

Healthcare Law UPDATE

FEDERAL UPDATE

HHS to Distribute \$560 Million in Phase 4 COVID-19 Provider Relief Funds

On February 24, 2022, the U.S. Department of Health & Human Services (HHS) [announced](#) that it was beginning the distribution of another \$560 million in Provider Relief Fund (PRF) Phase 4 General Distribution payments to more than 4,100 healthcare providers affected by the COVID-19 pandemic across the country. This is the third batch of payments in the PRF Phase 4, bringing the total amount of distributed payments in this phase to nearly \$11.5 billion to more than 78,000 providers in all



50 states, Washington D.C., and the five U.S. territories. The payments are in addition to the American Rescue Plan (ARP) Rural payments of almost \$7.5 billion, which have been given to more than 44,000 providers since November 2021.

According to HHS, “Phase 4 payments have an increased focus on equity, including reimbursing a higher percentage of losses for smaller providers and incorporating bonus payments for providers who serve Medicaid, Children’s Health Insurance Program (CHIP), and Medicare beneficiaries.”

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To receive funds, providers must demonstrate revenue losses and expenses associated with the COVID-19 pandemic between July 1, 2020, and March 31, 2021. As of the date of the HHS announcement, about 86% of all Phase 4 applications have been processed, and the remaining applications will be processed in early 2022. So far, providers in New Jersey (2,589) [have received](#) the ninth (9th) highest PRF payment amounts during the PRF Phase 4, collecting an aggregate payment amount in excess of \$336 million, or approximately 3% of the total \$11,706,640,021 distributed nationwide.

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Justice Department Reveals \$5.6 Billion in False Claims Act Recoveries in 2021

The U.S. Department of Justice (DOJ) [recently published](#) that it received more than \$5.6 billion in settlements and judgments from civil cases involving fraud and false claims against the government during the fiscal year ending September 30 2021. The DOJ announced that this amount ranks as the second highest annual total in the False Claims Act (FCA) history and the largest since 2014. These substantial DOJ recoveries should serve as a warning for all healthcare industry participants as over \$5 billion relates to matters involving such participants.

Among the diverse healthcare industry actors contributing to the settlements and judgments collected were (1) settlements with prescription opioid manufacturers, (2) resolution of allegations of unlawful kickbacks for improper payments by drug manufacturers, hospitals, and medical device companies, among others, (3) matters related to the Medicare Advantage Program, also known as Medicare

Part C, (4) resolution of allegations against medical providers for billing unnecessary medical services without regard for a patient's actual clinical needs, and (5) allegations of fraud related to the COVID-19 pandemic, including improper payments under the Paycheck Protection Program.

The DOJ recoveries under the FCA highlight that enforcement under the statute continues to be a priority for the government. Healthcare participants should remain diligent in ensuring that they have comprehensive compliance policies and procedures in place, including compliance officers, training, and ongoing auditing and monitoring activities.

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Crackdown on Illegal Healthcare Kickbacks Involving Physicians and Nurse Practitioner

The U.S. Attorney's Office for the Northern District of Texas [announced](#) a 26-count indictment of ten people, including two medical doctors and a nurse practitioner, in an alleged \$300 million healthcare fraud scheme involving Medicare and other federal healthcare programs. The defendants—founders of several laboratory companies—are accused of offering or paying for illegal kickbacks to healthcare professionals, conspiracy to commit healthcare fraud, conspiracy to commit to pay and receive healthcare kickbacks, and soliciting kickbacks.

The indictment alleges that the founders, through their laboratories, paid kickbacks to induce medical professionals to order medically unnecessary tests paid by the Medicare program and used marketers to pay fees to physicians for "advisory services" that were not performed, in exchange for lab test referrals. In addition, the labs allegedly paid portions of the salaries of referring physician offices' staff and property lease expenses contingent upon the number of monthly referrals of lab tests to the laboratories. If convicted, the defendants could face up to 55 years or more in federal prison.

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OIG Calls for Increased Scrutiny of Payments to Nonhospice Providers

According to a data brief from the U.S. Department of Health & Human Services, Office of Inspector General (OIG) issued on February 14, 2022, Medicare paid a total \$6.6 billion to nonhospice providers for services provided to hospice beneficiaries between 2010 and 2019. Nonhospice payments are payments for items and services provided to beneficiaries by nonhospice providers outside the Medicare hospice benefit during a hospice period of care. The OIG's data analysis demonstrates that:

- The majority of the \$6.6 billion in payments to nonhospice providers for hospice beneficiaries were for Medicare Part B items and services.
- Nonhospice payments for Medicare Part A services decreased 45 percent while payments for Part B items and services increased 38 percent.
- Almost half of the 1.2 to 1.6 million annual hospice beneficiaries received nonhospice items and services during a hospice period of care.
- The number of for-profit hospices relative to nonprofit hospices has grown significantly, and the majority of nonhospice payments were associated with for-profit hospices.

