

# HEALTHCARE LAW UPDATE

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### OIG Releases Semiannual Report to Congress Regarding Healthcare Industry Oversight

The U.S. Department of Health and Human Services Office of Inspector General (OIG) [released](#) its semiannual report to Congress for the six-month period ending March 21, 2023. Generally, these reports are intended to keep the Secretary and Congress informed about significant findings and recommendations by the OIG. Highlights of the OIG's actions during this period include the following:

- Conducted and issued 62 audit reports and identified \$200.1 million in expected audit recoveries.
- Recommended 213 new audits and evaluations.
- Reported on its fraud and abuse efforts, including \$892.3 million in expected investigative recoveries, 345 criminal actions, civil monetary penalties against 324 individuals, and exclusion of 1,365 individuals from federal health care programs.
- Continued investigations and prosecutions of individuals who exploited the COVID-19 response.
- Reported on nursing homes and better protections needed for future emergencies.
- Continued enforcement activities to protect enrollees from prescription drug abuse.

In the future, the OIG looks to promote the effectiveness of HHS programs for the next pandemic, understand what drives nursing home performance and ensure that these homes prioritize patient care, and utilize oversight and enforcement activities to identify and criminally prosecute physicians who improperly prescribe. The OIG's report demonstrates the government's vast and varied oversight of HHS's programs and its commitment to coordinated law enforcement actions for bad actors.

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### New Jersey Oncologist Pleads Guilty to Unlawfully Selling Medication for Profit

On May 31, 2023, a New Jersey oncologist [pleaded guilty](#) to unlawfully selling prescription medication. The oncologist was recruited by a business person who owned a pharmacy and two wholesale drug distribution companies. In exchange for \$5,000 per month, the oncologist used her medical license and allowed others to use her medical license, to purchase prescription drugs typically used to treat cancers, macular degeneration, and autoimmune diseases. These individuals were able to purchase these drugs that they would not otherwise have been permitted to purchase and then sell these drugs for a profit. These individuals made false and misleading representations to the pharmaceutical manufacturers and authorized distributors when purchasing the drugs. They represented that the medications purchased would be used to treat the oncologist's patients and that the drugs would not be resold. Through the scheme, the individuals purchased millions of dollars of prescription drugs in the oncologist's name.

The sale of prescription drugs purchased by a healthcare entity is punishable by a maximum three-year prison sentence and a \$10,000.00 fine. The oncologist's plea agreement provides that she will make restitution for the full amount of any loss resulting from the scheme.

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## CMS Issues Categorical Waiver for Microgrid Systems as Alternate Power Sources in Health Care Facilities

On March 31, 2023, the Centers for Medicare & Medicaid Services (CMS) issued a [categorical waiver](#) allowing healthcare facilities to use alternate power sources other than generators or battery systems. The previous requirement, based on the 2012 edition of the National Fire Protection Association (NFPA) Health Care Facilities Code (NFPA 99), mandated that facilities have a primary electrical power source and an emergency power source supplied by generators or batteries for certain patient care areas. The new waiver, based on the 2021 edition, permits the use of Health Care Microgrid Systems (HCMS), which are small-scale electrical grids that can operate independently or in tandem with a larger grid. An HCMS can be powered or supplemented by clean energy technologies like fuel cells, solar panels, wind turbines, and energy storage systems, offering enhanced reliability, efficiency, and sustainability compared to traditional generators. Long-term care facilities providing life support systems are excluded from this waiver.

To utilize the waiver, both new and existing healthcare facilities must comply with CMS and NFPA requirements, choose to adopt the categorical waiver, and document the use of a HCMS to CMS. A survey entrance conference is conducted to review the documentation and ensure that the HCMS meets the applicable requirements. Once the survey team confirms that the necessary level of patient protection is met, the healthcare facility is deemed compliant.

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## CMS Proposes CY2024 Payment Rules for Outpatient Hospital Services and ASCs

On July 13, 2023, the Centers for Medicare & Medicaid Services (“CMS”) published a [proposed](#) rule setting forth the Calendar Year (CY) 2024 Hospital Outpatient Prospective Payment System (OPPS) and ASC Payment System (ASCPS). In addition to setting CY2024 payment rates under the OPPS and ASCPS, the proposed rule includes policies that align with several key goals of President Biden’s Administration, including strengthening Medicare, promoting health equity, expanding access to behavioral health care, improving transparency in the health system, and promoting safe, effective, and patient-centered care.

