

June 2018

Dear Health Law Section Members:

The Health Law Section (“HLS”) website has been updated with May through June 2018 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 its Health Law Section. HLS thanks the following volunteers who have generously donated their time to prepare these summaries for our members:

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COMPLIANCE UPDATES

DOJ Announces Policy Against “piling-on” in Government Enforcement Actions

On May 9, 2018, Deputy Attorney General Rod Rosenstein announced a new Department of Justice (“Department”) policy that encourages coordination among Department components and other enforcement agencies when imposing multiple penalties for the same conduct in order to avoid unfair duplicative penalties. In making the announcement, Deputy Attorney General Rosenstein stated that “piling on” can deprive a company of the benefits of certainty and finality ordinarily available through a full and final settlement. He also stated that: “We need to consider the impact on innocent employees, customers, and investors who seek to resolve problems and move on. We need to think about whether devoting resources to additional enforcement against an old scheme is more valuable than fighting a new one.” In determining whether the imposition of multiple penalties is warranted, the new policy instructs enforcers to consider the egregiousness of the wrongdoing; statutory mandates regarding penalties; the risk of delay in finalizing a resolution; and the adequacy and timeliness of a company’s disclosures and cooperation with the Department’s investigation.

A copy of the Department’s new policy has been incorporated into the U.S. Attorneys’ Manual and is available at: <https://www.justice.gov/opa/speech/file/1061186/download>

Submitted by: Christian Pérez Font, Esq., OPKO Health, Inc.

FDA Requires E-Cigarette Makers to Provide Information to Evaluate Youth Use of Their Products

During April and May 2018, the Food and Drug Administration (“FDA”) announced that it had sent several official requests for information on marketing practices, effects of product design, public health impact, adverse experiences and complaints to several electronic cigarette manufacturers. Through this initiative, the FDA aims to be able to better examine e-cigarette usage and trends in the midst of growing concerns around youth access to these products. The companies have until July 12, 2018, to respond to the agency. Concurrently, earlier in April, the FDA announced a new Youth Tobacco Prevention Plan, which kicked off with a nationwide blitz of brick-and-mortar and online retailers that resulted in the issuance of several warning letters to businesses that engaged in the sale of these products to minors. The agency also issued numerous warning letters to manufacturers, distributors and retailers of e-liquids used in e-cigarettes that had labeling and/or advertisements that resembled kid-friendly products.

A copy of the FDA release is available at:
<https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm607935.htm>

Submitted by: Christian Pérez Font, Esq., OPKO Health, Inc.

Update on Corporate Integrity Agreements in Florida

As Medicare, Medicaid, and commercial reimbursement rates decline, there is growing pressure on healthcare providers to find innovative ways to make up for lost revenue. However, providers should note that healthcare transactions and payment models are fraught with the potential for fraud and abuse.

OIG's Corporate Integrity Agreements

The United States' Office of Inspector General ("OIG") may impose penalties or exclude a provider from participating in Medicare and other federal healthcare programs if they run afoul of fraud and abuse laws. In certain cases, the OIG will allow healthcare providers to continue practicing and participating in federal payment programs provided they enter into a corporate integrity agreement ("CIA") with the OIG. CIAs typically address seven distinct categories to assess whether the entity's compliance program is effective:

- 1) Leadership and structure, including a demonstration by the entity that it has a compliance officer and compliance counsel
- 2) Written standards
- 3) Education and training
- 4) Internal lines of communication
- 5) Auditing and monitoring
- 6) Ability and method of response to potential violations
- 7) Corrective action procedures

CIAs are typically in effect for a period of five (5) years.¹ Providers under CIAs are required to submit periodic interim reports throughout the five years demonstrating compliance with the CIA.² Often, a third party Independent Review Organization is assigned to review the practices and procedures of the provider to ensure compliance throughout the duration of the CIA. In the event a provider sells any or all of its business, successors are then obligated to adhere to the CIA unless a specific permission is sought by the successor prior to the consummation of the transaction.³

