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Healthcare Law UPDATE

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FEDERAL UPDATE

President Biden Announces 6-Pronged Plan To Combat COVID-19

On September 9, 2021, President Biden announced the White House's "six-pronged, comprehensive national strategy" to combat COVID-19. The plan comes in response to a surge in COVID-19 cases due to the delta variant of the virus and continued resistance to vaccination.

The six prongs of the White House Plan include:

- Vaccinating the unvaccinated
- Furthering protection for the vaccinated
- Keeping schools safely open
- Increasing testing and requiring masking
- Protecting our economic recovery
- Improving care for those with COVID-19

Of most significance for healthcare providers, the President's plan calls on the Department of Labor's Occupational Safety and Health Administration (OSHA) to develop a rule that will require all employers with 100 or more employees to ensure their workforce is fully vaccinated or require any workers who remain unvaccinated to produce a negative test result on at least a weekly basis before coming to work. OSHA will issue an Emergency Temporary Standard (ETS) to implement that requirement. On June 21, 2021, OSHA issued a Healthcare Emergency Temporary Standard (ETS), relating to COVID-19 that applied only to healthcare employers.

In addition, the plan also authorizes the Centers for Medicare & Medicaid Services (CMS) to require COVID-19 vaccination for workers in most healthcare settings that receive Medicare or Medicaid reimbursement, including hospitals, dialysis facilities, ambulatory surgical settings, and home health agencies. This action is in addition to the vaccination requirement for nursing facilities recently announced by CMS and will apply to nursing home staff as well as staff in hospitals and other CMS-regulated settings, including clinical staff, individuals providing services under arrangements, volunteers, and staff who are not involved in direct patient, resident, or client care. This requirement is an attempt to create a consistent standard across the country for vaccination and testing requirements for healthcare providers, particularly in response to the various

states which have adopted healthcare sector vaccination mandates, such as Executive Order 252 issued by New Jersey Governor Murphy on August 6, 2021.

No draft regulations have yet been proposed for the above measures.

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Spreading COVID-19 Vaccine Misinformation May Put Medical License at Risk

On July 29, 2021, the Federation of State Medical Boards (FSMB), which supports its member state medical licensing boards, released a statement in response to the increased spread of COVID-19 vaccine misinformation by physicians and other healthcare professionals. The statement reads: "Physicians who generate and spread COVID-19 vaccine misinformation or disinformation are risking disciplinary action by state medical boards, including the suspension or revocation of their medical license. Due to their specialized knowledge and training, licensed physicians possess a high degree of public trust and therefore have a powerful platform in society, whether they

recognize it or not. They also have an ethical and professional responsibility to practice medicine in the best interests of their patients and must share information that is factual, scientifically grounded, and consensus-driven for the betterment of public health. Spreading inaccurate COVID-19 vaccine information contradicts that responsibility and threatens to further erode public trust in the medical profession, and puts all patients at risk."

On September 9, 2021, the American Board of Family Medicine (ABFM), the American Board of Internal Medicine (ABIM), and the American Board of Pediatrics (ABP) issued a statement in support of the FSMB's statement. The aforementioned boards want all physicians certified by such boards to know that such unethical or unprofessional conduct may prompt their respective boards to take action that could put their certification at risk.

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HHS Announces New Funding Available to Providers Under Provider Relief Fund

The U.S. Department of Health & Human Services (HHS) has made $25.5 billion in new funding available for healthcare providers affected by the COVID-19 pandemic. The new funding includes $17 billion for Provider Relief Fund (PRF) Phase 4 for providers who can document revenue loss and expenses associated with the pandemic. It also includes $8.5 billion in American Rescue Plan (ARP) resources for providers who serve rural Medicaid, Children's Health Insurance Program (CHIP), or Medicare patients. The application portal for the new funding opened on September 29, 2021.

Administered by the Health Resources and Services Administration (HRSA), the Phase 4 payments will be based upon providers' lost revenues and expenditures between July 1, 2020, and March 31, 2021. Phase 4 will also include new elements specifically focused on equity, such that HRSA will reimburse smaller providers at a higher rate compared to larger providers. Phase 4 will also include bonus payments for providers who serve Medicaid, CHIP, and/or Medicare patients, in which bonuses will be paid at the typically higher Medicare rates. The ARP rural payments will be based on the amount of Medicaid, CHIP, and/or Medicare services provided to patients who live in rural areas as defined by the HHS Federal Office of Rural Health Policy. The rural payments will be based on Medicare reimbursement rates.