While the data brief does not contain new recommendations from the OIG, it reiterates recommendations previously made to CMS to establish oversight and scrutiny of Medicare nonhospice payments. Previous OIG recommendations to CMS include (1) working directly with hospices to ensure that they are providing drugs covered under the hospice benefit, and (2) executing a strategy to ensure that Medicare Part D does not pay for drugs that should be covered by the Part A hospice benefit. In response to the OIG's recommendations, CMS has stated that services unrelated to the terminal illness and related conditions should be exceptional, unusual and rare given the comprehensive nature of the services covered under the Medicare hospice benefit. The OIG plans to

conduct additional audits related to nonhospice items and services provided during a hospice period of care to determine whether Medicare payments for these items and services were made in accordance with the foregoing and other Medicare requirements.

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HHS Issues Guidance to Healthcare Providers Regarding Federal Civil Rights Protections for Individuals with Disabilities During COVID-19 Public Health Emergency

On February 4, 2022, the U.S. Department of Health & Human Services (HHS), Office for Civil Rights (OCR) issued guidance to healthcare providers regarding the applicability of civil rights protections for treating people with disabilities during a public health emergency. The purpose of the guidance is to make clear that “in light of the continuing public health emergency, when resources can be scarce, it is vital that individuals with disabilities are not prevented from receiving needed healthcare benefits and services.”



The applicable laws addressed in the guidance include Section 504 of the Rehabilitation Act of 1973 (Section 504) and Section 1557 of the Affordable Care Act (Section 1557). Section 504 applies to healthcare providers who receive financial assistance from any Federal department or agency, including HHS. Section 1557 applies to any health program or activity receiving federal financial assistance from HHS. Both laws prohibit discrimination in the treatment of patients based on disability. OCR’s position is that healthcare providers subject to Section 504 and Section 1557 may

not discriminate on the basis of disability in offering their health programs and services to disabled individuals and that doing so is a violation of both Section 504 and Section 1557. The guidance also addresses the impact of Section 504 and Section 1557 on healthcare providers’ policies and procedures regarding visitation, vaccination, testing, and contact tracing as they relate to the COVID-19 public health emergency.

In connection with the release of the guidance, HHS indicated that its position and the issuance of the guidance is “one of many comprehensive action steps taken by HHS to support President Biden’s National Strategy for the COVID-19 Response and Pandemic Preparedness to protect those most at risk, advance equity, and address disparities in rates of infection, illness, and death.”

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DOJ Files Statement of Interest in Nevada Non-Compete Dispute

On February 25, 2022, the U.S. Department of Justice (DOJ) submitted its first 2022 statement of interest in a Nevada State court case. The case was filed by a group of anesthesiologists challenging the non-compete provisions in their employment agreements with their employer. The DOJ’s statement does not weigh in on the merits of the state law challenges to those non-compete agreements. Instead, the DOJ argues that assessing the potential competitive effects of non-compete agreements under the Sherman Act (15 U.S.C. § 1) “may inform the Court’s determination whether Nevada law treats them as void and unenforceable.” Accordingly, the DOJ’s statement highlights the antitrust implications of post-employment non-competition restrictions and how such implications impact the enforceability of non-competes under state law.

This DOJ statement of interest may be viewed as an indication that the DOJ intends to increase antitrust enforcement with respect to certain contractual arrangements, including non-compete agreements.

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STATE UPDATE

New Rules Would Allow all New Jersey Professional Boards to Discipline Licensees for Bias or Harassment

On March 7, 2022, in order to address systemic racism and other barriers to equity for historically disadvantaged groups, New Jersey Acting Attorney General Andrew J. Bruck proposed [new rules](#) that would allow professional boards to suspend or revoke professional licenses where a licensee has discriminated against or harassed a current or prospective client, patient, student, supervisee, colleague or employee. Essentially, the rules establish that such conduct would constitute professional or occupational misconduct for all professions, and could result in discipline. To date, only three boards have explicit anti-discrimination regulations: the Board of Social Work Examiners, N.J.A.C. 13:44G-10.7(e); the Alcohol and Drug Counselor Committee, N.J.A.C. 13:34C-1.9(b)5; and the Board of Psychological Examiners, N.J.A.C. 13:42-10.4(d).

