HEALTHCARE LAW UPDATE

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STATE UPDATE

Murphy Administration Highlights Need for Health Care Affordability

The Murphy administration recently published several reports by the New Jersey Department of Banking and Insurance analyzing information on health care spending, quality, access, and affordability in New Jersey. The reports indicated that increases in health care spending were not due to an increase in services provided, but rather from increases in the actual cost of health care. Additionally, while quality and access have remained consistent or improved for many New Jerseyans, affordability has decreased due to increased spending for out-of-pocket medical costs and health care premiums. The reports also addressed health care inequalities, with the burden of medical costs being the greatest among low income residents. As the Murphy administration and future administrations focus on health care costs, quality, and accessibility, providers should be aware of legislation being adopted and proposed to address these issues, such as the recently adopted Louisa Carman Medical Debt Relief Act, which is intended to curb predatory medical debt collections.

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FEDERAL UPDATE

FTC Finalizes Eyeglass Rule to Promote Competition and Patient Choice for Glasses

The "Eyeglass Rule" became effective September 24, 2024, pursuant to the Ophthalmic Practice Rules issued by the Federal Trade Commission. Per the final rule, ophthalmologists and optometrists must comply with the following requirements:

- Provide patients with a copy of their prescription immediately following a refractive eye exam, before products for sale are offered to the patient.
- If using a paper prescription, patients need to acknowledge receipt of their prescription and prescribers must maintain such acknowledgement for three years.
- If using a digital prescription, patients must consent to the method of delivery (email, portal, text message, etc.) before the prescription is sent, and prescribers must maintain confirmation that the prescription was sent for three years.

These requirements do not apply to prescribers who do not have a financial interest in the sale of eye wear, or to prescribers who are employed by any federal, state, or local government.

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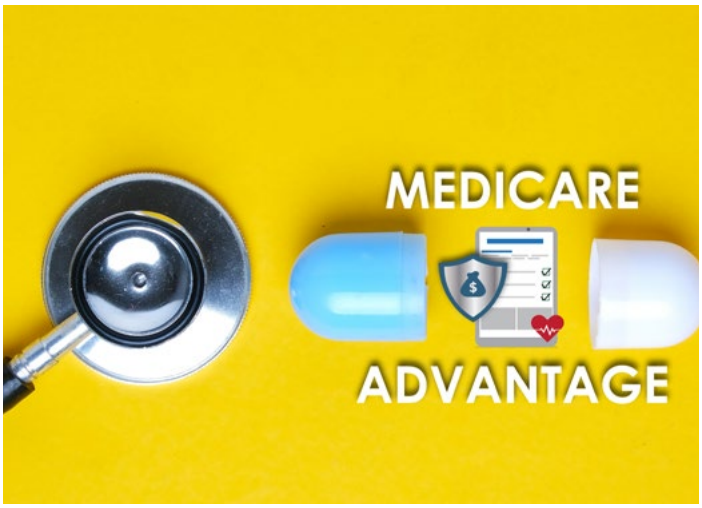
OIG Sheds Light on Medicare Advantage Gainsharing Arrangements

On September 13, 2024, the Department of Health and Human Services Office of Inspector General (OIG) issued an unfavorable Advisory Opinion in response to a Medicare Advantage Organization (MAO) seeking to share its savings (the Gainshare Payment) with group

health plans that contract to participate in the MAO's Employer Group Waiver Plans (EGWPs).

In its proposed arrangement, the MAO sought to make available a Gainshare Payment to groups that reach a negotiated medical loss ratio, calculated by dividing certain expenses incurred by the MAO by certain revenues it receives. Groups would be able to use the Gainshare Payments for any purpose, unlike other MA plans which require participating groups to use rebates to pay for supplemental benefits or reduce enrollees' premiums. The proposed arrangement would allow the



MAO to unilaterally terminate or modify the Gainshare Payment percentage amount if the number of enrollees falls below a negotiated threshold.