Providers will apply for both programs in a single application, and HRSA will use existing Medicaid, CHIP, and Medicare claims data to calculate payments. Phase 4 fund recipients will be required to notify HHS of any merger with, or acquisition of, another healthcare provider during the period in which the payments may be used. Recipients who report a merger or acquisition are more likely to be audited to confirm that the PRF funds were applied properly for COVID-19 related costs.

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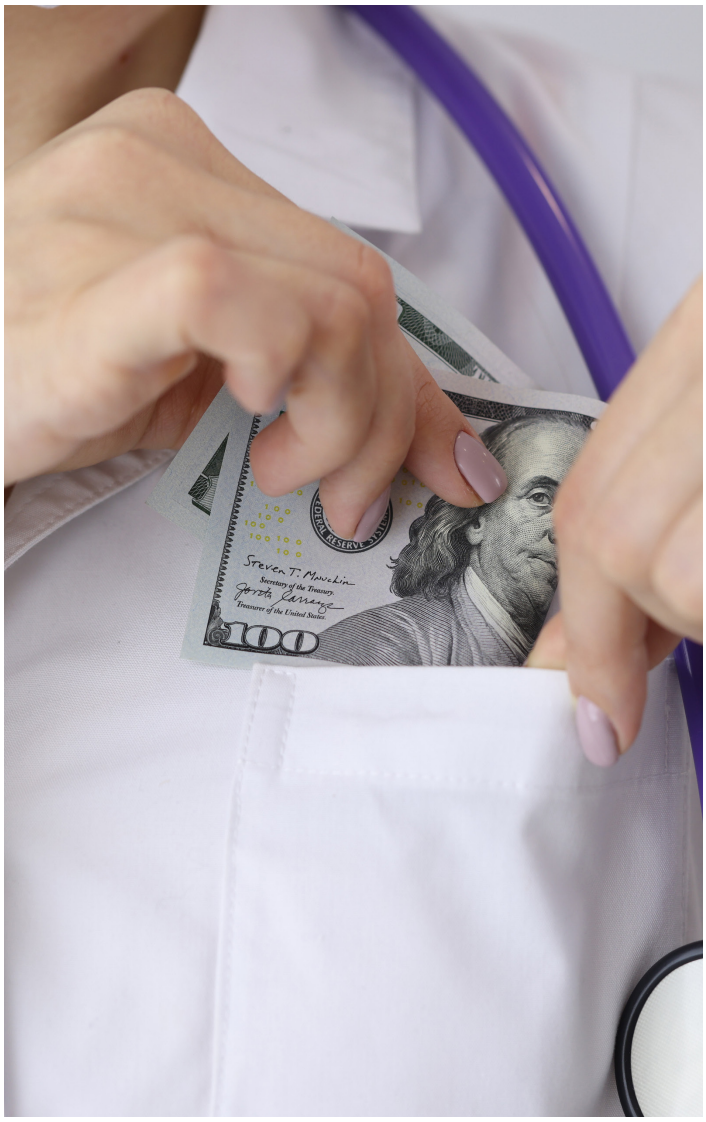
DOJ Announces Charges in $1.4B Fraud Scheme, Including by Use of Telemedicine

On September 17, 2021, the U.S. Department of Justice (DOJ) announced criminal charges against 138 defendants, including 42 doctors and other healthcare providers in 31 federal districts across the country, alleging participation in various healthcare schemes resulting in approximately $1.4 billion in alleged losses.

The largest target is fraud committed using telemedicine, in the amount of approximately $1.1 billion, resulting from allegedly false and fraudulent claims submitted by more than 43 defendants. Allegations include telemedicine executives paying doctors and nurse practitioners to order unnecessary durable medical equipment (DME), genetic and other diagnostic testing, and pain medications either without any patient interaction or with only a brief telephonic conversation with patients the providers had never met or seen. DOJ alleges that DME companies, genetic testing laboratories, and pharmacies then purchased those orders in exchange for illegal kickbacks and other bribes and submitted false and fraudulent claims to Medicare and other government payers. Allegations also included "sham" telemedicine consultations.

DOJ alleges the kickbacks and other monies received were used to purchase luxury items such as vehicles, yachts, and real estate.



COVID-19 fraud cases totaling over $29 million are alleged against nine of the defendants. Allegations include exploiting policies put into place by Centers for Medicare & Medicaid Services to increase access to care during the COVID-19 pandemic, such as expanded telehealth regulations. Charges include misuse of patient information to submit claims to Medicare for unrelated laboratory testing that was expensive and unnecessary, including cancer genetic testing. Also targeted were sober homes, including allegations of over $133 million in false and fraudulent claims for tests and treatments relating to drug and alcohol addiction. Nineteen defendants were charged with illegal prescription and/or distribution of opioids, with over $14 million in false billings.

