

Healthcare Law UPDATE

FEDERAL UPDATE

HHS Releases New Guidance on Arbitration Process under No Surprises Act

As previously reported in our March 8, 2022 [client alert](#), a Texas court set aside key parts of the Independent Dispute Resolution (IDR) process under the federal No Surprises Act. In light of the court's ruling, the U.S. Departments of Health & Human Services, Treasury, and Labor released [guidance](#) on April 12, 2022 updating the IDR process with respect to the arbitrator's analysis for determining the applicable out-of-network reimbursement.



The Texas court ruled that the initial regulations established under the No Surprises Act improperly instructed arbitrators to presume the Qualify Payment Amount (QPA) – the payor's

median in-network contracted rate – is the appropriate reimbursement. The provider must then rebut that presumption with credible evidence of other factors that the arbitrator will consider in order to deviate from the QPA, but those factors must show that the QPA is “materially different” from the appropriate out-of-network rate. The No Surprises Act statute enacted by Congress, however, did not give extra weight to the QPA. The updated guidance outlines credible information that must be considered by the arbitrator as well as factors the arbitrator may not consider.

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OIG Approves Arrangement that Provides Cash Equivalents to Substance Abuse Disorder Patients

In a recently published [Advisory Opinion](#), the Office of Inspector General (OIG) for the U.S. Department of Health & Human Services approved a program through which a digital health company provides digital contingency management tools and incentives, including cash equivalents, to motivate behavioral health changes in individuals who suffer from substance use disorders. The program's services include appointment and medication reminders, saliva and breathalyzer testing, cognitive behavioral therapy, certified recovery coaching, and virtual support groups. The program provides incentives via a smart debit card that may not be used in certain locations, such as bars or liquor stores, when individuals complete certain events, such as attending a treatment session, or achieve certain behavioral goals, such as a negative substance test.

Key components of the program include:

- While individuals may self-enroll in the program, the company typically contracts with health plans, addiction treatment providers, and other providers that pay a flat monthly fee for each eligible member or select a pay-for-performance model under which they pay for achieving certain agreed-upon targets for abstinence.
- Each incentive payment is small, and annual incentive payments are capped at \$599 annually per individual.
- The company itself is not enrolled in and does not receive remuneration from any federal healthcare program, and the company certified that the fees it charges are consistent with fair market value and do not vary based on the volume or value of referrals.

The OIG noted that the proposed program included two streams of remuneration that could potentially

violate the federal Anti-Kickback Statute (AKS) or the civil monetary penalty prohibition on federal beneficiary inducements (CMP), including the fee paid by customers for the program's services, some of which could incentivize a member to receive a federally billable service, and the incentive payments paid by the company, some of which may be paid to individuals for obtaining services that are billable to a federal health care program. However, although neither remuneration stream satisfies an AKS safe harbor or an exception to the CMP, the OIG determined that the program presents a minimal risk of fraud and abuse since:

- The incentives are part of an evidence-based treatment program rather than an inducement to seek federally reimbursable treatment.
- The program's incentives are relatively low in value.
- Most of the incentives are not tied to federally payable services.
- The company is not enrolled as a provider or supplier in any federal health care program.

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New Reporting Requirements for Cyber Incidents and Ransomware Payments under the Strengthening American Cybersecurity Act of 2022

On March 15, 2022, President Biden signed into law the [Strengthening American Cybersecurity Act of 2022](#), which, among other things, seeks to improve cybersecurity disclosures and protections by operators of federal infrastructure and federal civilian agencies. The new law requires critical infrastructure sectors, defined under [Presidential Policy Directive 21 \(PPD-21\)](#) to include healthcare and public health, to:

- Report to the U.S. Department of Homeland Security, Cybersecurity and Infrastructure Security Agency (CISA) any substantial cyber incidents within 72 hours and ransomware payments within 24 hours.
 - Submit follow-up reports to CISA.
 - Preserve, and possibly produce to CISA, certain data related to the cyber incident or ransomware payment.
- Reports may be designated as proprietary and will be

treated accordingly, cannot be used for enforcement or other regulatory actions, and are not subject to disclosure under the Freedom of Information Act. The new reporting requirements will become effective once CISA promulgates its final regulations, including what specific entities within each critical infrastructure sector must report and what specific types of cyber incidents and payments must be reported.

