HEALTHCARE LAW UPDATE

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STATE UPDATE

DEA and HHS Extend Telemedicine Flexibilities for Controlled Medications through 2025

On November 15, 2024, the United States Drug Enforcement Administration (DEA) and the Department of Health and Human Services (HHS) announced that they have extended the current telemedicine flexibilities for the prescription of controlled medications through December 31, 2025. The extension means that DEA registered practitioners will continue to be able to prescribe controlled substances via telemedicine without having to conduct an in-person medical evaluation of the patient so long as certain conditions are met. The full text of the extension, entitled the "Third Temporary Extension of Covid-19 Telemedicine Flexibilities for Prescription of Controlled Medications", can be found here. The extension provides the DEA and HHS time to promulgate proposed and final regulations that are consistent with public health and safety, and that also effectively mitigate the risk of possible diversion. Furthermore, the extension provides additional time for providers to come into compliance with any new standards or safeguards eventually adopted in a final set of regulations.

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Atlantic Diagnostic Laboratories Overcharged Medicaid $7.3 Million

On October 3, 2024, the New Jersey Office of the State Comptroller (OSC) released an audit report revealing that Atlantic Diagnostic Laboratories (ADL) overcharged New Jersey's Medicaid program for urine drug testing services and owes the State Medicaid program $7.3 million in repayment. The OSC audited claims from January 2015 through June 2018 and found that ADL violated Medicaid regulations by charging up to $1,035 per drug test, while billing other payers as little as $2.38 for the same test. Medicaid paid ADL between $63.40 and $180.40 for these services. Medicaid regulations require laboratories to charge Medicaid the lowest possible rate and only perform medically necessary tests.

In 88 of the 261 instances sampled, ADL either billed for tests that had not been ordered or lacked the necessary documentation or signatures. The audit also uncovered that ADL improperly unbundled claims, a practice that typically results in higher reimbursement rates, which is prohibited. OSC is seeking to recover $2,943,586 for documentation deficiencies, $1,140,043 for unbundled claims, and a $3,269,332 civil penalty for knowingly submitting claims that violate Medicaid regulations prohibiting higher charges to Medicaid for the

same services. In addition to overcharging Medicaid, ADL also sponsored three golf outings for one of its referring providers, which is prohibited by State law.

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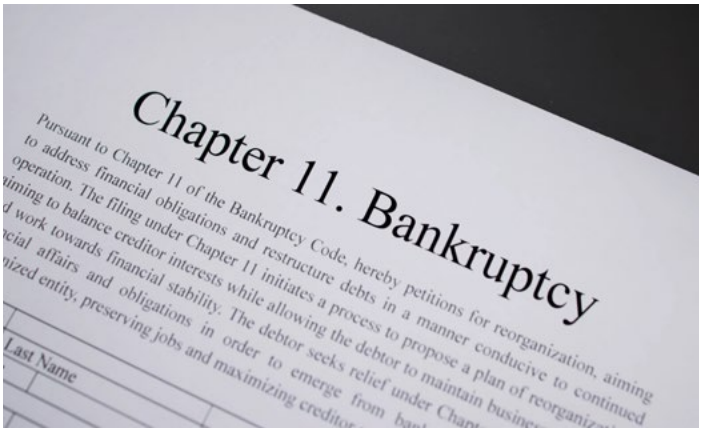

Jersey City Based CarePoint Health System Files for Chapter 11 Bankruptcy

On November 3, 2024, CarePoint Health System filed for Chapter 11 bankruptcy in the District of Delaware. CarePoint, which includes Bayonne Medical Center, Hoboken University Medical Center and Christ Hospital in Jersey City, provides care to sixty percent of Hudson County's population, the majority of whom are uninsured or underinsured. CarePoint stated that the decision to file for Chapter 11 was driven by the dramatic increase in direct costs of operating the hospitals after the COVID-19 pandemic, insufficient state funding and persistent reimbursement challenges that hospitals across the country have been facing. Chapter 11 bankruptcy will allow CarePoint to reorganize its finances and continue operating. CarePoint has obtained $67 Million in funding to continue its operations and ensure that the three CarePoint hospitals remain open during the bankruptcy proceedings with no interruptions in patient care. Just days before the bankruptcy filing, CarePoint and Hudson Regional Hospital in Secaucus announced that they will merge to form a new healthcare system, Hudson Health.

