

Healthcare Law UPDATE

FEDERAL UPDATE

OSHA Issues COVID-19 Healthcare ETS

On June 10, 2021, the U.S. Department of Labor, Occupational Safety and Health Administration (OSHA) announced an [emergency temporary standard](#) addressing steps that employers must take to protect their employees from the risk of COVID-19. The rule applies only to the healthcare industry, and not other high-risk work environments. Its purpose is to protect the frontline healthcare workers who face the highest coronavirus hazards – those working in healthcare settings with patients with suspected or confirmed COVID-19 diagnoses. Specifically, hospitals, nursing homes, assisted living facilities, emergency responders, home healthcare workers, and employees of ambulatory care settings who work directly with suspected or confirmed COVID-19 patients are to abide by this emergency temporary standard. The rule requires employers covered by the rule to, among other things:

- Conduct a hazard assessment and have a written plan to mitigate the spread of COVID-19;
- Screen and triage all clients, patients, residents, and other visitors entering the setting;
- Provide proper personal protective equipment including facemasks and respirators;
- Ensure 6 feet of distance between workers – if not possible, erect barriers between employees where feasible;
- Follow standard practices for cleaning and disinfection of surfaces and equipment;
- Ensure proper ventilation;
- Screen each employee before each workday and shift for COVID-19 symptoms;
- Offer paid time off to get vaccinated and to recover from side effects; and
- Offer paid time off, remote work, or be separated from other workers if positive COVID-19 test.

The rule provides that those who are vaccinated do not need to wear face masks, distance, or set

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up barriers where there is no reasonable expectation that any person will be present with suspected or confirmed coronavirus.

The rule is effective immediately. Employers must comply with most provisions within 14 days of the effective date and the remaining provisions within 30 days of the effective date. OSHA offers [guidance](#) to help employers determine if their workplace is covered under this ETS, answers to [frequently asked questions](#), and other [resources](#) to help maintain compliance with this standard.

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HHS Announces New Usage and Reporting Deadlines for Provider Relief Fund Recipients

The U.S. Department of Health & Human Services (HHS) has released an updated [Notice of Reporting Requirements](#) (Notice) for healthcare providers who received one or more Provider Relief Fund (PRF) payments exceeding \$10,000 in the aggregate during any “Payment Received Period.” The new deadlines to expend funds and to report on the usage of funds varies depending on the time period during which the PRF payment was received. PRF recipients who do not report within the respective reporting time period are out of compliance with payment Terms and Conditions and may be subject to recoupment.

Further information may be found in our [Healthcare Law Alert](#) on this topic.

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Greater Access to the COVID-19 Vaccine

On June 9, 2021, the Centers for Medicare & Medicaid Services (CMS) [announced](#) its decision to increase the Medicare payment amount providers receive when administering in-home COVID-19 vaccinations. CMS approximates there are 1.6 million adults, 65 and older, who have difficulty leaving their



homes to obtain the COVID-19 vaccine. To reach these individuals, CMS is incentivizing providers to administer in-home vaccinations by increasing the payment amount from approximately \$45 to approximately \$75 per vaccine dose; for a two-dose vaccine it would mean a total payment of approximately \$150. This is approximately a \$70 increase.

CMS notes the payment amount will be geographically adjusted to where

the service is provided. The increase in payment amount is to account for the clinical time needed to monitor a patient after receiving the vaccination and up-front costs associated with providing in-home vaccinations. As the COVID-19 vaccine has unique storage, handling, and administration requirements, the Centers for Disease Control and Prevention (CDC) has published [guidance](#) to assist providers in overcoming challenges associated with providing in-home COVID-19 vaccinations.

The federal government has and continues to provide the COVID-19 vaccine free of charge or with no-cost sharing for all people living in the United States. For the underinsured, providers may submit a reimbursement request to the [COVID-19 Coverage Assistance Fund](#), after a claim has been denied or partially paid. For uninsured patients, providers may submit for reimbursement through the [Provider Relief Fund](#). Providers are not permitted to bill Medicare beneficiaries for COVID-19 vaccinations. For private health plans and issuers, the vaccine is free for those enrolled, and its administration is covered without cost-sharing for most participants.