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Bayada Pays $17 Million to Settle AKS Whistleblower Allegation

Bayada Home Health Care, Inc. and some of its affiliates (Bayada) have agreed to pay $17 million to settle false claims allegations relating to Bayada's purchase of home health facilities in Arizona. According to the allegations brought by the U.S. Department of Justice (DOJ), Bayada allegedly violated the Federal Anti-Kickback Statute (AKS) by paying a kickback to a retirement home operator by purchasing two home health agencies from the seller to secure patient referrals from retirement communities operated by the seller throughout the United States. The AKS prohibits parties who participate in federal healthcare programs from knowingly and willfully offering, paying or receiving any remuneration to induce referrals for items or services that are reimbursable under covered federal healthcare programs.

In its announcement of the settlement, the DOJ emphasized that the government will continue to pursue parties that offer kickbacks in exchange for referrals, no matter how those kickback arrangements are disguised. The settlement includes the resolution of claims brought by a former high-ranking employee of Bayada under the *qui tam*, or whistleblower, provisions of the Federal False Claims Act, who will receive more than $3 million as part of the settlement. The allegations against Bayada serve as a reminder that in structuring transactions between

healthcare providers, it is imperative to consider the parties' true intentions in entering into a transaction and how those intentions might implicate laws governing healthcare providers, such as the AKS.

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STATE UPDATE

New Law Revises Long-Term Care Facility Outbreak Response Plans

On August 5, 2021, Governor Phil Murphy signed Bill S2798 into law to revise the requirements for long-term care facilities to establish outbreak response plans. The new law now requires, as a condition of licensure, nursing homes, assisted living facilities, comprehensive personal care homes, residential healthcare facilities, and dementia care homes to develop outbreak response plans within 180 days of the new law's effective date of August 5, 2021. The plan must be customized to the facility, based upon national standards and developed in consultation with the facility's infection prevention and control committee. Before the new law, outbreak response plans were not a condition of licensure.

Nursing homes must also establish an infection prevention and control committee and assign to the facility's infection prevention and control committee a physician who has completed an infectious disease fellowship and an individual designated as the infection preventionist who (i) has primary professional training in medicine, nursing, medical technology, microbiology, epidemiology or a related field, (ii) is qualified by education, training, and at least five years of infection control experience, or by certification in infection control by the Certification Board of Infection Control and Epidemiology, (iii) is employed by the facility consistent with the requirements of the new law and (iv) has completed specialized training in infection prevention and control. Assisted living facilities, comprehensive personal care homes, residential care facilities, and dementia care homes must also establish infection prevention and control committees, but they are not required to assign a physician to the committee and the infection preventionist must be an individual who is a licensed healthcare provider and who has five years of experience in infection control or an individual who has completed an online infection prevention course through the federal Centers for Disease Control and Prevention or the American Health Care Association.

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Department of Health Adopts Registration Rules for Telemedicine and Telehealth Organizations

Effective August 16, 2021, the New Jersey Department of Health (DOH) has adopted registration rules for telemedicine and telehealth organizations. The new rules implement the requirements of New Jersey's telemedicine and telehealth statute, which requires each telemedicine or telehealth organization operating in New Jersey to register with the DOH on an annual basis. A telemedicine or telehealth organization is defined as a corporation, sole proprietorship, partnership, or limited liability company that is organized for the primary purpose of administering services in the furtherance of telemedicine or telehealth. Healthcare facilities that simply utilize telemedicine or telehealth services in addition to in-person evaluation and care services are not required to register or pay registration fees. Under the new rules, organizations must register electronically on the DOH portal on an annual basis and pay a fee of $1,500.

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Brach Eichler In The News

On September 16, Healthcare Member **Lani Dornfeld** was quoted in *Modern Healthcare* about the FTC Health Breach Notification Rule and how health apps and medical devices safeguard the data they collect.

On September 15, Brach Eichler was spotlighted for being named *New Jersey Law Journal's* 2021 Healthcare Litigation Department of the Year.

On August 26, Managing Member and Healthcare Law Chair **John D. Fanburg** discussed transaction delays for UnitedHealth Group and Change Healthcare merger in *Modern Healthcare.*

On August 19, 17 Brach Eichler attorneys were included in The Best Lawyers in America© 2022 and six attorneys were named to "Ones to Watch."

On August 12, Managing Member and Healthcare Law Chair **John D. Fanburg** talks about the decision to block the Hackensack Meridian Health acquisition of Englewood Health in *The Record.*

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 Keith J. Roberts and Counsel Colleen Buontempo.