Update on Florida CIAs

Currently, there are approximately 450 organizations/individuals nationwide that are bound by a CIA,⁴ about 50 (11%) of which are located in the State of Florida.⁵ According to the OIG, the following is a list of the organizations/individuals currently under a CIA in Florida along with the effective date of each CIA:⁶

Entity Name	Entity Location	Effective Date of CIA
21st Century Oncology, Inc.	Fort Myers	11/17/17
21st Century Oncology, LLC	Fort Myers	12/17/15
American Sleep Medicine, LLC	Jacksonville	12/17/12
AmeriCare ALS, Inc. (See AmeriCare Ambulance Service, Inc. and AmeriCare ALS, Inc.)	Seffner	01/25/18

Entity Name	Entity Location	Effective Date of CIA
Apple Medical and Cardiovascular Group see Portnow, M.D., P.A., Arthur S. D/B/A Apple Medical and Cardiovascular Group, D/B/A Apple Medical Group, and Arthur S. Portnow, M.D.	Sarasota	11/21/17
Associates in Dermatology, Inc.	Orlando	01/22/15
Century Ambulance Service, Inc.	Jacksonville	05/06/15
Daller, M.D., Meir and Gulfstream Urology, P.A.	Fort Myers	01/31/17
Florida Pain Medicine Associates, Inc.	Boynton Beach	04/12/16
Freedom Health Inc. and Optimum Healthcare, Inc.	Tampa	05/11/17
Gatz, M.D., Bart (See Florida Pain Medicine Associates, Inc.)	Boynton Beach	04/12/16
Gulf Region Radiation Oncology Centers, Inc.	Pensacola	09/12/13
Gulfstream Urology, P.A. (See Meir Daller, M.D.)	Fort Myers	01/31/17
Halifax Health (See Halifax Staffing, Halifax Hospital Medical Center)	Daytona Beach	03/10/14
Haven Hospice see North Central Florida Hospice, Inc.	Gainesville	12/20/17
Health and Palliative Services of the Treasure Coast, Inc., and The Hospice of Martin and St. Lucie, Inc., and Hospice of the Treasure Coast, Inc.	Stuart	11/21/17
Hebrew Homes Health Network, Inc.	North Miami Beach	06/16/15
Hernando-Pasco Hospice	Hudson	07/18/13
Hospice of Citrus and The Nature Coast, Inc.; The Nature Coast, Inc.	Lecanto	11/04/15
Hospice of the Comforter, Inc.	Altamonte Springs	10/24/13
Hospice of the Treasure Coast, Inc. (See Health and Palliative Services of the Treasure Coast, Inc., and The Hospice of Martin and St. Lucie, Inc., and Hospice of the Treasure Coast, Inc.)	Stuart	11/21/17
Ioannides, M.D., L.L.C., Tim (See Ioannides, M.D., Dr. Tim, and Tim Ioannides, M.D., L.L.C., d/b/a Treasure Coast Dermatology)	Port St. Lucie	12/20/17

Entity Name	Entity Location	Effective Date of CIA
Lowrey, Gerald, M.D. (See Gulf Region Radiation Oncology Centers, Inc.)	Pensacola	09/12/13
Norman Parathyroid Center, P.A. and Norman Parathyroid Center, P.A (See James Norman, M.D.)	Wesley Chapel	07/18/17
North Broward Hospital District	Fort Lauderdale	08/31/15
North Central Florida Hospice, Inc. d/b/a Haven Hospice	Gainesville	12/20/17
Optimum Healthcare, Inc. (See Freedom Health Inc.)	Tampa	05/11/17
Physician Group Services, P.A.	Jacksonville	08/29/16
Portnow, M.D. Arthur S. (See Portnow, M.D., P.A., Arthur S. d/b/a Apple Medical and Cardiovascular Group, d/b/a Apple Medical Group, and Arthur S. Portnow, M.D.)	Sarasota	11/21/17
Renta, M.D., Alexis (See Florida Pain Medicine Associates, Inc., and Albert Rodriguez, M.D.)	Boynton Beach	04/12/16
Rose Radiology Centers, Inc. and Manuel S. Rose, M.D.	Trinity	12/29/15
South Miami Hospital, Inc.	South Miami	12/05/16
Southeast Orthopedic Specialists	Jacksonville	12/08/16
Steppie, Michael, M.D. (See Associates in Dermatology, Inc.)	Orlando	01/22/15
The Hospice of Martin and St. Lucie, Inc. (See Health and Palliative Services of the Treasure Coast, Inc., and The Hospice of Martin and St. Lucie, Inc., and Hospice of the Treasure Coast, Inc.)	Stuart	11/21/17
The Nature Coast, Inc. (See Hospice of Citrus and The Nature Coast, Inc.)	Lecanto	11/04/15
Treasure Coast Dermatology (See Ioannides, M.D., Dr. Tim, and Tim Ioannides, M.D., L.L.C., d/b/a Treasure Coast Dermatology)	Port St. Lucie	12/20/17

