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Healthcare Law UPDATE

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FEDERAL UPDATE

DOJ Places High Priority on Fraudulent Healthcare Claim Enforcement

The federal Department of Justice (DOJ) continues its efforts in cracking down on fraudulent claims. In fiscal year 2019, the DOJ recovered more than $3 billion in federal losses from fraud and false claims prosecution, which does not include the state government dollars recovered from related prosecutions. Nearly all were recovered from businesses in the healthcare industry. Additionally, of the $3 billion recovered in 2019, $2.1 billion came from whistleblower lawsuits.

Two of the largest 2019 recoveries were from the drug industry, specifically opioid manufacturers. Insys Therapeutics paid $195 million to settle allegations of kickbacks, taking the form of sham speaking events, jobs for family and friends of prescribers, and extravagant meals and entertainment. Reckitt Benckiser Group plc (RB Group) paid $1.4 billion to resolve claims for promoting its opioid drug to physicians to write prescriptions that were allegedly unsafe, ineffective, and medically unnecessary and for its allegedly misleading marketing claims that the drug was less susceptible to diversion, abuse, and accidental pediatric exposure than similar drugs.

Some of the other enforcement efforts that led to recoveries in fiscal year 2019 from the healthcare industry included claims of billing government programs for: medically unnecessary procedures, grossly substandard or worthless nursing home services, pharma kickbacks to generate referrals, billed claims for which co-pays were never collected, and providing inaccurate information to government programs to maximize reimbursements.

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HHS Voluntary Resolution Agreement with Health System Over Auxiliary Aids

In a press release issued January 16, 2020, the U.S. Department of Health & Human Services, Office for Civil Rights (OCR) announced that the OCR and CHRISTUS Trinity Mother Frances Health System (CTMF Health System) entered into a Voluntary Resolution Agreement requiring the health system to strengthen the provision of auxiliary aids and services and comply with its obligations under Section 504 of the Rehabilitation Act of 1973 (Rehabilitation Act) and Section 1557 of the Affordable Care Act (ACA Section 1557). Section 504 of the Rehabilitation Act generally prohibits discrimination based on disability for any program or activity receiving federal financial assistance or conducted by an executive agency or the U.S. Postal Service. ACA Section 1557 generally prohibits discrimination on the basis of race, color, national origin, sex, age, or disability in health programs or activities that receive federal financial assistance or are administered by an executive agency or any entity established under Title 1 of the ACA, and requires, among other things, the provision of auxiliary aids for disabled and limited English proficiency patients.

OCR initiated a compliance review and investigation of CTMF Health System after it received a patient complaint that a clinic and hospital of the health system failed to provide adequate or timely interpreter services despite multiple requests. OCR received subsequent statements from patients alleging deficiencies in the health system's provision of auxiliary aids and services to individuals who are deaf or hard of hearing.

As a result of the review and investigation, the health system has agreed to take steps to strengthen the provision of auxiliary aids and services under the Voluntary Resolution Agreement, which includes, among other actions, performing communication assessments at patient intake and reassessing communication effectiveness regularly; improving and upgrading its review, assessment, and provision of qualified interpreters, including in-person and by video remote interpreting; and providing annual staff training on effective communication.

The Voluntary Resolution Agreement should serve a reminder to healthcare providers receiving federal financial assistance, including through participation in the Medicare and Medicaid programs, of their obligation to comply with federal and state laws regarding provision of auxiliary aides, interpreter services, and other services to disabled and limited English proficiency patients.