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FEDERAL UPDATE

Teva Pharmaceuticals Pays $450 Million to Settle Anti-Kickback and False Claims Act Allegations

On October 10, 2024, the U.S. Department of Justice (DOJ) announced that Teva Pharmaceuticals USA Inc. and Teva Neuroscience Inc. (collectively, Teva) agreed to pay $450 million to settle two alleged kickback schemes and alleged submission of false claims. The first settlement resolves allegations that Teva conspired to violate the Anti-Kickback Statute and False Claims Act by paying Medicare patients' copays for the multiple sclerosis drug Copaxone while steadily increasing Copaxone's price. As part of this scheme, the DOJ alleged Teva conspired with a specialty pharmacy and independent copay assistance foundations to ensure donations to the foundations were used to cover copays of Medicare Copaxone patients, causing Teva to submit false claims to Medicare. In a second settlement, Teva agreed to resolve allegations that it conspired with other generic drug manufacturers to fix prices for pravastatin, clotrimazole and tobramycin. To resolve related criminal charges, Teva USA had previously entered into a deferred prosecution agreement with the DOJ's Antitrust Division and paid a criminal penalty of $225 million.

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Corporate Transparency Act Deadlines Fast Approaching

The Corporate Transparency Act of 2019 (CTA) was enacted to create a federal database of the beneficial ownership information of certain U.S. corporate entities and provide law enforcement with access to such data for the purpose of detecting, preventing and punishing terrorism, money laundering and other misconduct. Effective January 1, 2024, certain entities (Reporting Companies) are required to file beneficial ownership information reports (BOI Reports) with the FinCEN, a department within the U.S. Department of Treasury. BOI Reports identify who owns or controls certain entities and the applicants who formed or registered these entities. Entities created or registered on or after January 1, 2024, have 90 days (after such creation or registration) to file their initial BOI Reports. Entities created or registered

prior to January 1, 2024 have until January 1, 2025 to file their initial BOI Reports. Reporting Companies must file their BOI Reports electronically.

The CTA provides exemptions from BOI Reporting for certain entities including, tax-exempt entities, inactive entities, sole proprietorship not created by filing documentation with a secretary of state and certain "Large Operating Entities." Large Operating Entities may qualify for exemption if they meet certain key criteria, including: (1) employing more than 20 full time employees in the United States; (2) filing a federal income tax or information return showing more than $5 Million in gross receipts for the previous year; and (3) reporting greater than $5 Million as gross receipts or sales on the entity's applicable IRS forms. Entities that existed on January 1, 2024, even if they were subsequently dissolved, must still file a BOI Report by December 31, 2024. Additionally, entities that were formed in 2024, but were dissolved before the 90 day filing deadline, must still file a BOI Report even though the filing deadline has not yet passed. The deadline to file remains at 90 days from formation of the entity.

Under the CTA, willful failure to complete or update an entity's BOI Reports or providing false or fraudulent information can result in civil or criminal penalties. Civil penalties include monetary fines of up to $500 for each day that the violation continues, while criminal penalties include imprisonment for up to two years and/or a fine of $10,000.

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Senators Cassidy and Hassan Seek Fair Billing Policy Reforms

Senators Bill Cassidy (R-LA) and Maggie Hassan (D-NH) recently unveiled a comprehensive framework for establishing site-neutral payment policy reforms and reinvesting savings into rural and safety net health care providers. If enacted, these reforms would lower healthcare costs for patients by ensuring that hospitals charge the same prices for the same health care services regardless of where the service is delivered. Under the plan, Medicare reimbursements would be equalized for common outpatient services at hospital-owned offsite locations, ambulatory surgery centers and other clinics. According to Senators Cassidy and Hassan, the plan is being proposed at least partially in response to the prevalence of physician practices and other outpatient sites being acquired by hospitals and health systems, who are often accused of steering patients to the hospital or health system affiliated facilities with the highest Medicare reimbursement rates for the particular outpatient procedure.

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CMS Releases 2025 Physician Fee Schedule

The Centers for Medicare & Medicaid Services (CMS) recently published the calendar year (CY) 2025 Physician Fee Schedule (PFS) final rule, finalizing changes for Medicare payments under the PFS and other policies related to Medicare Part B reimbursement. Under the new rule, average reimbursement rates under the PFS will be reduced by 2.93%, which incorporates a 0% overall update to PFS reimbursement rates as required by statute, the expiration of a temporary 2.93% increase in payment rates for CY 2024 that was required by statute, and a 0.02% adjustment to reimbursement rates that is necessary to account for changes in work relative value units for some services. According to CMS, the CY 2025 PFS final rule is one of several final rules that reflect a broader strategy of the Biden Administration to create a more equitable health care system that results in better accessibility, quality, affordability, empowerment and innovation for all Medicare beneficiaries.

Under the final rule, CMS has established new coding and payment rules for several categories of services,

including caregiving training and services, behavioral management and modification training, wound care and infection control. The final rule also expands Medicare reimbursement of telehealth services to include PrEP counseling and caregiving training services, and expands the categories of modalities that may be used to provide telehealth services to include two-way, real-time, audio-only communication technology. CMS has also modified the reimbursement rules for outpatient evaluation and management (E&M) visits to allow providers to include certain complexity add-ons when the provider provides certain add-on services on the same day that the provider provides an annual wellness visit, vaccine administration or any Medicare Part B preventative service in an office or outpatient setting.