The OIG concluded that the proposed arrangement would implicate the Federal anti-kickback statute, and that risk of fraud and abuse was not sufficiently low, for the following reasons:

1. The Gainshare Payment could incentivize groups to choose the requestor's EGWP over similar plans that are unwilling or unable to provide a similar incentive, since the Gainshare Payment may be used for any purpose.
2. Groups that select the requestor's EGWP may steer its members to enroll in the plan to prevent the requestor from reducing or terminating the Gainshare Payment due to low enrollment.
3. Groups selecting a EGWP are not required to negotiate for better benefits or lower costs for enrollees and therefore can engineer its arrangement with the MAO to increase its chance of receiving a larger Gainshare Payment.

Notwithstanding the foregoing, the OIG stated that a savings-sharing arrangement between MAOs offering a EGWP and group health plans could be permissible if structured differently than the proposed arrangement.

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Enhancing Oversight of Remote Patient Monitoring in Medicare

In September 2024, the Department of Health and Human Services Office of Inspector General (OIG) published a report entitled Additional Oversight of Remote Patient Monitoring in Medicare is Needed. Remote patient monitoring (RPM) enables patients to collect their own health data, such as blood pressure, using a connected medical device that automatically transmits the information to their healthcare provider. The healthcare provider then uses this data to manage or treat the patient's condition.

The OIG found that from 2019 to 2022, the provision of RPM services to Medicare enrollees significantly increased. However, the report noted that approximately 43% of Medicare enrollees receiving RPM services did not receive all required components of the service, raising concerns about whether RPM is being used as intended. Both the OIG and the Centers for Medicare & Medicaid Services (CMS) have expressed concerns about potential fraud associated with RPM. Additionally, the OIG expressed that CMS lacks critical oversight information, such as details about the providers who order RPM for Medicare enrollees.

To address these issues, the OIG recommends that CMS take several steps to enhance RPM oversight, including: implement safeguards to ensure the proper use and billing of RPM services; require RPM to be ordered by a provider and require that the provider's information be included in claims and encounter data; develop methods to track the health data being monitored and provide education for providers on proper RPM billing practices; and identify and monitor companies billing for RPM services.

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Federal Government Claims Preventive Care at Risk Unless Supreme Court Intervenes

The federal government is asking the United States Supreme Court to reverse a federal appeals court decision that could end the right to free preventive services required under the Affordable Care Act (ACA). The preventive services requirement is a popular provision of the ACA that has been in effect since 2010 and extends coverage of evidence-based preventive services, such as cancer screening, tobacco cessation, contraception, and immunizations, without cost-sharing to more than 150 million people each year.

At issue is the constitutionality of the U.S. Preventive Services Task Force, which issues recommendations on preventive care. In June, the Fifth Circuit ruled partially in favor of the plaintiffs, four individuals who provide health coverage to their families and two businesses that provide health coverage for employees, finding that the requirement to cover medication for HIV prevention violates the rights of plaintiffs who have religious objections. The federal government has appealed the Fifth Circuit's decision, claiming that the holding jeopardizes health care protections for preventive services without cost sharing that have been in place for more than a decade and which are currently relied upon by millions of Americans.

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CMS Finalizes Plan for Next Medicare Drug Price Negotiation Cycle

Earlier this month, the Centers for Medicare & Medicaid Services (CMS) released final guidance on the process for the second cycle of negotiations under the Medicare Drug Price Negotiation Program. CMS had previously set prices for the first ten drugs covered under the Program, to be effective starting January 1, 2026, marking the beginning of CMS's efforts to reduce drug costs for Medicare beneficiaries. CMS will announce the selection of up to fifteen additional drugs covered by Part D for the second cycle of negotiations by February 1, 2025. This second cycle of negotiations with participating drug companies will occur during 2025, and any negotiated prices for this second set of drugs will be effective starting January 1, 2027. The guidance also outlines requirements and parameters for how participating drug companies must ensure that eligible beneficiaries with Medicare prescription drug coverage will have access to the negotiated prices for 2026 and 2027, including procedures that apply to participating drug companies, Medicare Part D plans, pharmacies, mail order services, and other entities that dispense drugs covered under Medicare Part D.