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Hospitals Sue HHS Over Site-Neutral Payment Policy

Hospital associations and dozens of hospitals filed lawsuits in January 2020 against the U.S. Department of Health & Human Services (HHS) for continuing to reduce Medicare payments in calendar year 2020 for hospital outpatient services provided in off-campus, provider-based departments. Under the 2019 Medicare Outpatient Prospective Payment System (OPPS) final rule, the Centers for Medicare & Medicaid Services (CMS) made payments for clinic visits site-neutral by reducing payments by 60 percent for evaluation and management services at off-campus sites. In litigation filed against HHS in 2019 for the payment cuts, a federal judge ruled in September 2019 that CMS exceeded its statutory authority by making the payments site-neutral and overturned the relevant portions of the 2019 OPPS final rule. The court, however, did not restore the full payments and instead sent the case back to CMS. CMS appealed the court's ruling and decided to continue the payment cuts in the 2020 OPPS final rule. Since the court's ruling only applied to the 2019 OPPS rule, the hospital associations and hospitals filed the new lawsuits to stop the 2020 payment reductions.

The basis for the court's 2019 ruling that CMS had exceeded its authority is the Bipartisan Budget Act of 2015, passed by Congress in 2015. Section 603 of the statute provides for Medicare to pay the same rates for medical services regardless of whether they are provided in a physician's office or in a hospital department that is located away from the main campus of the hospital. Congress, however, made an exception to this amendment for all off-campus hospital outpatient departments that were providing services before the enactment of Section 603, November 2, 2015.

Hospitals have argued that services provided in hospital outpatient departments are more costly than the same services provided in independent physician offices. Furthermore, at the time hospitals were creating off-campus outpatient departments prior to the 2015 statute, the hospitals did so with the expectation of receiving the same Medicare reimbursements as they had received for many years which would allow the financial viability of these off-campus departments. Hospitals have argued the 60 percent payment reduction would have placed these clinics under severe financial strain. It was for this reason that the off-campus facilities in existence prior to the 2015 statute were grandfathered from the pay cuts. The hospitals and hospital associations continue to argue in the current litigation, as they did in 2019, that CMS has overstepped its statutory authority with the 2020 payment cuts.

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DOJ and FTC Release Draft New Guidelines for Vertical Mergers

On January 10, 2020, the U.S. Department of Justice (DOJ) and Federal Trade Commission (FTC) released, for the first time in 36 years, new guidelines for vertical mergers and acquisitions (collectively referred to as "vertical mergers"). Vertical mergers involve the combination of two or more companies that operate at different levels in the same supply chain. The guidance outlines the DOJ's and FTC's analytical process in determining whether a vertical merger violates federal antitrust laws. Federal law prohibits mergers if "in any line of commerce or in any activity affecting commerce in any section of the country, the effect of such acquisition may be substantially to lessen competition, or to tend to create a monopoly."

The draft guidelines generally: (1) describe potential anticompetitive effects resulting from vertical mergers, which may include both unilateral and coordinated effects; (2) consider as elements of antitrust harm the reduction or elimination of the supply of downstream products to rival companies, known as foreclosure, and the raising of rivals' costs and access to competitively sensitive information; (3) discuss how the elimination of double marginalization, which occurs when two vertically related firms that individually charge a profit margin on their products choose to merge, may eliminate the potential anticompetitive effects of vertical mergers; (4) discuss merger efficiencies that are specific to vertical mergers; and (5) provide examples to offer more clarity about the agencies' analytical methods in evaluating vertical mergers.

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STATE UPDATE

New Jersey Legislative Update

New Hospital Transparency Laws Enacted – Three Bills requiring hospitals to disclose additional information about their finances and transactions with related parties became law in January 2020. The Bills were introduced in November 2019 after concerns arose over the possible closure of Bayonne Medical Center.

Bill A5916 authorizes the Commissioner of Health to notify elected officials of financial distress of certain hospitals. If the Commissioner determines that a hospital is in financial distress or at risk of being in financial distress, the Commissioner may provide notice of the hospital's financial state to the mayor, city administrator, and members of the Legislature who represent the municipality in which the hospital is located. If the Commissioner appoints a monitor to prevent further financial deterioration at the hospital, the Commissioner must provide notice of the appointment within 30 days to the mayor, city administrator, and members of the Legislature who represent the municipality in which the hospital is located.