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CMS Issues 2025 Hospital Outpatient and ASC Fee Schedule

The Centers for Medicare & Medicaid Services (CMS) recently published the calendar year 2025 Hospital Outpatient Prospective Payment System and Ambulatory Surgery Center (ASC) Payment System final rule. Under the new rule, CMS will increase payment rates by 2.9% for ASCs and for hospitals that meet certain quality reporting requirements. According to CMS, the final rule includes policies that align with several key goals of the Biden Administration, including responding to the maternal health crisis, addressing health disparities, expanding access to behavioral health care, improving transparency in the health system and promoting patient-centered care. In addition, the final rule advances CMS's commitment to strengthening Medicare, and applies lessons learned from the COVID-19 pandemic to inform the approach to quality measurement, focusing on changes that help address health inequities.

In addition to updating reimbursement rates, the final rule requires hospitals to meet new quality standards for obstetrical care, including new staffing and training requirements, standards to ensure that basic obstetrics equipment is readily available, and requirements related to the hospital's readiness to provide emergency services. CMS has also finalized rules for implementing certain provisions of the Consolidated Appropriations Act of 2023 that provide temporary additional payments for certain non-opioid treatments for pain relief in the hospital outpatient department and ASC settings through December 31, 2027. The final rule also provides updates to Medicare payment rates for intensive outpatient program services and partial hospitalization program services furnished in hospital outpatient departments and Community Mental Health Centers.

In the final rule, CMS has also introduced additional requirements under the ASC, Hospital Inpatient, Hospital Outpatient and Rural Emergency Hospital quality reporting programs, including updates to the categories of metrics that facilities must report, such as metrics related to social drivers of health and to the facility's commitment to health equity. According to the final rule, a facility's failure to meet quality program reporting requirements may result in a reduction to reimbursements by up to 2%, depending on the scope of the failure.

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LEGISLATIVE AND REGULATORY UPDATE

Electronic Medical Records Rule Proposal for Medicaid/NJ FamilyCare

The New Jersey Department of Human Services is proposing a new regulation, which would set forth the requirements for a provider to use electronic medical records and electronic signatures to both maintain and submit documentation to Medicaid/NJ FamilyCare. The proposed rule would be consistent with existing Federal requirements, and does not mandate the use of electronic records or signatures. This new regulation would outline the requirements for a provider if he/she should elect to use electronic records and electronic signatures for submissions to Medicaid/NJ FamilyCare. Such requirements would include requiring a provider to develop organizational policies to use electronic records and signatures, ensuring compliance with HIPAA, and ensuring compliance with all existing Federal and State laws regarding recordkeeping.

Medicaid Reimbursement for Mental Health Rehabilitation Services Bill Advances

Senate Bill 2606, introduced in the New Jersey State Senate on February 8, 2024, was just passed by the Senate on October 28, 2024. It is currently before the Assembly Aging and Human Services Committee. This Bill if passed would require Medicaid reimbursement of mental health rehabilitation services provided via a clubhouse program. A "clubhouse program" is defined as a non-residential, community-based psychosocial rehabilitation program accredited by Clubhouse International. Clubhouse International is a nonprofit organization that assists people with mental illness by creating community-based recovery programs.

Codey Law Exceptions Expanded

On October 30, 2024, New Jersey Governor Murphy signed into law Assembly Bill 4447, which expands the permissible exceptions for a health care practitioner to self-refer. The Codey Law prohibits healthcare practitioners from referring patients for a health care service in which the practitioner or the practitioner's immediate family has a significant beneficial interest. This new exception to the Codey Law allows oncology practitioners with a financial interest in a pharmacy integrated with their practice to refer patients to that pharmacy, as long as the pharmacy:

- dispenses medications exclusively to the practice's patients;
- has direct access to the practice's medical records;
- communicates with each patient in person or via telemedicine to review the prescription instructions and assesses the patient for interactions with other drugs and food;
- synchronously consults with the treating physicians as needed; and
- complies with the State Board of Pharmacy requirements for timely delivery of medications, hours of operation, and recordkeeping.

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HIPAA CORNER

Failure to Timely Provide Access to Health Records is Costly

The U.S. Department of Health and Human Services, Office for Civil Rights recently issued penalties relating to two separate investigations based on complaints that a health care provider failed to timely provide the patient with access to the patient's healthcare records as required by HIPAA. On October 17, 2025, the OCR announced the imposition of a $70,000 civil monetary penalty against a Maryland dental practice for the failure to timely provide a parent with copies of her children's dental records. In this instance, the failure continued for more than two years after the initial records request. OCR was unpersuaded by the dental provider's argument that the reason for the failure to timely provide the records was due to the parent's refusal to pay the $25 records fee and because the provider believed the parent would use the records to commit insurance fraud. The civil monetary penalty marks the OCR's 50th "Right of Access" enforcement action.