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Laboratory Pays $27 Million to Settle Alleged False Claims and Anti-Kickback Violations

On October 2, 2024, the U.S. Department of Justice (DOJ) announced that Precision Toxicology LLC (Precision), a toxicology laboratory that markets and performs urine drug testing (UDT) nationwide, agreed to a settlement to resolve allegations that Precision violated the False Claims Act (FCA) , which prohibits knowingly submitting false claims to federal healthcare programs, and the Anti-Kickback Statute (AKS), which prohibits remuneration to induce referrals of services covered by federal healthcare programs. According to the DOJ, Precision violated the FCA by allowing physicians to order UDT without first determining that the UDT was reasonable and medically necessary. In addition, the DOJ also accused Precision of violating the AKS by offering physicians free point-of-care urine test cups under the condition that the physicians would return the samples to Precision for testing. Under the terms of the settlement, Precision agreed to pay a $27 Million fine and agreed to enter into a corporate integrity agreement with the U.S. Department of Health and Human Services Office of Inspector General (OIG) in exchange for the OIG not initiating an administrative action to exclude Precision from participation in federal health care programs. The settlement also resolved three lawsuits brought under the whistleblower protections of the FCA.

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LEGISLATIVE AND REGULATORY UPDATE

New Exception to New Jersey Codey Law Proposed

Assembly Bill No. 4447, which was passed by the New Jersey State Senate and is before the New Jersey General Assembly for a second reading, would expand 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. The Codey Law does permit certain exceptions, and if enacted this Bill would add an exception to allow 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.

Proposed Legislation to Require Individualized Postpartum Plans

Senate Bill No. 912, passed by both the New Jersey General Assembly and New Jersey Senate as of September 26, 2024, would require practitioners offering prenatal care, including physicians, advanced practice nurses and midwives, to assist patients in making an individualized postpartum care plan during the first trimester. An individualized postpartum care plan would need to include such items as: (i) the name, phone number, and office address of the patient's care team; (ii) the time, date, and location for the patient's postpartum checkup and the phone number to schedule or reschedule such appointment, if needed; (iii) guidance regarding breastfeeding; (iv) a reproductive life plan and appropriate contraception; (v) notes about any of the patient's pregnancy complications and recommended follow-ups or test results; (vi) guidance regarding signs or symptoms of postpartum depression or anxiety; (vii) recommendations for the management of postpartum issues (pelvic floor exercises, urinary incontinence, etc.); and (viii) a treatment plan for ongoing physical and mental health conditions. If a patient waives the right to develop a plan with the practitioner, the practitioner is required to educate the patient about the risks of forgoing adequate postpartum care.

Bill Introduced to Make NJ FamilyCare Provider Enrollment Process Easier

Assembly Bill No. 2804, passed in the New Jersey General Assembly on September 26, 2024, would require the State Board of Medical Examiners (BME) and the Department of Human Services, Division of Medical Assistance and Health Services (DHS) to implement standards to improve efficiency for reviewing NJ FamilyCare provider applications. The BME would be required to: (i) notify DHS within five days after it issues a license number to an applicant; and (ii) notify DHS within five days if it denies an applicant's licensure.

DHS would be required to: (i) process each NJ FamilyCare provider application immediately upon receipt of the application, provided the application contains the necessary licensure information; and (ii) notify an applicant within 15 days of receiving the applicant's license number from the BME if any additional information or documentation is required to enroll the applicant as a NJ FamilyCare provider.

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HIPAA CORNER

Fourth OCR Ransomware Settlement: $250,000

The Department of Health and Human Services Office for Civil Rights (OCR) has announced a settlement with a privately-owned health care provider offering ophthalmology, dermatology and cosmetic services, relating to a ransomware attack on the provider. This marks only the fourth OCR settlement relating to ransomware, despite that the OCR advises that "the agency sees 264% increase in large ransomware breaches since 2018."