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EHR Developer Pays \$3.8 Million to Settle Kickback Claims

CareCloud Health, Inc. f/k/a CareCloud Corporation (CareCloud), a developer of electronic health records (EHR), has agreed to pay [\\$3.8 million to settle](#) claims by the federal government that it paid unlawful kickbacks to promote its EHR products.

By way of background, in 2017, a former senior manager at CareCloud filed a [federal qui tam](#), or whistleblower, action alleging, among other claims, that CareCloud paid kickbacks to clients to promote their services. As a result, the whistleblower alleged, the program violated the federal Anti-Kickback Statute and False Claims Act (FCA). The United States reviewed the whistleblower’s claims and decided to prosecute the case against CareCloud. The United States alleged that CareCloud gave existing clients cash equivalent credits, cash bonuses, and success payments to recommend its services to potential new clients. In addition, clients participating in the incentive program were prohibited from giving negative information about CloudCare to potential clients.

The whistleblower will receive \$803,269.97 for bringing the original lawsuit. The whistleblower got the idea to bring a lawsuit by reading about a previous settlement of \$155 million by EHR vendor eClinicalWorks. These settlements are a reminder to all in the healthcare industry to maintain a robust compliance program, including addressing marketing efforts.

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STATE UPDATE

Governor Murphy Signs Legislation and Executive Order Ending COVID-19 Public Health Emergency

On June 4, 2021, Governor Murphy signed [legislation](#) enabling the end of the COVID-19 Public Health Emergency that has been in place since March 9, 2020. Immediately following the signing of the legislation, Governor Murphy signed Executive Order No. [244](#), ending the COVID-19 Public Health Emergency.

Under the new legislation, a majority of the Governor's pandemic-era executive orders (EO) will expire on July 4, 2021. The new legislation, however, keeps fourteen pandemic-era executive orders active until January 1, 2022, unless Governor Murphy revokes or modifies them sooner. Notable executive orders that will remain active include:

- EO No. 111: Directs healthcare facilities to report data concerning their capacity and supplies on a daily basis. This EO was issued to ensure that the State has complete data on the healthcare system's existing capacity to prepare for and respond to the outbreak of COVID-19.
- EO No. 112: Removes barriers to healthcare professionals joining New Jersey's COVID-19 response and provides protections for front-line healthcare responders. This EO incentivizes participation by providing immunity from civil liability for any damages alleged to have been sustained as a result of any act or omission undertaken in good faith, whether or not within the scope of the licensee's practice if done in the course of providing healthcare services in support of the COVID-19 response in New Jersey.

Notwithstanding EO No. 112 remaining in place until January 1, 2022, the civil and criminal immunity given to healthcare professionals and facilities, including long-term care facilities, and existing waivers of regulations involving staffing ratios, overtime, shifts, and vacation time will expire on September 1, 2021. The civil immunity for healthcare professionals shall continue beyond September 1, 2021, only for individuals specifically engaged in vaccinations or testing related to COVID-19. According to the legislation, the State may continue to issue orders, directives, and waivers that are related to COVID-19 vaccination and testing efforts, implementation of CDC recommendations, coordination of local health departments, and other aspects of New Jersey's recovery from the pandemic.

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Appeals Court Rules That a Draft Operating Agreement Not Signed by All LLC Members is Not a Final and Binding Agreement

In *Premier Physician Network, LLC v. Maro*, the issue was whether an operating agreement of a limited liability

company (LLC) that was signed by only some of the original members was a final and binding agreement. The original members of the LLC had agreed to the formation of the LLC upon the execution of a "Letter of Intention Agreement." A draft operating agreement was then circulated among the members, but it was signed only by some, but not all the members. A few years after the LLC's formation, some of the members who had not signed the operating agreement voluntarily left the LLC. The LLC sued the departing members alleging that they owed certain shortfall amounts and penalties under the terms of the operating agreement.