Submitted by: Ben Assad Mirza, Esq., Master of Public Health and Administration Candidate, Yale University

FRAUD AND ABUSE UPDATES

Tampa Resident Sentenced to More Than 20 Years for TRICARE Fraud Scheme

On April 17, 2018, Monty Ray Grow, a collegiate and professional football player turned marketing professional and salesman, received a federal prison sentence after a Miami jury convicted him for his involvement in a health care fraud scheme, accepting kickbacks, and money laundering.

Between September 2014 and June 2015, Grow received kickbacks from a Broward County, Florida compounding pharmacy in exchange for TRICARE patient referrals through his independent marketing company, according to the initial indictment. The Government accused Grow and his co-conspirators of defrauding TRICARE by using telemedicine companies to provide unnecessary and expensive prescriptions without conducting the requisite patient examinations. The indictment further accused Grow of laundering the proceeds of the scheme through luxury purchases, including real estate, cars and securities.

At trial, prosecutors established that Grow targeted TRICARE beneficiaries, referred them to the pharmacy, and paid them either directly for personal prescriptions or indirectly for prescriptions for family and friends. TRICARE paid inflated prices for those prescriptions through manipulated drug formulations and artificially engineered ingredients. The pharmacy split the profits from those TRICARE payments with Grow, who received nearly \$20 million from the scheme.

The jury's task included deciding whether Grow intentionally defrauded TRICARE or merely received extravagant, but legitimate, sales commissions from the pharmacy.

On February 5, 2018, the jury convicted Grow of conspiracy to commit health care fraud, conspiracy to pay and receive health care kickbacks, unlawful receipt of health care kickbacks, and money laundering.

Grow received a 262-month prison sentence, and the court ordered him to pay more than \$18 million in restitution.

United States v. Grow, No. 1:16-cr-20893-FAM (S.D. Fla. Apr. 25, 2018).

Submitted by: Erin J. Hoyle, Esq., Carlton Fields

LICENSURE UPDATES

Health Care Clinic Certificate of Exemption Only Valid for Two Years

Effective July 1, 2018, Florida health care clinics holding a certificate of exemption from the Florida Agency for Health Care Administration ("AHCA") must renew their exemption certificate every two years. Health care clinic exemptions granted previously did not expire. Section 59 of Senate Bill 622, which passed on March 21, 2018, amends Section 400.9935, Florida Statutes,

changing the effectiveness of health care clinic certificates of exemption from an indefinite duration to a maximum of two years. Changing certificates of exemption from an indefinite duration to a two-year maximum was adopted to improve the integrity of the exemption process. Senate Bill 622 makes no changes to non-exempt health care clinic licensure, leaving health care clinic licenses valid for two years.

By way of background, the Florida Statutes define a “clinic” as an entity that provides health care services to individuals and “tenders charges for reimbursement” to third-party payers (e.g., Medicare or private insurance). *See* FLA. STAT. § 400.9905(4). The Florida Statutes require clinics to be licensed, unless an exemption applies. Health care clinic exemptions include ownership by a hospital, pharmacy, optometrist, or physician, among others. *See id.* § 400.9905(4)(a)-(n). Exempt health care clinics are not required to apply for a certificate of exemption, but may do so voluntarily. However, third-party payers often require health care clinics claiming an exemption to produce a copy of the clinic’s certificate of exemption during enrollment and renewal. Establishing, owning, operating, managing, maintaining a health care clinic, or offering or advertising services that require clinic licensure without a license when an exemption does not apply is a felony. *Id.* § 400.9935(4).

