I. COVID-19 LEGAL UPDATES

Brach Eichler keeps abreast of the numerous legal developments that are related to the nationwide novel coronavirus (COVID-19) public health emergency. Brach Eichler has created a COVID-19 Resource Center that consolidates our various important client alerts and webinar series information in one place. Please visit the Resource Center for updates at https://www.bracheichler.com/covid-19-resource-center/.

II. NEW JERSEY DEVELOPMENTS

A. Governor Murphy Signs Executive Order 292 Terminating the COVID-19 Public Health Emergency

On March 4, 2022, Governor Murphy signed Executive Order (EO) 292, which terminates the Public Health Emergency (PHE), effective March 7, 2022. The State of Emergency declared in EO 103 will remain in place to ensure that the State continues to have necessary resources as COVID-19 is managed on an endemic level. Additionally, several EOs listed below will remain in full force and effect under the State of Emergency.

- EO 111: Requiring healthcare facilities to report their capacity and supplies, including bed capacity, ventilators, and Personal Protective Equipment (PPE) inventory, on a daily basis.
- EO 112: Granting the Division of Consumer Affairs (DCA) the authority (i) to temporarily reactivate certain inactive healthcare licenses and allow the licensure of physicians licensed and in good standing in another country, (ii) suspending and waiving certain licensure requirements for advanced practice nurses and physician assistants, (iii) relaxing registration requirements for the Prescription Monitoring Program; and (iv) waiving signature requirements for funeral agreements and authorizations. Importantly, the civil or criminal immunity related to the COVID-19 response bestowed by EO 112 shall no longer be in effect.
- EO 252: Requiring all covered healthcare and high-risk congregate settings to maintain a policy that requires all covered workers to either provide adequate proof that they have
been fully vaccinated or submit to COVID-19 testing at minimum one to two times weekly, as subsequently revised by EO 283.

- EO 283: Requiring healthcare facilities and high-risk congregate settings covered by the EO to adopt and implement policies requiring covered workers at covered settings to be up to date with their COVID-19 vaccinations, including having received a booster dose.
- EO 290: Revising timelines set forth in EO 283 to align the state timelines with updated Centers for Disease Control and Prevention (CDC) recommendations on optimal intervals between first and second doses of vaccination.

EO 292 also extends various Administrative Orders, Directives, and Waivers taken by the Executive Branch departments and agencies in response to the pandemic to allow for an orderly transition as the State moves towards an endemic.

**B. Governor Murphy Signs Executive Order 290, Modifies Executive Order 283, Drops COVID Test Option from EO 252, Requires Vaccines and Boosters for Health and Long-term Care Workers**

On March 2, 2022, Governor Murphy signed Executive Order (EO) 290, revising timelines set forth in EO 283, which was signed on January 19, 2022. EO 283 required healthcare facilities and high-risk congregate settings covered by the EO to adopt and implement policies requiring covered workers to be up to date with their COVID-19 vaccinations, including having received a booster dose. EO 290 now aligns the state timelines with updated CDC recommendations on optimal intervals between first and second doses of vaccination.

Previously, EO 252, which was issued on August 6, 2021, required covered healthcare facilities and high-risk congregate settings to maintain policies that require covered workers to either provide proof that they have been fully vaccinated or be subject to COVID-19 testing at minimum one to two times per week. EO 283 eliminated the testing option that was previously allowed and required covered workers to be fully vaccinated, including a booster dose, while leaving intact the ability to grant exemptions for those with disabilities, medical conditions, or deeply held religious beliefs. Any provisions of EO 252 that are inconsistent with the requirements of EO 283 are overridden by EO 283.

For purposes of EOs 290 and 283, healthcare and high-risk congregate settings include licensed ambulatory care facilities. The EOs do not cover private physician offices; however, practitioners that render services at hospitals or other licensed facilities covered by the EOs will be required to comply with the vaccination requirements of those facilities.

For purposes of EOs 290 and 283, “covered workers” are defined as:

- Full and part-time employees;
- Contractors; and
- Other individuals working in the covered setting, including individuals providing operational, custodial, or administrative support.
For purposes of EOs 290 and 283, a covered worker shall be considered “up to date” with his or her COVID-19 vaccinations if the worker has received a complete primary series and any booster dose(s) for which the worker is eligible as recommended by the CDC. It is notable that the requirement for covered workers to obtain a booster shot, when eligible, exceeds the current CMS Omnibus COVID-19 Healthcare Staff Vaccination interim final rule (CMS Rule) that is applicable to Medicare- and Medicaid-certified healthcare facilities covered by that rule.

For covered healthcare settings that are covered by EOs 290 and 283, and subject to the CMS Rule, the following deadlines apply:

- Unvaccinated covered workers must have obtained their first dose of the primary series of COVID-19 vaccination by January 27, 2022 and the second dose by February 28, 2022.
- All covered workers must provide adequate proof that they have received a booster dose by April 11, 2022, or within 3 weeks of becoming eligible for a booster dose, whichever is later.

For healthcare settings that are covered by EOs 290 and 283, but not subject to the CMS Rule, and for covered high-risk congregate settings, the following deadlines apply:

- Unvaccinated covered workers must have obtained their first dose of the primary series of COVID-19 vaccination by February 16, 2022.
- All covered workers must provide adequate proof that they are up to date with their COVID-19 vaccination by May 11, 2022. However, as to having received a booster dose, covered workers must provide adequate proof that they are up to date with their COVID-19 vaccinations by May 11, 2022, or within 3 weeks of becoming eligible for a booster dose, whichever is later.