The Appellate Division ruled in a [May 26, 2021 decision](#) that a draft operating agreement does not become the valid and controlling operating agreement of an LLC unless there is an agreement of all of the original members. The specific issue for the Court was whether the members of the LLC were bound by the terms of the draft operating agreement by "assent" under a New Jersey statute which states that "[a] person that becomes a member of a limited liability company is deemed to assent to the operating agreement." The court ruled that such "deemed" assent only binds future members of an LLC to an already agreed upon operating agreement. For the original members of the LLC, those members must show their assent to the operating agreement in writing, verbally, or by their acts. In this case, all of the parties agreed that the departing members did not agree in writing or verbally to the draft operating agreement, but they dispute whether their actions constituted consent to the draft operating agreement. That would be an issue for the trial court to resolve.

In light of this court decision, medical practices or other healthcare entities formed as LLCs must be careful to ensure that all original members of the LLC sign the operating agreement to avoid costly disputes in the future. Although the court made clear that future members of an LLC are deemed to assent to an operating agreement upon becoming

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a member, for the avoidance of any doubt, LLCs should ensure that all future members of the LLC sign a document joining them as parties to the operating agreement of the LLC.

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Governor Murphy Signs Legislation Creating COVID-19 Pandemic Task Force on Racial and Health Disparities

On June 11, 2021, Governor Phil Murphy signed [Bill A4004](#)

into law to create the Coronavirus Disease (COVID-19) Pandemic Task Force on Racial and Health Disparities. Key purposes of the task force include the following: (i) conduct a comprehensive study on how, and why the COVID-19 pandemic has disproportionately affected the State's minority and vulnerable communities, and the short-term and long-term consequences of the pandemic on these communities; (ii) study and make recommendations to improve existing data systems to ensure that the health information that

is collected relating to COVID-19 infections and deaths, includes specific race, ethnicity, and demographic identifiers to develop a better statistical understanding of how the COVID-19 pandemic has affected the State's minority and vulnerable communities; and (iii) reduce and eliminate disparities among the various racial and ethnic populations within the State's minority and vulnerable communities concerning health status, access to high-quality healthcare, and utilization of healthcare services.

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NJDOH Issues Revised COVID-19 Protocols for ASCs Resuming Services

On June 16, 2021, the Commissioner of the New Jersey Department of Health (NJDOH) issued a [Revised Executive](#)

[Directive](#) setting forth COVID-19 protocols for ambulatory surgery centers (ASCs) resuming elective surgeries and invasive diagnostic procedures. The protocols are in response to the declining number of COVID-19 cases and hospitalizations and the significant progress of the State's vaccination program.

Further information may be found in our [Healthcare Law Alert](#) on this topic.

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Revisions to Licensure Requirements for Nursing Homes

On May 12, 2021, [amendments](#) were signed into law that revises the licensure, operational, and reporting requirements for nursing homes. Specifically, the amendments revise a provision of current law that allows nursing homes to increase their total bed capacity by a limited amount without the need to obtain a certificate of need, to provide that beds added in this manner may not be transferred to another nursing home without obtaining a certificate of need. Additionally, the amendments prohibit the transfer of beds that are part of an unimplemented certificate of need to another nursing facility without obtaining a certificate of need. The prospective owner must apply to the New Jersey Department of Health (DOH), and DOH approval will be based on a review of the applicant's history of disciplinary actions in connection with other healthcare facilities, payment of all outstanding Medicaid audit claims against the current owner,

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and a background check of each proposed owner. A copy of the transfer of ownership materials must be published on the DOH's website and undergo a period of public comment.

The amendments also provide that a nursing home may not delegate substantial management control of the nursing home's operations without providing prior written notice to the DOH. In addition, nursing homes will now be required to report to the DOH their rates or average rates for the lease, rent, or use of land or other real property. Lastly, the DOH will identify nursing homes that may be in acute financial distress or at risk of filing for bankruptcy protection by requiring each nursing home to report, within five business days, any default in the punctual payment when due of any: (i) debt service payment, where the debt is secured by real estate or assets of the nursing home; (ii) rent payment; (iii) payroll; or (iv) payroll tax obligation. The DOH may, as appropriate, provide, at the nursing home's expense, or direct such nursing home towards management support services and resources, as well as any other supports as may be necessary and appropriate to avoid bankruptcy proceedings or cessation of operations.