Stakeholders will need to update their cybersecurity compliance programs to ensure compliance with these new reporting requirements once the final regulations are promulgated by CISA.

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Biden Administration Proclaims Support for Black Maternal Health Week

On April 8, 2022, President Biden issued a [proclamation](#) emphasizing the Biden-Harris Administration's commitment to addressing Black maternal mortality and morbidity. The Biden-Harris Administration has been supporting policies to improve maternal health and equity since the President and



Vice President first took office. Initiatives include the marking of Black Maternal Health Week in April to raise awareness of the impact of systemic discrimination on Black maternal health. The President noted that Black women are more than three times as likely to die from pregnancy-related complications as white women, regardless of their income or education. To improve health outcomes, the Administration has championed policies to address areas of unequal access along racial

lines, including access to healthcare, adequate nutrition and housing, toxin-free environments, high-paying job sectors that provide paid leave, and workplaces free from harassment and discrimination.

The policies include (i) a commitment from the Office for Civil Rights to hold providers accountable for non-discriminatory obstetric and postpartum care to close the gap on health equity; (ii) the opportunity for states to provide 12 months of extended postpartum coverage to pregnant women enrolled in Medicaid and the Children's Health Insurance Program; (iii) the first-ever hospital quality designation by the Centers for Medicare & Medicaid Services specifically focused on maternity care; (iv) the launch of a program that provides pregnant and postpartum women and their children with comprehensive substance use treatment and recovery support services across residential and outpatient settings; (v) the expansion and diversification of the maternal health workforce; (vi) the improvement of maternal mental health treatment; (vii) the bolstering of community-based programs; (viii) expanded training of providers; (ix) enhanced research; and (x) better coordination of maternal care.

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DOJ Issues Guidance on ADA Protection for Individuals Recovering From Opioid Use Disorder

On April 5, 2022, the U.S. Department of Justice (DOJ), Civil Rights Division published [guidance](#) explaining how the Americans with Disabilities Act (ADA) protects people who are in treatment or recovery for opioid use disorder (OUD), including those who take prescription medications as part of that treatment.

The guidance states that individuals in treatment or recovery from OUD are considered disabled under the ADA unless they are currently engaged in illegal drug use. These individuals may be prescribed medications such as methadone, buprenorphine, or naltrexone that are approved by the Food and Drug Administration (FDA). Employers may not discriminate against employees who are in treatment for OUD and who use such medications. Additionally, employees with a history of OUD have a "record of" a disability and are protected



from discrimination. The ADA also protects from discrimination those who have a known association or relationship with someone who has a disability such as OUD.

Concerning employee drug testing, the guidance states that employers may test for illegal drug use. However, employers may not fire or deny employment to individuals legally using medication prescribed for OUD, unless the use of such medication renders the individual unable to safely and effectively perform the job, or otherwise disqualifies them under another federal law.

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STATE UPDATE

Bill Introduced to Require Medical Fee Schedule for Automobile Insurers to Reimburse Certain ASC Services at 300% of Medicare

On March 24, 2022, Bill [S2392](#) was introduced in the New Jersey Senate to require the New Jersey Department of Banking and Insurance medical fee schedule used for the reimbursement of medical expenses by certain automobile insurers to provide for reimbursement of services provided by an ambulatory surgical center that are not currently listed on the medical fee schedule at a rate of 300% of the Medicare payment rate for that service, provided that the services are reimbursable under current Centers for Medicare & Medicaid Services guidelines. Unlisted medical supplies utilized in conjunction with services that are not currently listed on the fee schedule would be required to be reimbursed at invoice cost plus 20%.