The rules available at N.J.A.C. 13:45C-4.1, 4.2 and 4.3 would apply to New Jersey's 51 professional and occupational boards and would affect approximately 720,000 licensees, including chiropractors, dentists, doctors, nurses, physical therapists and social workers.

Comments to the rules must be submitted by May 6, 2022 to the Acting Director of Consumer Affairs and may be submitted via email to DCAProposal@dca.lps.state.nj.us.

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Board of Medical Examiners Proposes Limitations on Prescribing Controlled Dangerous Substances

On February 22, 2022, the New Jersey State Board of Medical Examiners proposed [amendments](#) to its existing rules at N.J.A.C. 13:35-7.6 that would require certain practitioners, including physicians, podiatrists and physician assistants, to identify in advance psychological co-morbidities that affect the prescribing of opioids, overall treatment decisions and to assess whether continued opioid therapy is addressing a patient's



treatment needs. The purpose of the amendments is to ensure that practitioners have a clear understanding of a patient's history from the outset, assess a patient's predilection for addiction and develop treatment objectives accordingly, and continually evaluate whether opioid therapy is providing clinically meaningful improvement in pain and function. Comments on the proposed amendments must be submitted by April 23, 2022 and may be submitted online at <http://www.njconsumeraffairs.gov/Proposals/Pages/default.aspx>.

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Board of Nursing Proposes Power of Attorney and Loan Ban

On February 22, 2022, the New Jersey State Board of Nursing proposed [new rules](#) at N.J.A.C. 13:37-5.4 and 14.18 to prohibit nurses and certified homemaker-home health aides from having power of attorney over patients and former patients and from accepting loans from patients and former patients. In addition, if a nurse or a certified homemaker-home health aide were to receive a gift worth more than \$50.00 from a patient, patient's family, or patient's guardian, the nurse or certified homemaker-home health aide would be required to document the value of the gift and the date it was provided. This document would also need to include the name and signature of the patient, patient's family member, or patient's guardian who provided the gift. Comments on the proposed new rules must be submitted by April 23, 2022 and may be submitted online at <http://www.njconsumeraffairs.gov/Proposals/Pages/default.aspx>.

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Telemedicine Rules Adopted for Licensed Alcohol and Drug Counselors

The New Jersey State Board of Marriage and Family Therapy Examiners adopted [new rules](#) at N.J.A.C. 13:34C-7 authorizing licensed alcohol and drug counselors to engage in telemedicine and telehealth, effective February 22, 2022. Under the recently adopted rules, a licensee who provides services through telemedicine or telehealth will be held to the same standard of care and practice standards as are applicable when services are provided in person. Before a licensee can provide services through telemedicine or telehealth, the licensee must establish a licensee-client relationship by reviewing a client's history and



any available medical records. When a licensee provides services through telemedicine, the licensee must use interactive, real-time, two-way communication technologies that include a video component, unless the licensee determines, after reviewing a client's records, that the licensee can meet the standard of care for such services provided in person without video. In such situations, the licensee must use interactive, real-time, two-way audio in combination with technology that permits the transmission of images, diagnostics, data, and medical information.

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Direct supervision requires that the supervising pharmacist must be physically present at the pharmacy site and is responsible for accuracy and safety with respect to the actions of the pharmacy intern and pharmacy extern.

Board of Pharmacy Adopts Rules Regarding Vaccinations and Emergency Medications

The New Jersey State Board of Pharmacy adopted [new rules](#) at N.J.A.C. 13:39-4.21, effective March 7, 2022, to permit pharmacy interns and pharmacy externs to administer vaccinations and related emergency medications under the direct supervision of a pharmacist. A pharmacy intern is an individual who graduated from a school or college of pharmacy, has applied for licensure by reciprocity and needs to satisfy the Board's practice of pharmacy requirements, or is a graduate student participating in an American Society of Health-System Pharmacists (ASHP) accredited post-graduate pharmacy residency program awaiting licensure. A pharmacy extern is a person who is in the fifth or sixth college year, or the third or fourth professional year, at an American Council of Pharmaceutical Education (ACPE)-approved school or college of pharmacy, who is acquiring practical experience under the supervision of the school or college. Direct supervision requires that the supervising pharmacist must be physically present at the pharmacy site and is responsible for accuracy and safety with respect to the actions of the pharmacy intern and pharmacy extern.

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HIPAA CORNER

HHS Notice and Guidance on Gender Affirming Care, Civil Rights and Patient Privacy

On March 2, 2022, the U.S. Department of Health & Human Services, Office for Civil Rights (OCR) issued a [Notice and Guidance on Gender Affirming Care, Civil Rights, and Patient Privacy](#) (Notice). In the Notice, the OCR states that it “stands with transgender and gender nonconforming youth and their families—and the significant majority of expert medical associations—in unequivocally stating that gender affirming care for minors, when medically



appropriate and necessary, improves their physical and mental health” and “will continue working to ensure that transgender and gender nonconforming youth are able to access healthcare free from the burden of discrimination.”