Under the proposed rule, reimbursement rates for hospitals that meet applicable quality reporting requirements would be increased by 2.8%, and reimbursement rates for ambulatory surgical centers would be similarly increased by 2.8%. Under the proposed rule, CMS would continue to pay the statutory default rate for drugs and biologicals acquired under Section 340B of the Public Health Services Act. To further CMS’s goal of promoting price transparency, CMS is proposing to modify the standard charge display requirements for covered facilities and to update the enforcement provisions related to transparency compliance. CMS is also considering the implementation of a separate payment for establishing and maintaining access to a buffer stock of essential medicines.

The proposed rule would establish the Intensive Outpatient Program (IOP) under Medicare, which would address gaps in behavioral health coverage in Medicare and promote access to behavioral health care hospital outpatient departments, Community Mental Health Centers (CMHCs), Federally Qualified Health Centers and Rural Health Clinics. The proposed rule also contains provisions that would update Medicare payment rates for partial hospital program services in outpatient hospital departments and CMHCs. CMS is also proposing changes to the Hospital Outpatient Quality Reporting Program, the Ambulatory Surgical Center Quality Reporting Program and the Rural Emergency Hospital Quality Reporting in order to further meaningful measurement and reporting for quality of care in the outpatient setting.

Comments to the proposed rule are due by September 11, 2023, and CMS will issue a final rule in early November.

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## Connecticut Expands Noncompete Law for Healthcare Professionals and Imposes New Restrictions

On June 28, 2023, Connecticut Governor Ned Lamont signed [Public Act No. 23-97](#) into effect, amending Connecticut's noncompete law for physicians and extending it to include physician assistants (PAs) and advanced practice registered nurses (APRNs). Connecticut passed legislation in 2016 limiting the use of noncompete agreements for physicians in several material ways. Among other limitations, the law precludes employers from entering into agreements that restrict physicians from competing for a period of more than one year and outside of a fifteen-mile radius of the primary site where the physician practices. In addition, a physician noncompete agreement is enforceable only in the event that the physician resigns or is discharged for cause.

Under the amended law, PAs and APRNs may not be subject to noncompete agreements with a duration of more than one year, and restrictions on competition must be limited to a fifteen-mile radius from the PA's or APRN's primary site of practice. The amended law also places additional limitations on physician noncompete agreements. For example, any contract or agreement entered into, amended, extended, or renewed on or after October 1, 2023, will not be enforceable in the event the physician does not agree to a proposed material change to the compensation terms prior to or at the time of the extension or renewal of the agreement and the agreement expires or is terminated by the employer except for cause.

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## Nationwide Enforcement Action Against Health Care Fraud Results in \$2.5 Billion in Charges

On June 28, 2023, the Justice Department, along with federal and state law enforcement partners, [announced](#) a nationwide enforcement action targeting criminal schemes involving telemedicine, pharmaceutical, opioid distribution, and other types of health care fraud. A total of 78 defendants have been charged, with schemes amounting to over \$2.5 billion in fraud. In connection with the enforcement action, the Justice Department seized or restrained millions of dollars in cash, automobiles, and real estate.

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## LEGISLATIVE UPDATE

### Bill Would Require Cultural Competency and Implicit Bias Training for Health Care Professionals

[Assembly Bill 5516](#), introduced on June 5, 2023 to the New Jersey General Assembly and referred to the Assembly Health Committee, would require any certified or licensed health care professional, including homemaker-home health aides, who provide in-home health care services, to complete one credit of cultural competency and implicit bias training within one year following the effective date of the bill and biennially thereafter. The Department of Health, in consultation with relevant professional organizations, would develop the cultural competency and implicit bias training curriculum.

### Bill Would Require Insurance Coverage for Ovarian Cancer Screening

[Assembly Bill 5560](#), introduced on June 5, 2023 to the New Jersey General Assembly and referred to the Assembly Health Committee, would require hospital, medical, and health service corporations, commercial individual, small employer, and larger group insurers, health maintenance organizations, and the State Health Benefits Program to provide coverage for medically necessary expenses incurred in screening for ovarian cancer for symptomatic women or women at risk of ovarian cancer, which includes, but is not limited to, an annual pelvic examination, an ultrasound, and blood testing for cancer markers.