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Bill Introduced to Require Insurance Carriers to Satisfy Network Adequacy Requirements Related to Mental Health Care

On March 14, 2022, Bill [A3595](#) was introduced in the New Jersey Assembly to require insurance carriers to take certain actions to ensure that health benefits plans meet new network adequacy requirements related to mental health care. Under the Bill, the New Jersey Commissioner of Banking and Insurance or the New Jersey Commissioner of Human Services would approve the network for a health benefits plan only if the plan meets the following requirements concerning access to mental health providers: Each plan would be required to have a sufficient number of mental health providers to ensure that 100% of the plan's covered persons have access to either in-network mental health providers that can provide services delivered in person or access to in-network or out-of-network mental health providers that can provide services delivered through telemedicine or telehealth. The requirements would apply to "carriers," defined as an insurance company, health service corporation, hospital service corporation, medical service corporation, or health maintenance organization authorized to issue health benefits plans in New Jersey, and includes the State Health Benefits Program, the School Employees' Health Benefits Program, the Medicaid program, and Medicaid managed care organizations.

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Senate Passes Bill to Expand Health Care Professions Profiled under New Jersey Health Care Consumer Information Act

On March 24, 2022, the New Jersey Senate passed Bill [S760](#) to expand the number of health care professions profiled under the New Jersey Health Care Consumer Information Act. The Bill is now being reviewed by the New Jersey Assembly. It would amend the Act by requiring the Division of Consumer Affairs to develop and maintain publicly accessible profiles of all health care professionals licensed by the Division. Currently, only physicians, podiatrists, and optometrists have such profiles. The Bill would also expand the information collected for the profiles, including (i) restrictions at New



Jersey-based or out-of-State facilities; (ii) Medicare or Medicaid exclusions; and (iii) any actions taken by federal regulators such as the U.S. Food and Drug Administration or Drug Enforcement Agency.

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HIPAA CORNER

OCR Requests Public Comment on Provisions of the HITECH Act

On The U.S. Department of Health & Human Services (HHS), Office for Civil Rights (OCR) published a [Request for Information \(RFI\)](#) on April 6, 2022 to solicit public comment on certain provisions of the Health Information Technology for Economic and Clinical Health (HITECH) Act. The HITECH Act was enacted as part of the American Recovery and Reinvestment Act of 2009 and was signed into law on February 17, 2009, to promote the adoption and meaningful use of health information technology.

Subtitle D of the HITECH Act addresses the privacy and security concerns associated with the electronic transmission of health information, in part, through several provisions that strengthen the civil and criminal enforcement of the Health Insurance Portability and Accountability Act of 1996 (HIPAA). The RFI seeks public comment on the following provisions of the HITECH ACT:

Recognized Security Practices: Section 13412 of the HITECH Act, effective January 5, 2021, requires HHS to take into consideration certain "recognized security practices" of covered entities (health plans, health care clearinghouses, and most health care providers) and business associates when determining potential fines, audit results, or other remedies for resolving potential violations of the HIPAA Security Rule pursuant to an investigation, compliance review, or audit. The RFI seeks public comment on how covered entities and business associates are implementing "recognized

security practices,” and how they anticipate adequately demonstrating that recognized security practices are in place, and any implementation issues they would like OCR to clarify through future guidance or rulemaking.

Civil Money Penalty (CMP) and Settlement Sharing:

Section 13410(c)(3) of the HITECH Act requires HHS to establish by regulation a methodology under which an individual harmed by a potential violation of the HIPAA Privacy, Security, and/or Breach Notification Rules may receive a percentage of any CMP or monetary settlement collected with respect to such offense. Section 13140(d)(1) of HITECH requires that OCR base determinations of appropriate penalty amounts on the nature and extent of the violation and the nature and extent of the harm resulting from such violation. The HITECH Act does not define “harm,” nor does it provide direction to aid HHS in defining the term.