Bill A5917 expands the DOH's "Early Warning System," which detects signs that a hospital may be in or is approaching financial distress. In evaluating a hospital's finances, the DOH will be required to consider the amount of management fees, allocations, and other payments made to third-party entities, and the extent to which those fees, allocations, and payments reflect services actually rendered, with a particular focus on fees, allocations, and

other payments made to a related or affiliated entity. The DOH will also be required to review both the hospital's operating margin and the operating margin adjusted to account for third-party management fees, allocations, and other payments.

Bill A5918 expands the information hospitals are required to report to the New Jersey Department of Health (DOH). In addition to monthly and quarterly unaudited financial information and annual audited financial statements which hospitals are currently required to provide to the DOH, hospitals will also be required to post on their internet websites Internal Revenue Service Form 990 and all schedules and supporting documentation. If a hospital is owned or managed by a for-profit entity, the hospital will be required to provide the DOH with certain additional information.

Department of Health Establishes New Tuberculin Screening Process for Employees of Licensed Facilities – On December 13, 2019, the New Jersey Department of Health (DOH) issued a memo to all facilities and services licensed by the Department of Health regarding healthcare worker tuberculin skin testing. The memo supersedes the DOH's memo from March 2013 on the same subject. The memo provides that the DOH is adopting the "Tuberculosis Screening, Testing, and Treatment of U.S. Health Care Personnel: Recommendations from the National Tuberculosis Controllers Association and CDC, 2019" published by the Centers for Disease Control and Prevention (CDC) in the Morbidity and Mortality Weekly Report; May 17, 2019; Vol. 68; No. 19, as the guidelines for DOH-licensed facilities and services to follow in regard to tuberculosis screening, testing and treatment for an employee.

New Law Requires Facilities to Undertake End-of-Life Training – On January 21, 2020, Bill S3116 became law requiring certain medical facilities to undertake end-of-life planning and training. The new Law requires assisted living facilities, dementia care homes, nursing homes, assisted living residences, comprehensive personal care homes, residential healthcare facilities, hospitals, and long-term care facilities to require all administrative personnel and professional staff to complete annual training on advance care planning, end-of-life care, and the use of advance directives and Physician Orders for Life-Sustaining Treatment (POLST) forms. These facilities must also provide patients, residents, and their families with educational materials on POLST forms, advance directives, and hospice and palliative care, and develop and implement policies to identify and address end-of-life care issues for patients and residents upon admission to the facility.

New Law Requires Influenza Vaccinations for Healthcare Facility Employees – On December 13, 2019, Bill A1576 became law requiring certain healthcare facilities to provide, and employees to receive, annual influenza vaccinations. The new Law requires hospitals, nursing homes, and home healthcare agencies to establish and implement an annual influenza vaccination program in accordance with the current recommendations of the Advisory Committee on Immunization Practices of the federal Centers for Disease Control and Prevention and any rules and regulations adopted by the New Jersey Commissioner of Health. With limited exceptions, these facilities must provide an on-site or off-site influenza vaccination to each of its employees and each employee must receive an influenza vaccination annually.

New Law Addresses Disposal of Unused Prescription Drugs – On January 21, 2020, Bill A5667 became law requiring pharmacy practice sites and hospice programs to furnish patients with information and means to safely dispose of unused prescription drugs and medications. The new Law requires pharmacies that dispense prescription drugs, other than long-term care pharmacies, to, when dispensing to an individual located in New Jersey a prescription drug or medication which is a controlled dangerous substance, and when dispensing any other prescription drug or medication as may be designated by the Commissioner of Health by regulation: (1) provide the patient with written materials advising that there are risks when unused, unwanted, or expired drugs and medications are not properly, safely, and promptly disposed of; (2) have available onsite, for purchase or at no cost to the patient, at least one consumer method for individuals to dispose of unwanted or expired prescription drugs, including, but not limited to over-the-counter drug disposal solutions for use at home and secured medication collection kiosks or boxes; and (3) provide the patient with written materials concerning how to properly, safely, and promptly dispose of unused, unwanted, or expired drugs and medications.