The OCR reminds healthcare providers that the agency enforces federal civil rights laws that prohibit discrimination restrictions on access to healthcare ([Section 1557](#) of the Affordable Care Act and [Section 504](#) of the Rehabilitation Act of 1973).

In the Notice, the OCR also provides guidance concerning HIPAA and limitations on the circumstances under which healthcare providers and other entities covered under HIPAA may disclose protected health information (PHI) such as gender affirming physical or mental health care administered by a licensed provider. In particular, HIPAA prohibits disclosure of gender affirming care that is PHI without an individual’s written authorization, except in limited situations. The OCR specifically highlights that HIPAA permits,

but does not require, the disclosure of PHI without an individual’s authorization when the disclosure is required by another law and the disclosure complies with the requirements of the law. The OCR explains:

This “required by law” exception to the authorization requirement is limited to “a mandate contained in law that compels an entity to make a use or disclosure of PHI and that is enforceable in a court of law.” Where a disclosure is required by law, the disclosure is limited to the relevant requirements of such law. Disclosures of PHI that do not meet the “required by law” definition or exceed what is required by such law do not qualify as permissible disclosures under this exception.

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BRACH EICHLER

IN THE NEWS

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. Join us as a sponsor or an attendee and connect with over 200 professionals in the healthcare industry. Learn more and register today at www.njhmr.com.

The following Healthcare Law Members were named [2022 New Jersey Super Lawyers](#)! Congratulations to **John D. Fanburg, Joseph M. Gorrell, Carol Grelecki, Thomas Kamvosoulis** and **Keith J. Roberts**. Counsel **Shannon Carrol** was named a NJ Rising Star. Managing Member and Healthcare Law Chair **John D. Fanburg** was named to [NJBIZ’s 2022 Power 50 in Health Care](#).

On March 16, Healthcare Members **Isabelle Bibet-Kalinyak, Lani M. Dornfeld** and **Joseph M. Gorrell** presented a webinar on “[Federal Stark Law and Anti-Kickback Statute Changes for 2022 and Beyond](#).”

On March 10, Healthcare Law Member **Lani Dornfeld** issued a client alert about Executive Order 292, “[Governor Murphy Signs Executive Order Terminating the COVID-19 Public Health Emergency](#).” She also issued an alert on March 8, entitled “[Texas Court Sets Aside Key Parts of the Independent Dispute Resolution Process Under the Federal No Surprises Act – All Jurisdictions Affected](#)” and issued an alert on March 7, entitled “[Governor Murphy Signs Executive Order 290, Extending Vaccination Deadlines for Healthcare Workers](#).”

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 M. Dornfeld and Associate James J. Ko.



LANI M. DORNFELD

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

I have successfully closed a number of transactions involving the sale of medical businesses—surgery centers, home health and hospice agencies, medical practices, and dental practices, to name a few. Many of these

transactions have involved private equity partners, and so the issues can become quite complex. In addition, I have successfully defended clients in the government's investigation of large and small health care data and security breaches, and have ongoing breach matters throughout the year.

Why did you choose to focus your legal practice on healthcare law and the healthcare industry? I was a latecomer to law, starting law school when my children were very young. By that time, I already had a career managing dental practices, which I continued to do until taking the bar exam after graduating law school. This exposure to a portion of the healthcare industry made me choose Seton Hall Law School because of its health law certification program. I was in the second graduating class of students eligible to receive this certification. It is also the reason I chose Brach Eichler, which has been my career home since law school graduation.



JAMES J. KO

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

I was involved in a sizeable transaction last year involving a health care system purchasing a majority interest in our client's orthopaedic medical practice. The letter of intent was signed on November 15, 2021. Our client charged

us with closing the sale before the end of the year. Under the leadership of Carol Grelecki and Caroline Patterson, we assembled a team of attorneys who worked around the clock to meet the client's deadline; we closed on December 31, 2021. Although challenging, working as part of the team of attorneys on this transaction was extremely rewarding.

Why did you choose to focus your legal practice on healthcare law and the healthcare industry? My great-great-grandfather was the first westernized physician in Korea (back then, the country was called Joseon) and multiple men and women in my family followed his footsteps. Although I was also expected to be a doctor, I was afraid of blood, so clearly I could not treat patients myself. Instead, I decided to devote my career to practicing healthcare law. When I married my wife, a dentist, this motivation to become a healthcare lawyer became even stronger.

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