The RFI solicits public comments on the types of harms that should be considered in the distribution of CMPs and monetary settlements to harmed individuals, discusses potential methodologies for sharing and distributing monies to harmed individuals, and invites the public to submit alternative methodologies.

OCR encourages comments from all stakeholders, including patients and their families, HIPAA covered entities and their business associates, consumer advocates, health care professional associations, health information management professionals, health information technology vendors, and government entities.

Comments must be submitted on or before June 6, 2022.

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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 Member Riza I Dagli and Associate Cynthia Liba.



RIZA I DAGLI

Briefly describe a recent significant transaction, win or client victory. I recently represented a chiropractor who was criminally charged with violating the New Jersey Runner Statute which prohibits paying anyone to bring patients to a healthcare practice. The Runner Statute has a mandatory prison

requirement. However, based on my knowledge of the law and its applicability, I was able to advocate on behalf of the client and structure a plea where the chiropractor pled to another charge that did not have the prison requirement, and he was able to avoid prison entirely.

Why did you choose to focus your legal practice on healthcare law and the healthcare industry? I chose to focus on healthcare law when I joined the New Jersey Attorney General's Office as a prosecutor focusing on Medicare, Medicaid, and insurance fraud. That landscape creates a situation where individuals with less than noble ambitions can take advantage of federal and state healthcare programs through fraud. The bad apples make it more difficult and expensive for the overwhelming majority of honest healthcare professionals to provide quality and affordable care. After a career at the Attorney General's Office, I now enjoy helping providers navigate the laws and regulations of their industry, and assist them when problems arise or they become the target of an investigation.



CYNTHIA LIBA

Briefly describe a recent significant transaction, win or client victory.

I worked on a transaction whereby several orthopedic practices joined together to form one large group. To accomplish this endeavor, we worked collaboratively with member physicians from each orthopedic practice and

practice administrators. We structured this transaction and drafted organizational documents to meet the needs and expectations of all parties involved.

Why did you choose to focus your legal practice on healthcare law and the healthcare industry? I took medical ethics classes in college and became interested in the interplay between medicine and the law. I decided to enroll in a health law program in law school and further explored my interest in public health and access to care. I ultimately decided to practice healthcare law because it allows for the opportunity to perform meaningful work that touches the lives of everyone. Further, it is a compelling area of the law as it is constantly evolving.

Brach Eichler is excited to announce that we will be hosting our 2022 NJ Healthcare Market Review, May 11-12, 2022 at the Borgata Hotel Casino & Spa in Atlantic City, NJ. Register today and connect with over 200 professionals in the healthcare industry. Learn more today at www.njhmr.com.

Brach Eichler is proud to announce that both **John D. Fanburg**, Managing Member of the Firm and Chair of the Healthcare Law practice as well as **Isabelle Bibet-Kalinyak** have been selected as a 2022 “Leader in Law” by NJBIZ, recognizing “New Jersey’s leading legal professionals—lawyers and general counsels—whose dedication to their occupation and to their communities is outstanding.”

On April 25, **Isabelle Bibet-Kalinyak** presented with Cascade Partners’ Rajesh Kothari at the [ASCRS Foundation/ASOA Conference](#) in Washington D.C. on “Private Equity Investors 2022: Practice Lifecycle Match Made in Heaven.”

On April 14, Healthcare Law Member **Joseph Gorrell** is quoted in the [Bergen Record](#) about the state’s immunity provision for nursing homes.

On April 8, Healthcare Law Member **Isabelle Bibet-Kalinyak**, spoke at the 2022 OSMA Symposium on “[Rx for Providers: Practice Expansion Options for Successful Lifecycle Management](#).”

On April 6, Managing Member and Healthcare Law Chair **John D. Fanburg** was recognized as one of the most influential lawyers in New Jersey on the [ROI-NJ 2022 Power List Influencer in the Law](#).

On April 1, [Brach Eichler Promoted Ten Attorneys](#). Congratulations to Healthcare Law newly promoted Members **Edward Hilzenrath**, **Jonathan Walzman** and **Edward Yun**.



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