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Brach Eichler In The News

Litigation Co-Chair and Healthcare Law Member **Keith J. Roberts** addressed attorneys and physicians January 30 at the 2020 Allied Networking Event hosted by Comprehensive Monitoring Associates. His presentation covered "PIP: Provider Reimbursements After Policy Exhaustion."

In a January 29 *ROI-NJ* article, "Brach Eichler epitomizes today's thriving regional law firms," **John D. Fanburg** was quoted about the firm's growth over the past ten years.

In an Op-Ed on nj.com on medical marijuana January 17, Labor and Employment Chair **Matthew M. Collins** discussed the HR implications of a recent disability discrimination lawsuit against Amazon.

Managing Member and Healthcare Law Chair **John D. Fanburg** commented in northjersey.com on December 31 about the hospital consolidation trend in New Jersey over the last decade.

HIPAA CORNER

Individuals' Right of Access to Health Records – A lawsuit filed by Ciox Health, LLC (Ciox) has resulted in an amendment to federal Department of Health & Human Services (HHS) guidance relating to fee limitations for copies of medical records in certain circumstances. Under HIPAA, covered healthcare providers may charge only a reasonable, "cost-based" fee for copies of protected health information (PHI), such as medical records,

requested by an individual. 45 CFR 164.524. The rule supersedes any state laws that may permit a higher copying fee. Detailed guidance was issued by the HHS in 2016 to assist covered entities in complying with the rule (HHS Guidance). In the HHS Guidance, the HHS stated that the fee limitation applies both to requests made by individuals for copies of their own records, as well as requests for patient records made by third parties, such as, e.g., life insurance companies and law firms.

Ciox is a specialized medical records provider that contracts with healthcare providers to manage medical records requests, including patients seeking copies of their own medical records and third parties, such as life insurance companies and law firms, seeking copies of patient records for commercial or legal purposes. In 2018, Ciox filed suit against the HHS, challenging, among other things, the HHS Guidance limiting charges to the "reasonable cost-based fee" for requests for PHI from third parties, rather than from a patient.

On January 23, 2020, the United States District Court for the District of Columbia issued a Memorandum Opinion in which the court ruled, among other things, that the fee limitation set forth in the HHS Guidance does not apply to requests for copies of PHI made by third parties. The fee limitation, however, remains in place for requests made directly by an individual.

DHHS Bulletin Regarding HIPAA Privacy and Novel Coronavirus – On February 3, 2020, the federal Department of Health & Human Services, Office for Civil Rights, published a special Bulletin: *HIPAA Privacy and Novel Coronavirus*, to "ensure that HIPAA-covered entities and their business associates are aware of the ways that patient information may be shared under the HIPAA Privacy Rule in an outbreak of infectious disease or other emergency situation, and to serve as a reminder that the protections of the Privacy Rule are not set aside during an emergency." The Bulletin provides information about sharing patient information for various purposes, including treatment; public health activities; to family, friends and others involved in an individual's care and for notification; to prevent a serious and imminent threat; and to the media or others not involved in the care of the patient. The Bulletin also includes information regarding HIPAA's minimum necessary standard, safeguarding patient information and application of HIPAA to covered entities and business associates.

Reminder to File 2019 Breach Notifications by March 1st – Under the HIPAA Breach Notification Rule, covered entities must, in addition to other notification requirements, notify the federal Department of Health & Human Services (HHS) of any breach of unsecured protected health information (PHI).

If a breach affects 500 or more individuals, covered entities must notify the HHS "without unreasonable delay" and in no case later than 60 days following discovery of the breach. If, however, a breach incident affects fewer than 500 individuals, the covered entity may notify the HHS of such breach incidents on an annual basis. Reports of breach incidents affecting fewer than 500 individuals are due to the HHS no later than 60 days after the end of the calendar year in which the breaches are discovered. As such, for 2019 breaches affecting fewer than 500 individuals per incident, reporting must be made to HHS no later than March 1, 2020.

If you would like assistance with your HIPAA privacy and security program, in managing a breach incident or in business associate analysis and contracting, contact:

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