Submitted by: Timothy S. Wombles, Esq., Broad and Cassel, LLP

Expansion of Age Limit in Pediatric Organ Transplant Programs in Florida

Pediatric organ transplant programs are regulated, in part, by the Certificate of Need (“CON”) program in the State of Florida, which is housed in the Agency for Health Care Administration (“AHCA”). *See* FLA. STAT. § 408.036(1)(f); FLA. ADMIN. CODE r. 59C-1.044. The CON process is used by AHCA to analyze whether there is additional need for certain types of healthcare services, including pediatric organ transplantation, within predetermined service areas throughout the state. FLA. STAT. § 408.032(3).

In order to assess need, AHCA looks at various metrics, such as population size, growth, and utilization rates for the healthcare service being reviewed. FLA. STAT. § 408.034(3). A significant increase in the population size or the utilization rates for the healthcare service under consideration may lead AHCA to issue a notice indicating that there is a fixed need for additional programs of that type in the service area. Once that notice is issued, healthcare programs seeking to provide the healthcare service in that service area can submit an application to fill the need identified by AHCA. Alternatively, a healthcare entity seeking to provide services that are governed by the CON regulations can file an application to establish a healthcare program even when a fixed need has not been identified by AHCA, if the healthcare entity can establish that there is a “special” circumstance in the service area that creates the need for the program that was not captured by AHCA’s analysis. *See* FLA. ADMIN. CODE r. 59C-1.008(2)(d)3.

Traditionally, in Florida, pediatric organ transplant programs were only allowed to provide transplant services to patients who were under 15 years old. *See id.* 59C-1.044(2)(c). This policy conflicted with the Centers for Medicare & Medicaid Services’ (“CMS”) policies and regulations that defined pediatric transplant programs to be those who serve patients who are under 18 years old. Hospital Conditions of Participation: Requirements for Approval and Re-Approval of

Transplant Centers to Perform Organ Transplants, 72 Fed Reg. 15,198, 152,12 (Mar. 30, 2007) (codified at 42 C.F.R. § 482.76). Furthermore, CMS revised its interpretation of the Conditions of Participation for transplant programs in 2007 so that a transplant program that performs 50 percent or more of its total transplants in a 12-month period, on a given age group, either adult or pediatric, is not required to apply and be approved separately for the other age group. *Id.* at 15,212-13. This was meant to allow pediatric transplant programs “to continue transplanting young adults beyond the pediatric age range in order to maintain continuity of care for established patients.” *Id.*

In February 2018, AHCA proposed an amendment to Rule 59C-1.044, Florida Administrative Code, that would expand its age limit policy for pediatric organ transplant programs to be more aligned with the national standards for pediatric organ transplantation and pediatric care. Although Rule 59C-1.044(2)(c), Florida Administrative Code, still defines a pediatric transplant program as one that serves patients under 15 years old, AHCA included the following language in Rule 59C-1.044(11), Florida Administrative Code: “Pediatric transplant programs with a valid CON at a Medicaid designated transplant center may perform transplants for patients under the age of 21. In case of conflict between provisions in this rule, the provisions of this subsection shall prevail.” This language went into effect on April 18, 2018. *See* FLA. ADMIN. CODE r. 59C-1.044.

The change to the age limit for pediatric organ transplant programs is significant, not only because it will allow for increased continuity of care for pediatric transplant patients, but also because it may expand the population base that is being analyzed when AHCA is assessing need for pediatric transplant programs or it may create a basis for a program to argue that there is a “special” circumstance in its area that was not adequately captured in AHCA’s fixed need analysis. It may also increase the impact felt by adult transplant programs when a new pediatric transplant program is approved within the same service area, which is another factor that must be considered by AHCA when deciding whether to approve a new healthcare program. All of these issues are likely to be raised in the coming years as part of applicants’ CON applications and/or established programs’ opposition statements against applications for new pediatric organ transplant programs. These will be fertile points for analysis as part of the administrative litigation process, if they are raised by the applicants or opponents in an administrative proceeding.

