care by a member of a group practice[x] for DHS or other health care items or services that are prescribed or provided solely for such group practice's own patients, and, prior to the passage of SB 768, are provided or performed "by or under the direct supervision" of the referring heath care provider or a member of the referring health care provider's group practice (the "Florida In-Office Ancillary Services Exception" or the "FL IOASE").[xi] The PSRA defined "direct supervision" in this context as "supervision by a physician who is present in the office suite and immediately available to provide assistance and direction throughout the time services are being performed."[xii]

Physicians with ownership in or compensation arrangements with their group practices that refer patients within the group for the furnishing of DHS[xiii] billable to Medicare are also required to comply with the federal counterpart to the PSRA, the Ethics in Patient Referrals Act, or the "Stark Law"[xiv]. Similar to the PSRA, the Stark Law contains an exception for DHS referred within the group,[xv] which requires, among other elements, that the DHS be furnished by the referring physician or a member[xvi] of the referring physician's group practice or under the supervision of the referring physician or another physician in the group practice,[xvii] provided that the supervision complies with "all other applicable Medicare payment and coverage rules" for the services (the "Stark IOASE").

The varying supervision standards between the FL IOASE and Stark IOASE has created difficulties for Florida physicians who are required to comply with both in order to enable them to refer DHS within their group practices with which they have ownership interests. As a result, because the FL IOASE is stricter than the FL IOASE, there has always been a theoretical possibility that a DHS that may not require direct supervision under applicable Medicare payment and coverage rules (such as certain diagnostic tests) are still required to be performed under direct supervision in order to comply with the FL IOASE.

In an effort to align the FL IOASE more closely with the Stark IOASE, SB 768 modifies the FL IOASE' s supervision requirements, eliminating the requirement for direct supervision and the need for a physician to be in the same office suite, allowing for remote supervision of such services

under certain circumstances. Under this new supervision requirement, Florida health care providers will have greater flexibility with the supervision they provide so long as they comply with applicable Medicare payment and coverage rules for the service being provided, in accordance with the Stark IOASE.

SB 768 provides potentially significant benefits for Florida health care providers. For example, easing supervision requirements may result in cost savings because the need for a physician's constant presence during the provision of services is reduced. Eliminating the direct supervision requirement will also afford referring physicians in solo practices and group practices enhanced flexibility in their scheduling.

Additionally, prior to the amendment, there was a risk of inadvertent non-compliance by physicians who billed for services rendered under supervision they believed was appropriate from a Medicare perspective, without being aware that the PSRA contained stricter standards. To the extent this occurred, any such claims for payment would have been prohibited under the PSRA, a strict liability statute, even if otherwise permissible under the Stark Law. By aligning the supervision requirements with the Stark IOASE, this mitigates the risk of physicians violating the PSRA so long as all applicable Medicare supervision requirements are adhered to.

Although this change offers potential benefits, it also requires careful oversight to ensure that the correct level of supervision is provided for each service requiring it. Failure to provide the correct level of supervision can result in the submission of a prohibited claim, creating overpayment liability at a minimum, and potentially False Claims Act liability, if the patient is a federal health care program participant. Additionally, submitting a prohibited claim or making a prohibited referral could result in disciplinary action against the practitioner's license. Florida group practices and health care providers should carefully review and understand the Medicare coverage and payment rules (which incorporate and require adherence to applicable state licensure supervision requirements, which also have the potential to be stricter than Medicare requirements) applicable to the services they provide in order to ensure compliance with the new supervision requirement.

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PRIVACY

New Florida Law Will Ban Offshoring of Certain Patient Data

Effective July 1, 2023, a new Florida law will limit certain health care providers from storing patient information offshore. CS/CS/SB 264 (Chapter 2023-33, *Laws of Florida*), amends the Florida Electronic Health Records Exchange Act to require health care providers who use certified electronic health record technology to ensure that patient information is physically maintained in the continental United States or its territories or Canada.

The law broadly applies to "all patient information stored in an offsite physical or virtual environment," including patient information stored through third-party or subcontracted computing facilities or cloud computing service providers. Further, it applies to all qualified electronic health records that are stored using any technology that can allow information to be electronically retrieved, accessed, or transmitted.

- The new law is limited to health care providers listed below who use "certified electronic health record technology" or CEHRT – a term of art applicable to technology certified to the certification criteria adopted by the U.S. Department of Health and Human Services (HHS): Certain entities licensed by the Florida Agency for Health Care Administration (AHCA), including hospitals, healthcare clinics, ambulatory surgical centers, home health agencies, hospices, home medical equipment providers, nursing homes, assisted living facilities, intermediate care facilities for persons with developmental disabilities, laboratories authorized to perform testing under the Drug-Free Workplace Act, birth centers, abortion clinics, crisis stabilization units, short-term residential treatment facilities, residential treatment facilities, residential treatment centers for children and adolescents, nurse registries, companion services or homemaker services providers, adult day care centers, adult family-care homes, homes for special services, transitional living facilities, prescribed pediatric extended care centers, healthcare services pools, and organ, tissue, and eye procurement organizations;
- Certain licensed health care practitioners, including physicians, physician assistants, anesthesiologist assistants, pharmacists, dentists, chiropractors, podiatrists, naturopathic physicians, nursing home administrators, optometrists, registered nurses, advanced practice registered nurses, psychologists, clinical social workers, marriage and family therapists, mental health counselors, physical therapists, speech language pathologists, audiologists, occupational therapists, respiratory therapists, dieticians, orthotists, prosthetists, electrologists, massage therapists, licensed clinical laboratory personnel, medical physicists, genetic counselors, opticians, certified radiologic personnel, and acupuncturists;
- Licensed pharmacies;
- Certain mental health and substance abuse service providers and their clinical and nonclinical staff who provide inpatient or outpatient services;
- Licensed continuing care facilities; and
- Home health aides.