Keith J. Roberts

Keith J. Roberts is an accomplished civil trial attorney certified by the New Jersey Supreme Court. He has tried over 50 cases to a jury verdict in addition to bench trials, as well as complex administrative actions and arbitrations. Keith is a recognized expert in healthcare litigation matters comprising of insurance coverage and reimbursement disputes, insurance fraud defense, disciplinary proceedings before state licensing boards, and complex business disputes. As a member of the Healthcare Law Practice at Brach Eichler, Keith is often called upon to represent hospital systems, surgical centers, medical practices, and a wide array of healthcare professionals.

Outside of the office, Keith enjoys photography, the pursuit of culinary skills, and is an enthusiast of Napa Valley Cabernet.

Colleen Buontempo

Colleen Buontempo represents clients primarily in PIP arbitration with approximately 65-70% of cases settling and approximately a 93% success rate for cases that proceed through arbitration. She has successfully represented and recovered millions of dollars for her clients including individuals, ambulatory care facilities, hospitals, physician groups, and healthcare entrepreneurs.

On the weekends, Colleen likes to spend time with her husband and children attending swimming, soccer, and softball events. Colleen volunteers at her church as a youth minister and also plays women's soccer herself.

HIPAA CORNER

Healthcare Breach Report: Who is Getting Breached? – In its *2021 Healthcare Data Breach Report*, Critical Insight reported that "[d]ata on cyberattacks from the first half of 2021 shows criminals are changing targets within the healthcare ecosystem, with breaches increasing for outpatient facilities and business associates. The data also shows some long-term trends continuing, with overall attacks on an upward trend." The report highlights 2020 as "a year memorable for both COVID-19 and an explosion of ransomware attacks."

Although the number of breaches reported to the U.S. Department of Health & Human Services in the first half of 2021 declined from the second half of 2020, this number gives "false hope," since a breach like the Blackbaud ransomware attack was one of the biggest breaches of the year, impacting millions of individuals. Categories of breach incidents include theft, improper disposal, loss, unauthorized access/disclosure, and hacking/IT incident, the last of which "captures any breach that's the result of criminal hackers or compromise in cybersecurity systems and is the main cause of breaches."

Targets of cyberattacks are changing—outpatient family medicine and specialty clinics and business associates have become primary targets. The report also addresses the extreme costs associated with healthcare data breaches: according to IBM's *Cost of a Data Breach Report 2021*, an average of $9.23 million, a 29.5% increase from IBM's previous report.

The report includes suggestions for healthcare providers, including assessing third-party risk, management of business associate agreements, ransomware prevention and response, implementing strong access controls, and practicing basic security hygiene. Of course, these items are all important components of a compliant and active privacy and security

program as required under HIPAA. Healthcare providers previously taking a casual approach to HIPAA compliance should take heed and consider updating, implementing, or supplementing their HIPAA compliance programs, including the educational component, to assist in preventing small and large-scale breach incidents and the collateral damage associated with such breaches.

Health App Designers Beware: FTC Will Enforce Health Breach Notification Rule – On September 15, 2021, the Federal Trade Commission (FTC) issued a policy statement in which the FTC affirmed that health apps and connected devices that collect or use consumers' health data must comply with the Health Breach Notification Rule (HBN Rule). Per the FTC:

The FTC's Health Breach Notification Rule helps to ensure that entities who are not covered by the Health Insurance Portability and Accountability Act ("HIPAA") nevertheless face accountability when consumers' sensitive health information is compromised. Under the Rule's requirements, vendors of personal health records ("PHR") and PHR-related entities must notify U.S. consumers and the FTC, and, in some cases, the media, if there has been a breach of unsecured identifiable health information, or face civil penalties for violations. The Rule also covers service providers to these entities. In practical terms, this means that entities covered by the Rule who have experienced breaches cannot conceal this fact from those who have entrusted them with sensitive health information.

Although the HBN Rule was promulgated in 2009, the FTC admitted in the policy statement that it has never enforced the rule, "and many appear to misunderstand its requirements." The FTC issued the policy statement to clarify that vendors of personal health records that contain individually identifiable health information and developers of health apps or connected devices that collect and use such personal data must comply with the rule. In relevant part, the HBN Rule requires notification to individuals and the FTC, and in some cases the media, in the event of a breach of individually identifiable health information. In many respects, the breach notification requirements track the requirements of the HIPAA Breach Notification Rule.

The FTC further advised entities covered by the HBN Rule that "a 'breach' is not limited to cybersecurity intrusions or nefarious behavior. Incidents of unauthorized access, including sharing of covered information without an individual's authorization, triggers notification obligations under the Rule." Most notably, the FTC warns that, despite its prior lack of enforcement, it intends to bring actions to enforce the HBN Rule going forward. Violations of the Rule may trigger civil penalties of $43,792 per violation per day.

For more information or assistance with your privacy and security program or managing a breach incident contact:

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