Submitted by: Angelina Gonzalez, Esq., Panza, Maurer & Maynard, P.A.

PRIVACY AND SECURITY UPDATES

GDPR Finally Effective in the EU

The new European Union (“EU”) General Data Protection Regulation (“GDPR”), adopted on April 14, 2016 and replaced the 1995 Data Protection Directive, became fully enforceable on May 25, 2018. The new regulation, which is also applicable to foreign corporations that control or process the data of EU residents, significantly expands the scope of privacy regulation and enforcement, and gives regulators the ability to impose severe penalties in case of violation which can go as high as 4 percent of worldwide turnover or €20 million, whichever is higher. It is expected that the cost of compliance with the new regulation will be as high as €200 billion for EU companies and \$41.7 billion for U.S. companies (*See* <https://www.gigacalculator.com/calculators/gdpr-compliance-cost-calculator.php>). The regulation is expected to have a high impact on U.S. healthcare

multinationals operating in the EU, particularly in the context of human resources matters, clinical trials and cross-border transmission of protected health information, including diagnostics and clinical laboratory data.

More information on GDPR can be found at <https://www.eugdpr.org/>

Submitted by: Christian Pérez Font, Esq., OPKO Health, Inc.

REGULATORY UPDATES

CMS Finalizes Policy Changes for the Prescription Drug Benefit Program for 2019

Last month, the Centers for Medicare and Medicaid Services (“CMS”) released a final rule establishing finalized policy changes and updates for Medicare Advantage and the Prescription Drug Benefit Program for contract year 2019.⁷ The proposed rule contained a controversial draft proposal that aimed to curb the opioid epidemic by prohibiting automatic refills of high dose opioid prescriptions (90 milligrams of morphine per day or more). Pursuant to the proposal, patients seeking to obtain such high dose opioid prescriptions would have had to obtain prior authorization from their insurance company before obtaining the medications. Many doctors and patients specifically opposed this proposal. After receiving hundreds of letters during the comment period, which ended March 5, 2018, CMS concluded that the proposal, as drafted, would have little clinical impact against opioid overuse. The final policy, published on April 16 2018 with an effective date of June 15, 2018, reflects this overall consensus. When a pharmacist receives a prescription for a dosage of 90 milligrams of morphine or more per day, they will be required to talk to the prescriber, document the discussion and, if the prescriber approves, fill the prescription for the patient.

The final rule can be downloaded from the Federal Register at <https://www.federalregister.gov/documents/2018/04/16/2018-07179/medicare-program-contract-year-2019-policy-and-technical-changes-to-the-medicare-advantage-medicare>

Submitted by: Anne L. Kelley, J.D. Candidate, U.F. Levin College of Law

FDA Approves Drug Used to Treat Opioid Withdrawal Symptoms

On May 16, 2018 the U.S. Food and Drug Administration (“FDA”) announced that it approved the first non-opioid treatment for management of opioid withdrawal symptoms in adults. In a press release announcing the approval for the drug, Lucemyra, the FDA announced that “encouraging more widespread innovation and development of safe and effective treatments for opioid use disorder remains top agency priority.”⁸ The agency noted in its release that while the newly approved drug may lessen the severity of withdrawal symptoms, it is only approved for treatment for up to 14 days. The agency stated that Lucemyra may not completely prevent symptoms and, as such, is not a treatment for opioid use disorder (“OUD”), but should instead be used as part of a broader, long-term treatment plan for managing OUD.