At this time, the HHS certification program includes inpatient EHRs for hospitals and ambulatory EHRs for eligible health care providers, the only provider types eligible to participate in the Centers for Medicare and Medicaid Services (CMS) payment programs requiring CEHRT. While other health care providers such as ambulatory surgery centers, pharmacies, long-term post-acute care providers, home health and hospice are not eligible to participate in those CMS payment programs, they arguably fall within the scope of the Florida offshoring prohibition if they "utilize" CEHRT. Further, given its broad language, the statute could technically be read as covering all patient information stored by a health care provider utilizing CEHRT, even if that patient information is stored in an application that is not so certified.

The new law also amends Florida's Health Care License Procedures Act to require entities submitting an initial or renewal licensure application to AHCA to sign an affidavit attesting under the penalty of perjury that the entity is in compliance with the new requirement that patient information be stored in the continental United States or its territories or Canada. Entities licensed by AHCA must remain in compliance with the data storage requirement or face possible disciplinary action by AHCA.

Furthermore, the new law requires an entity licensed by AHCA to ensure that a person or entity who possesses a controlling interest in the licensed entity does not hold, either directly or indirectly, an interest in an entity that has a business relationship with a "foreign country of concern" or that is subject to section 287.135, Florida Statutes, which prohibits local governments from contracting with certain scrutinized companies. "Foreign country of concern" is defined by the new law as "the People's Republic of China, the Russian Federation, the Islamic Republic of Iran, the Democratic People's Republic of Korea, the Republic of Cuba, the Venezuelan regime of Nicolás Maduro, or the Syrian Arab Republic, including any agency of or any other entity of significant control of such foreign country of concern."

Written by Amy Leopard and John Hood. This article was originally published blog post, "New Florida Law Will Ban Offshoring of Certain Patient Data," was originally published on *Online and On Point* by Bradley Arant Boult Cummings LLP. Copyright 2023.

The FTC Sends Another Warning to Digital Healthcare Platforms About Use of Tracking Pixels

The Federal Trade Commission (FTC) continues to prioritize the protection of consumers' digital health information. The agency has demonstrated this commitment through enforcement actions against GoodRx and BetterHelp for sharing consumer health information for advertising purposes (see our blog posts on each respective action here and here), and in a post published by the FTC Office of Technology on March 16, 2023, titled "*Lurking Beneath the Surface: Hidden Impacts of Pixel Tracking*." The FTC post provides a deep dive on the technical aspects of the GoodRx and BetterHelp enforcement actions, including a primer on pixel tracking technology and how it works to collect data and personal information of website visitors and users of mobile apps. The post also confirms that the GoodRx and BetterHelp enforcement actions arose from the companies' sharing of consumers' health information with tracking technology vendors. In light of these recent developments, digital healthcare platforms must understand how they collect, use, and share consumer health information.

FTC's Pixel Primer

Consumers use the internet every day but may be completely unaware that tracking pixels exist and are collecting detailed information on how the consumer utilizes a web page. Tracking pixels are pieces of code invisibly embedded into websites to track personal data on how a consumer interacts with a web page, including viewing the page, clicking on items on the page (including advertisements), purchasing products, or even typing within a form on the page. Companies often use third-party pixel tracking vendors to assist with collecting, tracking, and refining information on consumer interactions with a web page. The FTC post explains how digital health platforms and their third-party tracking technology vendors may try to monetize the information collected by tracking pixels.

FTC's Concerns with Pixel Technology

In the recent post, the FTC outlines three concerns with the use of pixel tracking:

1. Consumers cannot easily avoid their interaction with widespread, invisible pixels, as current control technology does not always prevent pixels from collecting and sharing information, and consumers often do not know tracking pixels exist.
2. Companies that use tracking technology often do not fully understand how the data is collected, stored, and used (and that it may include health information), potentially resulting in the improper exposure of personal information. Further, digital health platforms may not have visibility into how the technology tracking companies use the data they collect.
3. Pixel tracking may attempt to remove personally identifiable information, such as names or email addresses, but removal is often not guaranteed.

The FTC warns that the use of pixel tracking to disclose consumers' personal information to third parties may violate federal and state privacy laws and regulations, including for example, the FTC Act, the FTC's Health Breach Notification Rule, the HIPAA Privacy, Security, and Breach Notification Rules, and state or other federal privacy rules. The GoodRx and BetterHelp

enforcement actions show that the FTC is willing to back up its warning by pursuing those companies offering digital health platforms that inappropriately collect, use, and share consumers' personal health information.