## Bill Would Establish Pilot Program to Improve Black Maternal Health in New Jersey

[Assembly Bill 5634](#), introduced on June 20, 2023 to the New Jersey General Assembly and referred to the Assembly Health Committee, would require the Department of Health to establish a three-year Obstetric Discrimination Prevention and Mitigation Pilot Program in which maternity care hospitals and licensed birthing centers would utilize and evaluate the effectiveness of a perinatal quality improvement measurement tool in (1) recognizing and reporting obstetric discrimination; (2) evaluating the presence and magnitude of obstetric discrimination and its impact on the birthing experiences of Black mothers; and (3) improving maternal health care provided to Black mothers during childbirth hospitalizations and reducing adverse pregnancy-related experiences and outcomes.

## Companion Bills Would Allow, and Reimburse For, Remote Monitoring Rendered to Certain Pregnant Medicaid Patients

Assembly Bills 5608 and 5609 were introduced on June 15, 2023 to the New Jersey General Assembly and referred to the Assembly Health Committee. [Assembly Bill 5608](#) would establish a voluntary, three-year pilot program to provide certain pregnant Medicaid beneficiaries with remote maternal health services, including remote patient monitoring, remote non-stress tests, and tele-ultrasound services upon referral. State licensed physicians and midwives would be permitted to refer a pregnant Medicaid beneficiary to the pilot program if the provider determines that remote maternal health services are in the beneficiary's best interests or that the beneficiary has an increased likelihood of a high-risk pregnancy due to: pre-existing medical conditions; age; lifestyle factors; or a diagnosed pregnancy-related condition, such as preeclampsia. [Assembly Bill 5609](#), would allow a health care provider who establishes a proper provider-patient relationship with a pregnant patient to remotely monitor the patient if the patient is unable to receive in-person services at a physician's office or other licensed health care facility. This Bill would also require Medicaid reimbursement for remote patient monitoring rendered to certain Medicaid beneficiaries.

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## HIPAA CORNER

### HSCC Publication: Coordinated Healthcare Incident Response Plan

A new [publication](#) by the Healthcare and Public Health Sector Coordinating Council, titled “Coordinated Healthcare Incident Response Plan (CHIRP)”, provides a template incident response plan intended as a tool for organizations in the health and public health sector to develop their own tailored incident response plans. “The Healthcare and Public Health Sector Coordinating Council (HSCC) is a coalition of private-sector critical healthcare infrastructure entities organized to partner with and advise the government in the identification and mitigation of strategic threats and vulnerabilities facing the sector’s ability to deliver services and assets to the public.”

The template plan includes topics such as cybersecurity incident identification and the associated roles and responsibilities; incident response, including a governance team responsible for overseeing and coordinating efforts; communication strategy; containment strategy; and guidance for implementation of interim technical solutions to manage processes and the business prior to full system restoration.

With ever increasing cyber threats and the government’s continued focus on cybersecurity and providing tools to the health and public health sector to address those threats, health care providers must make HIPAA compliance a priority in their businesses. This includes having in place written policies and procedures, privacy and security officers who possess sufficient knowledge and training to serve in such roles, regular and meaningful staff training, and periodic security risk analyses to assess compliance with security requirements and identify the risks and vulnerabilities of systems that house patient information so that measures may be taken to address those risks and vulnerabilities.

**If you need assistance with your HIPAA compliance program, an OCR investigation, or a data breach incident, 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 Members Edward J. Yun and Isabelle Bibet-Kalinyak.



**EDWARD J. YUN**

## **What advice can you share with a client who might need your services?**

Generally speaking, it is better for a client to be proactive than reactive when addressing any licensure, reimbursement, fraud and abuse, or transactional matter. Although this is not always possible, it allows the client to have more control over the situation. In either case, Brach Eichler provides sound legal advice and business guidance to clients.

## **What are some best practices for healthcare clients?**

Healthcare is one of the most highly regulated industries and is constantly evolving. Accordingly, healthcare clients need to be diligent in staying on top of all of the latest developments. Brach Eichler is well equipped to assist clients in doing so.



**ISABELLE BIBET-KALINYAK**

## **What advice can you share with a client who might need your services?**

Many of our healthcare clients underestimate the need for keeping adequate corporate formalities for their business entities. This can lead to numerous unintended consequences that can cause friction between partners during the recruitment, the departure or the retirement of a partner, hinder business growth, create hurdle in raising capital, slow down M&A transactions or a business sale, or even decrease a business valuation. Corporate formalities are legal

requirements and not merely busy work.