The full announcement is available at the FDA's website at the following address: <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm607884.htm>

Submitted by: Anne L. Kelley, J.D. Candidate, U.F. Levin College of Law

TRANSACTIONS UPDATES

Japanese Giant Takeda Announces Purchase of Shire

Takeda Pharmaceutical Company Ltd. ("Takeda") and Shire P.L.C. ("Shire") announced on May 8, 2018 that they had reached an agreement on the offer by Takeda to acquire the entire issued ordinary share capital of Shire for a total price of \$62 billion. The transaction would create a new Top 10 industry behemoth with combined annual revenue of approximately \$31.2 billion. The proposed transaction has been approved by the boards of directors of both companies, and is expected to close in the first half of calendar year 2019 subject to the obtainment of all regulatory and customary corporate approvals.

More details on the proposed transaction are available on the press release which is available at Takeda's website at: <https://www.takeda.com/newsroom/newsreleases/2018/proposed-acquisition-of-shire-plc-by-takeda/>

Submitted by: Christian Pérez Font, Esq., OPKO Health, Inc.

Reps and Warranties Insurance: Does it Improve Your Health(care) Deal?

During transaction negotiations, buyers and sellers expend significant time, effort, and resources to negotiate representations and warranties ("R&W") and indemnification provisions, which are the essential risk allocation provisions of any transaction document. These are often the most contentious deal terms to negotiate, aside from the financial aspects of a transaction.

R&W insurance ("RWI") offers an opportunity for a buyer to recover directly from an insurance carrier for losses arising out of a breach of the seller's R&W, sometimes in lieu of pursuing indemnification claims directly against the seller. The purchase of a RWI policy allocates the risk for such losses from the seller to an insurer, which allows the parties to limit the seller's liability while giving the buyer comfort that its investment is protected against certain unforeseen and unexpected issues. Additionally, RWI can be utilized to provide a longer indemnification period and higher recovery amounts than would otherwise be offered if the seller is bearing 100 percent of the risk.

While RWI for corporate transactions has been available for many years, there has been a proliferation of its use in recent years. According to the 2017 American Bar Association ("ABA") Private Target Deal Points Study,⁹ 29 percent of the private target deals the ABA analyzed referenced RWI in the definitive transaction agreement.¹⁰ Of the transactions in which RWI was referenced, RWI was a closing condition in 50 percent of the deals.¹¹ In 23 percent of transactions analyzed, RWI was the buyer's sole source of recovery for all R&W,¹² and in an additional 18

percent of deals, RWI was the buyer's sole source of recovery only for non-fundamental R&W.¹³ Further, 45 percent of deals required the buyer to pursue indemnification claims under the RWI policy.¹⁴ Of note, the use of RWI will vary widely by the type of transaction, type of buyer, and industry.

While its popularity has increased over the years, RWI remains a product of imperfect application, particularly in health care transactions, where most of the R&W that carry the greatest risk are often carved out from RWI policies. The breadth of the policy is often dictated by the ability of the underwriter to conduct extensive due diligence, and gain comfort with the seller's historic activity, including legal representation, existing insurance coverage, and compliance program.

In the healthcare realm, the coverage in these RWI policies frequently resembles Swiss cheese with significant gaps in coverage. If a RWI policy does not insure against breaches related to healthcare billing and fraud and abuse risks, the buyer may determine that the policy is essentially useless. However, insurance carriers have begun to offer healthcare-specific products, which include coverage for R&W related to government payors, which carry some of the greatest risk in a healthcare transaction. Carriers are even insuring against breach of compliance R&W, including False Claims Act¹⁵ violations, Stark Law¹⁶ violations, Anti-Kickback Statute¹⁷ violations, and payment disputes with government and commercial payors. However, the coverage for breach of these R&W may be narrowly tailored, and premiums on these policies may be cost prohibitive.

An increasing number of insurance carriers are now issuing RWI policies, making it easier to obtain a policy and creating more competition among insurance carriers to offer competitively priced policies with reasonable terms. Further, as insurance carriers have standardized RWI policies, the timeframe for underwriting has shortened and the ability to obtain a policy quickly allows interested parties to obtain a policy on relatively short notice without delaying the closing of a transaction. The cost of obtaining RWI has decreased as well, with lower premiums and retention amounts (i.e., deductibles), which makes the policies more appealing to buyers.