FTC's Research Questions

In the post, the FTC also identifies topics regarding online tracking for which continued research could be useful. These subjects include:

- industry conditions and competitive dynamics;
- consumer harms;
- business rationales;
- data processing, use, and monetization; and
- data retention and management.

Next Steps

The GoodRx and BetterHelp enforcement actions demonstrate that digital healthcare platforms must be careful when using pixel tracking technologies because of the risk of collecting and sharing consumers' personal information without appropriate notice and consent. Digital healthcare platforms should:

- ensure they understand what data is collected by the tracking technologies they use and how that data is shared with third-parties, including tracking technology vendors;
- review their existing agreements with tracking technology vendors to understand how those vendors may use data provided by the platform and to confirm that use comports with applicable federal and state privacy laws;
- ensure their actual business practices regarding collecting, sharing, and using personal information align with their privacy notices;
- monitor future FTC guidance and enforcement actions related to use of online tracking; and
- work closely with counsel to implement proper privacy practices to ensure collected health information is not improperly exposed or shared through the use of tracking pixel technology.

Those wishing to follow these developments should visit Tech@FTC, where the agency's technologists released their analysis.

Written by: Jordan Cohen, Elizabeth F. Hodge and Lauren Gandle

[i] SHO 23-002 (denoting that Section 5131 of subtitle D of title V of division FF of the CAA added new reporting requirements for all states under Section 1902(tt) of the Social Security Act).
[ii] Florida Healthy Kids is currently available with low premiums to children through age 18 whose family's income is less than 215% of the Federal Poverty Level. During the 2023 session of the Florida Legislature, House Bill 121 was passed which would expand the program's eligibility to children with family income up to 300% of the Federal Poverty Level. *See* Fla. HB 121 (2023) (presented to Governor DeSantis June 12, 2023).
[iii] See https://www.nhpco.org/wp-content/uploads/NHPCO-Facts-Figures-2020-edition.pdf
[iv] At present there are an estimated 8,262 hospice providers in the US, which represents a 22.4 % increase from the number of hospice providers in 2014.(6,749) See https://www.ibisworld.com/industry-statistics/number-of-businesses/hospices-palliative-care-centers-united-states/
[v] See https://www.nhpco.org/wp-content/uploads/NHPCO-Facts-Figures-2020-edition.pdf
[vi] See https://www.justice.gov/criminal-vns/united-states-v-michael-j-ligotti
[vii] *See* Fla. Stat. § 456.053(1).
[viii] "Health care provider" means a physician licensed under Chapter 458 (medicine), Chapter 459 (osteopathic medicine), Chapter 460 (chiropractic medicine), or Chapter 461 (podiatric medicine); an advanced practice registered nurse ("APRN") registered for autonomous practice under Section 464.0123, Florida Statutes; or any health care provider licensed under Chapter 463 (optometry) or Chapter 466 (dentistry). *See* Fla. Stat. § 456.053(3)(i).
[ix] "Designated health services" includes "clinical laboratory services, physical therapy services, comprehensive rehabilitative services, diagnostic-imaging services, and radiation therapy services." Fla. Stat. § 456.053(3)(c).
[x] "Group practice" means "a group of two or more health care providers legally organized as a partnership, professional corporation, or similar association: (1) [i]n which each health care provider who is a member of the group provides substantially the full range of services which the health care provider routinely provides, including medical care, consultation, diagnosis, or treatment, through the joint use of shared office space, facilities, equipment, and personnel; (2) [f]or which substantially all of the services of the health care providers who are members of the group are provided through the group and are billed in the name of the group and amounts so received are treated as receipts of the group; and (3) [i]n which the overhead expenses of and the income from the practice are distributed in accordance with methods previously determined by members of the group." Fla. Stat. § 456.053(h).
[xi] Fla. Stat. § 456.053(3)(p)3.f (2022).
[xii] Fla. Stat. § 456.053(3)(e) (2022).
[xiii] Note that the Stark Law's definition of "DHS" varies from the PSRA's definition of DHS, as it encompasses additional categories of services. 42 C.F.R. § 411.351; Fla. Stat. § 456.053(3)(c). However, in addition to "DHS", the PSRA also applies broadly to "any other health care item or service", thus essentially encompassing all other categories of services considered to be "DHS" under the Stark Law (in addition to any other health care item or service). *See* Fla. Stat. § 456.053(5)(a)-(b).
[xiv] 42 U.S.C. § 1395nn.
[xv] 42 C.F.R. § 411.355(b). The definition of a "group practice" for purposes of the Stark Law is highly technical and can be found at 42 C.F.R. § 411.352.
[xvi] "Member of a group practice" means, generally, a physician owner or employee of the group practice, but not an independent contractor. 42 C.F.R. § 411.351.
[xvii] A "physician in the group practice" means a member of the group practice as well as an independent contractor physician during the time the independent contractor is furnishing patient care services for the group under a contractual arrangement. 42 C.F.R. § 411.351.