## **What are some best practices for healthcare clients?**

1. Laws and regulations affecting the healthcare industry are constantly in flux at the federal, state, local and payer level. In this period of turnover and strained access to talent, providers need to delegate legal and compliance functions within their teams to ensure that not all responsibilities fall on a single person. The responsibilities can be documented in the personnel job descriptions and linked to Policies and Procedures. If one employee leaves, it will be easier to retrain the person filling in and ensure perennity of the organization. In addition to continuity, this empowers teams to understand and feel an integral part of the compliance system. This can prevent negative outcomes during billing audits and transactions, including potential decrease in valuation and payout.
2. Compliance with laws and regulations is not universal. Keep in mind that what your peers are doing is not necessarily correct or sufficient under the law, nor is it perhaps a “best practice.” Stay informed through your local and national professional societies and management organizations.
3. Scope of practice is a hot topic. However, consolidation and the rise of private equity investments in healthcare have led to the shrinking of local professional societies’ membership because private equity-backed medical groups do not reimburse their employees for the membership fees. This trend has had a tremendous negative impact on the lobbying budgets of professional societies at the state and national level. Providers need to support the lobbying efforts of their professional societies if they consider scope of practice a critical issue. Funding is paramount to lobbying efforts. Professional societies can lobby state and federal legislative and administrative bodies through Political Action Committees (PACs). Providers can contribute personally to PACs even if their employer will not participate in or contribute to such PACs or professional societies. Every donation counts, regardless of the amount.

**BRACH EICHLER** IN THE NEWS

On July 24, Brach Eichler's Managing Member, Healthcare Law Practice Chair, and Co-Chair of the Cannabis Practice, **John D. Fanburg, Esq.**, along with **Charles X. Gormally, Esq.**, Member and Co-Chair of the Cannabis Practice, were recognized by [NJBIZ Power 50 in Law](#). The list recognizes forward-thinking leaders across the state who are impacting the legal industry in a positive way.

On July 19, Brach Eichler was selected for the "[Litigation Department of the Year](#)" award for Healthcare Specialty, an award won in 2021 and 2022. Healthcare Member, and Litigation Chair, **Keith Roberts, Esq.** said, "We are proud to be leaders and attribute this win to our experienced team of Healthcare Litigation Counsel, Associates, and professional staff. This award is a testament to their skill and dedication." In addition, Brach Eichler Healthcare Law Member **Joseph M. Gorrell, Esq.** has been selected as a distinguished "[Mentor of the Year](#)" honoree and Real Estate Chair and Executive Committee Member **Allen J. Popowitz, Esq.** is being recognized as one of the "[Dealmakers of the Year](#)" finalists.

On July 19, Healthcare Law Member **Lani Dornfeld** presented on the Policy & Strategy Panel at the Medical Society of New Jersey about "[Social Media and Online Safety](#)." Lani discussed steps physicians can take to protect themselves when they conduct business online and how social media can be used by physicians.

On July 17, **Brach Eichler** was selected as one of the "[Best Places to Work](#)" in the medium-sized (50 – 249 employees) company category of [NJBIZ's 2023 Best Places to Work in New Jersey](#) for the second year in a row. The Best Places to Work program identifies and honors the top 125 companies in New Jersey that benefit the state's economy, workforce, and fellow businesses. The firm will be honored during an awards dinner and ceremony on September 28 at The Event Center at iPlay America in Freehold, New Jersey.

Healthcare Law Member **Isabelle Bibet-Kalinyak** issued two Healthcare Law Alerts entitled "[2023 Ohio Maximum Fees for Copying Medical Records](#)" and "[New Jersey ASCs "Standard Charges" Posting Requirements](#)."

On July 3, Employment Law Member **Jay Sabin** was interviewed by New Jersey 101.5 to discuss "[Artificial intelligence in the workplace – NJ Lawyer Discusses the Threats](#)."

On June 22, **Brach Eichler** was recognized as a recipient of NJBIZ's inaugural "[Empowering Women](#)" recognition program. Our firm and the other honorees will be recognized at a gala on August 1, 2023, for their support to elevate and advance women in the workplace and local communities.

On June 20, Patent, Intellectual Property & Information Technology Chair **Jonathan Bick** bylined an article in *The New Jersey Law Journal* entitled "[Fact, Fiction or Privacy Infringement: Artificial Intelligence and Deepfake Liability](#)."

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