It is likely that RWI will become increasingly common in healthcare transactions, as it has in other industries, but buyers and sellers should be cognizant of carve-outs in coverage, and aware that the RWI may limit, but not eliminate, liability and risk for both parties.

Submitted by: Erica C Mallon, Esq., Carlton Fields

Summary of 2018 Healthcare Partnerships and Transactions

The healthcare industry's steady movement to consolidation is undeniable, as evidence by a few recent healthcare partnerships and transactions noted by Becker's Hospital Review in May 2018:

1. Cleveland Clinic / Baptist Health selected as the two potential affiliates to partner with Boca Raton Regional Hospital. The final decision is expected this summer.
2. FTC-approved proposed partnership between DeKalb Medical and Emory Healthcare.

3. Northwestern Memorial HealthCare and Centegra Health System (Illinois) anticipate closing their merger deal by September 1, 2018.
4. Rennova Health (West Palm Beach, Florida) announced that it expects to close a deal to acquire 85-bed Tennova Healthcare (Jamestown, Tennessee).
5. HCA Healthcare and KKR & Co. (private equity) have teamed up to make an offer for Envision Healthcare.

Tangentially, earlier this year, Miami Medical Center filed for Chapter 11 bankruptcy protection and on May 21, 2018, U.S. Bankruptcy Judge Laurel M. Isicoff granted a motion approving bidding procedures for the sale of the hospital and to approve certain protections to the stalking horse purchaser Nicklaus Children's Hospital. The hospital will be sold in auction during the week of June 18, 2018.

Links to Original Articles:

1. <https://www.beckershospitalreview.com/hospital-transactions-and-valuation/4-recent-healthcare-partnerships-and-transactions-51418.html>
2. <https://www.beckershospitalreview.com/hospital-transactions-and-valuation/6-recent-healthcare-partnerships-and-transactions-2.html>
3. <https://www.beckershospitalreview.com/hospital-transactions-and-valuation/bankrupt-miami-hospital-will-be-sold-in-auction.html>

Submitted By: Anushree (“Anu”) Sagi-Nakkana, Esq., ASN Law Firm

¹ See generally, *Corporate Integrity Agreements Snapshot*, CMS.GOV (Aug. 2016), <https://www.cms.gov/Medicare-Medicaid-Coordination/Fraud-Prevention/Medicaid-Integrity-Education/Downloads/ebulletins-corporateintegrity-agreement.pdf>.

² G.D. Pozgar, *Legal Aspects of Health Care Administration* (Jones & Bartlett Learning, LLC 2012).

³ *Corporate Integrity Agreement FAQ*, OFFICE OF INSPECTOR GENERAL U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, <https://oig.hhs.gov/faqs/corporate-integrity-agreements-faq.asp>.

⁴ Reference to CIAs includes Certification of Compliance Agreements and Settlement Agreements with Integrity Provisions.

⁵ *Corporate Integrity Agreement Documents*, OFFICE OF INSPECTOR GENERAL U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES (Updated May 24, 2018), <https://oig.hhs.gov/compliance/corporate-integrity-agreements/cia-documents.asp>.

⁶ *Id.*

⁷ *CMS Finalizes Policy Changes and Updates for Medicare Advantage and the Prescription Drug Benefit Program for Contract Year 2019*, CMS.GOV (April 2, 2018), <https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2018-Fact-sheets-items/2018-04-02.html>.

⁸ *FDA approves the first non-opioid treatment for management of opioid withdrawal symptoms in adults*, U.S. FOOD & DRUG ADMINISTRATION, FDA NEWS RELEASE (May 16, 2018), <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm607884.htm>.

⁹ *Private Target Mergers & Acquisitions Deal Points Study (Including Transactions from 2016 and H1 2017)*, AMERICAN BAR ASSOCIATION (Dec. 9, 2017).

¹⁰ *Id.* at 106.

¹¹ *Id.* at 108.

¹² *Id.* at 109.

¹³ *Id.*

¹⁴ *Id.*

¹⁵ 31 U.S.C. §§ 3729 – 3733.

¹⁶ 42 U.S.C. § 1395nn.

¹⁷ *Id.* § 1320a-7b.