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Brach Eichler In The News

On June 17, Healthcare Law Member **Lani M. Dornfeld** issued a Healthcare Law Alert entitled "[NJDOH Issues Revised COVID-19 Protocols for ASCs Resuming Services.](#)"

Labor and Employment Members **Matthew Collins** and **Anthony Rainone** and Counsel **Jay Sabin** hosted a webinar on June 23 entitled "The Road Back to the Office: Key Employment Law Issues That Employers Should Consider Now." They addressed the many unanswered questions employers, business leaders, human resources professionals, and in-house counsel have as COVID-19 restrictions are lifted and the public health emergency comes to an end.

On June 8, **Matthew Collins** talks in the *New Jersey Law Journal* about the end of the NJ Public Health Emergency in "[NJ No Longer Emergency Territory, Declares Murphy in Signing Bill.](#)"

Healthcare Member **Lani M. Dornfeld** issued a Healthcare Law Alert on May 20 "[OIG Issues Favorable Advisory Opinion on ASC Investment by a Health System, Physicians, and a Management Company](#)" and one on June 8 "[NJ Healthcare Transparency Act Effective on July 1, 2021.](#)"

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 Joe M. Gorrell and Counsel Debra W. Levine.



Joe Gorrell

Joe Gorrell has over 35 years of experience counseling hospitals, medical staffs, nursing homes, and individual practitioners on a broad scope of issues ranging from defense of licensure prosecutions and insurance fraud cases to

practice acquisitions and other physician transactions. He has successfully represented numerous physicians before the New Jersey State Board of Medical Examiners and New York's Office of Professional Conduct, defending claims, avoiding disciplinary actions, and achieving favorable settlements.

On the weekends, Joe enjoys golf with his friends and looks forward to time with his two grandsons. He also has a passion for theater and opera, with Turandot's best-known aria "Nessun dorma" being Joe's favorite.



Debra W. Levine

Debra Levine brings an extensive background in the law governing healthcare and professional licensure to Brach Eichler, specifically in the areas of state regulation, the corporate practice of medicine, disciplinary matters, and the

interrelationship between the various scopes of practice associated with different categories of licenses. She focuses her work on the business aspects of the practice of medicine as well as on provider disciplinary matters. Prior to joining Brach Eichler, Debra was counsel to the New Jersey State Board of Medical Examiners, where she was responsible for advising the Board on disciplinary, investigative, and regulatory matters.

In her spare time, Debra enjoys hiking and kayaking. She is an avid reader and book club participant and looks forward to resuming international travel as well as attending an art gallery or museum exhibit in the near future.

HIPAA CORNER

White House Urges Businesses to Protect Against the Threat of Ransomware – On June 2, 2021, Annie Neuberger, Deputy Assistant to the President and Deputy National Security Advisor for Cyber and Emerging Technology, released a [memo](#) urging businesses to take steps to protect themselves against the threat of ransomware. This is in response to the number and size of recent ransomware incidents in the United States and around the world. The memo addresses the critical responsibility the private sector has in protecting against these threats.

According to the memo, these immediate steps will help protect businesses, their customers or consumers, and the broader economy:

- Implement the five best practices from the [President's Executive Order](#); this includes:
 - Multifactor authentication;
 - Endpoint detection and response;
 - Encryption; and
 - A skilled and empowered security team.

- Back up your data, system images, and configurations, regularly test them and keep the backups offline;
- Update and patch systems promptly;
- Test your incident response plan;
- Check your security team's work; and
- Segment your networks.

“Business executives should immediately convene their leadership teams to discuss the ransomware threat and review corporate security posture and business continuity plans to ensure you can continue or quickly restore operations,” Neuberger wrote. She notes that ransomware attacks have affected organizations and hospitals around the world. As the federal government is working with other countries to hold ransomware actors and the countries that harbor them accountable, the private sector can assist by implementing these practices within their businesses. The White House also released a [fact sheet](#) and [guidance](#) to assist in carrying out these measures.

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

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