On November 19, 2024, the OCR announced its 51st "Right of Action" enforcement action. In this instance, the OCR imposed a $100,000 civil monetary penalty against a California mental health center for its failure to timely provide healthcare records to an individual. In this instance, records were provided 216 days after the individual's initial request during the COVID-19 pandemic, which was followed by multiple other requests. OCR was unpersuaded by the provider's argument that the failure to timely provide the records was due to changes in the provider's infrastructure resulting from the pandemic and the state's "Safer at Home" order.

Both enforcement actions highlight:

- HIPAA's strict requirement to provide individuals with access to their healthcare records within the timeframes set forth in HIPAA. This means requests must be fulfilled within 30 calendar days, which may be extended one time per request for an additional 30 calendar days if the provider notifies the individual in writing within the initial 30 days that there will be a delay and provides the reason for the delay.
- OCR's hard-line stance on HIPAA's right of access rule.

For additional information or if you need assistance with your organization's privacy and security program, please contact:

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ATTORNEY **SPOTLIGHT**

Get to know the faces and stories of the people behind the articles in each issue. This month, we invite you to meet Counsel Tracy Miller and Counsel Erika Marshall.

TRACY MILLER

What is an interesting trend in Healthcare Law?

AI holds tremendous promise for improving health care diagnosis, treatment, research and the efficiency of clinical care. It is currently used for some clinical applications, such as analysis of radiology images and preparation of notes of physician encounters with patients. While certain laws in areas such as patient privacy clearly apply to AI, implementation requires new policies and training for health care providers. New federal and state regulations specific to AI are just emerging. In October 2023, President Biden issued an Executive Order mandating the establishment of standards for AI, including standards to advance security, privacy and safety. This was followed in May 2024 by a Final Rule issued by the Department of Health and Human Services Office for Civil Rights prohibiting discrimination on the basis of race, color, national origin, sex, age or disability in the use of AI in healthcare settings. The Final Rule applies to AI tools that support clinical decision-making and to entities, including health care providers and plans, that receive federal funds, requiring them to take reasonable steps to identify and mitigate the potential discriminatory impact of AI in patient care decision support tools. In order to unlock the potential of AI in clinical practice, health care providers will need to tackle the novel questions of transparency, privacy, consent and discrimination that AI poses.

What achievement am I most proud of?

Serving as General Counsel and outside counsel to health systems, hospitals, and other providers, I am deeply proud of the work I have conducted to enable clients to realize their business and strategic objectives. While it is hard to select one transaction or initiative, the role of EVP & General Counsel of a large health system comprised of six hospitals, over 2000 physicians and 17,000 employees carried special resonance and responsibility during the COVID-19 pandemic. The Health System faced novel, pressing questions of law almost on a daily basis, with intensive, rapidly evolving state and federal regulations. The issues cut across operations and clinical care, including labor and employment law and policy, licensure and professional practice, the rapid expansion of telehealth, and the distribution of limited life-saving medications and resources such as ventilators among severely ill patients. It was a privilege to work with the System's leadership to serve our patients and support our frontline staff as the pandemic unfolded.

ERIKA MARSHALL

What is an interesting trend in Healthcare Law?

The growing interest from Washington in private equity's involvement in healthcare and how this interest will impact pricing, competition, quality of care, and the structure of future healthcare transactions.

What achievement are you most proud of?

I am proud of the trusted client relationships that I have built over the past six years while with Brach Eichler.

Save the Date!! The 13th Annual New Jersey Healthcare Market Review, April 3-4, 2025 at the Borgata Hotel Casino & Spa, Atlantic City, NJ! Connect with over 200 attendees, comprised of hospital and ASC executives and stakeholders, physicians, practice owners/managers, and healthcare administrators. During this two-day event, industry experts will discuss timely topics and trends in the healthcare and legal space ranging from legislative issues to operating and business strategies for greater profitability. To learn more and register, please visit https://www.njhmr.com. For questions or additional information, please reach out to Jennifer Buneta at jbuneta@bracheichler.com.

On December 10, Managing Member and Healthcare Law Chair **John D. Fanburg** will be a panelist at Withum's 2024 Healthcare Symposium. John will delve into the current market and future outlook for private equity investments in healthcare, regulatory considerations and its impact on investment strategies and how to drive growth and operational improvements while mitigating risk with these investments.

On November 4, ROI-NJ spotlighted Healthcare Law Counsel **Tracy Miller** joining Brach Eichler's healthcare law practice. Additional articles on the topic were published by NJBIZ and Law360.

On November 1, Managing Member and Healthcare Law Chair **John D. Fanburg** was quoted in a Relias Media article entitled "New Patient Safety Initiatives Could Change Standard of Care."

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