"Cybercriminals continue to target the heath care sector with ransomware attacks. Health care entities that do not thoroughly assess the risks to electronic protected health information and regularly review the activity within their electronic health record system leave themselves vulnerable to attack, and expose their patients to unnecessary risks of harm," said OCR Director Melanie Fontes Rainer. "Ensuring the confidentiality of electronic protected health information is critical to protect health information privacy and integral to our national security in the health care sector. OCR urges all health care entities to take the essential precautions and stay vigilant to safeguard their systems from cyberattacks."

OCR's investigation ensued after it received a complaint alleging the provider experienced a ransomware attack. Through its investigation, OCR determined that approximately 291,000 files containing electronic protected health information were affected. OCR found multiple HIPAA violations, including the failure of the provider "to conduct a compliant risk analysis to determine the potential risks and vulnerabilities to ePHI in its systems, and to have sufficient monitoring of its health information systems' activity to protect against a cyber-attack."

As part of the settlement, the provider paid a $250,000 penalty to the OCR and will implement a corrective action plan.

If you need assistance with your data privacy and security program, please contact:

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BRACH EICHLER IN THE NEWS

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.

October 19, **Team Brach Eichler** raised money to support The American Heart Association Heart Walk! It was a beautiful day as attorneys, staff and their families walked together to support heart health and raise awareness for the American Heart Association.

October 15, Healthcare Law Chair **John D. Fanburg**, presented a legal update report at NJAASC 2024 Quarterly Member Meeting, at Forsgate Country Club, NJ.

October 21, Brach Eichler is pleased to announce **Tracy Miller**, Healthcare Law Counsel has joined the firm. Welcome to the firm Tracy!

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 Member Lani Dornfeld and Counsel Debra Levine.

LANI DORNFELD

What is an interesting trend in Healthcare Law?

An interesting trend I have been seeing is physicians and other healthcare providers speaking out against private equity investments in health care entities. I have been reading and hearing that some providers have become dissatisfied with what they perceive as the focus on profits and the "bottom line" over what is best for the patient. I am interested to see what will be the next big trend in healthcare and the impact on healthcare transactions and the industry in general.

What achievement are you most proud of?

Personally, of course, my family. Professionally, I am most proud of the fact that I chose the legal profession as my second career. I went to law school later than most, after I was married and had two children. I look back at what an amazing feat it was to hold a job, manage a household, raise two young children, go to law school at night, successfully graduate and pass both the NJ bar exam and the Florida bar exam, each on the first try. Twenty-five years later, I am still going strong.

DEBRA LEVINE

What is an interesting trend in Healthcare Law?

An interesting trend in Health Care Law is the advent of ownership and investment in Medi Spas by health care providers and lay persons. This practice area presents an attractive income opportunity for physicians in an era of decreasing reimbursements. Additionally, unlicensed individuals have management opportunities. The cosmetic services offered are in high demand and patients pay out of pocket as they are not covered by insurance. A full spectrum of services (including, but not limited to, cosmetic injectables, weight loss management, skin care services, laser treatments and infusions) can be offered as long as there is regulatory compliance. The issue of scope of practice of ancillary providers, physician delegation and physician involvement is nuanced and governed by regulations of multiple New Jersey Professional Licensing Boards. Medi Spas organized in appropriate legal ownership and management formats with protocols, delegation standards and referral patterns all in compliance with State and Federal law, are an interesting trend in Health Care Law. Given my background and professional licensure expertise, I have worked with both licensed and unlicensed clients to successfully establish compliant Medi Spa practices.

What achievement are you most proud of?

I have obtained New Jersey Medical Licenses for applicants whose educational and training experiences have not squarely met the New Jersey requirements for licensure. These worthy applicants were often educated and trained abroad. I conducted extensive reviews of the applicants' records, including curriculum, transcripts, training logs, procedure records, board certifications and employment experiences in order to compare the data to the required standards. I compiled and submitted detailed petitions demonstrating the substantial equivalency of the applicants' records to the New Jersey standard. I am proud to have achieved licensure for multiple clients, either educated or trained abroad or whose records are not otherwise in alignment with the New Jersey regulatory standards.

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