EOs 290 and 283 also require that covered workers currently subject to testing under EO 252 must continue once to twice weekly testing until they provide adequate proof that they are up to date with their vaccinations based on the respective applicable April 11, 2022 or May 11, 2022 deadline. Additionally, EO 283 requires covered settings to have a disciplinary process for noncompliance, including and up to termination of employment. Further, EO 290 requires a covered setting must take the first step toward bringing a noncompliant covered worker into compliance as part of the disciplinary policy within two weeks of the respective applicable April 11, 2022 or May 11, 2022 deadline.

C. Governor Murphy Signs Law Limiting Fees Charged to Patients for Medical Records

On January 18, 2022, Governor Murphy signed Bill S4233 into law to limit fees charged to patients and authorized third parties for copies of medical and billing records. The law would limit fees charged to patients, patients’ legally authorized representatives, and other authorized third parties by hospitals and healthcare professionals for electronic or paper copies of medical or billing records. Under the law, total costs for copies of a medical record, whether the record is stored electronically, on microfilm or microfiche, or paper, are capped at $50, including the administrative fee. Prior to the enactment of this law, regulations of the New Jersey State Board of Medical Examiners limited the fee for such records to $100, but the regulations were generally
III. FEDERAL DEVELOPMENTS

A. Texas Court Sets Aside Key Parts of the Independent Dispute Resolution Process Under the Federal No Surprises Act – All Jurisdictions Affected

On February 23, 2022, a federal district court in Texas vacated certain parts of the interim final rule (Rule) that implement the federal independent dispute resolution (IDR) process under the No Surprises Act (NSA). The court determined that the U.S. Departments of Health and Human Services, Labor, and the Treasury (collectively, the Departments) were mistaken in instructing arbitrators to give the qualified payment amount (QPA) extra weight compared to other factors during the IDR process.

By way of background, the NSA provides a “baseball-style” arbitration process by which, in an attempt to resolve payment disputes, providers and insurers each submit a proposed payment amount and explanation to the arbitrator. In setting forth the terms of the IDR process, the NSA states that, when determining an appropriate out-of-network (OON) rate, the IDR arbitrator “shall” consider multiple factors including the QPA, training and experience, complexity of procedure or medical decision-making, as well as any relevant information submitted by either party. The QPA is a rate set by each insurer based on the median of the contract rates that such insurer pays for the same or similar service in the same or similar specialty and region. The NSA does not impose any more or less weight to any of these factors.

However, in promulgating the Rule, the Departments created a presumption in favor of the QPA in the IDR process. It would then be up to the provider to overcome the rebuttable presumption that the QPA is the appropriate rate for the items or services provided. The Rule acknowledges that other factors, if credible, can be considered but that, in order to deviate from the QPA, providers must demonstrate that the QPA is “materially different” from the appropriate OON rate by submitting evidence in support of the other factors enumerated in the NSA.

The Texas Medical Association (TMA), a physician advocacy group, challenged the Rule’s rebuttable presumption that directed IDR arbitrators to assume that the QPA is the appropriate OON payment amount unless a party submits credible information that clearly demonstrates that the QPA is materially different from the appropriate OON rate. This standard, plaintiffs argued, is unlawful because it is inconsistent with the NSA and exceeds the scope of the Departments’ authority. TMA additionally argued that the Departments should have provided an opportunity for public notice and comment and asked the court to vacate the challenged provisions of the Rule.

The court agreed with the plaintiffs that the disputed provisions of the Rule are inconsistent with the text of the NSA and therefore vacated them. The vacated provisions of the Rule are:

- The definition of “material difference”;
The requirement that the IDR entity select the offer closest to the QPA unless there is credible information to demonstrate that this is not the appropriate rate;

The requirement that “additional information” clearly demonstrate that the QPA is materially different from the OON rate;

The four examples describing how IDR entities should choose between competing offers; and

The requirement that the IDR entity explain why it chose an offer not closest to the QPA.

The court also found that the Departments improperly and without justification bypassed the required “notice and comment” process under the Administrative Procedure Act when issuing the Rule. According to the court, this deprived healthcare providers the opportunity to explain (i) why the Rule is inconsistent with the NSA; (ii) how the Rule negatively impacts providers; and (iii) how the agencies could draft a rule consistent with the NSA. Following the court’s ruling, the Departments may now appeal the TMA decision to the Fifth Circuit Court of Appeals and request a stay pending their appeal.

It is critical to note that this decision does not invalidate the NSA nor does it invalidate the entire IDR process under the NSA. It only invalidates the above provisions. The IDR process remains available to resolve payment disputes between payors and OON providers. The Departments expect to issue the final IDR rule by May 2022.

B. SCOTUS Gives Green Light to CMS Vaccine Rule

On January 13, 2022, the Supreme Court of the United States (the SCOTUS) permitted the Centers for Medicare & Medicaid (CMS) to enforce its Omnibus COVID-19 Healthcare Staff Vaccination Final Rule (the CMS Rule). Based on this decision and added guidance issued by CMS, covered providers are now subject to key compliance deadlines, based on their location.

The CMS Rule mandates COVID-19 vaccination of healthcare workers at all Medicare-certified providers and suppliers covered by the CMS Rule, unless an exemption is granted for medical or religious reasons. Medicare-certified healthcare providers and suppliers covered by the CMS Rule include, but are not limited to, hospitals, psychiatric residential treatment centers, ambulatory surgical centers, long-term care facilities, home health agencies, and hospices. The CMS Rule does not directly apply to private medical practices, but employees placed to work in facilities covered by the CMS Rule may be required by such facilities to be vaccinated in order to provide services within such facilities.

There are three groupings of deadlines based on location. Group 1 encompasses 26 states including, New Jersey, New York, Pennsylvania, and Connecticut. Group 2 includes 24 states and Group 3 includes only Texas. The two primary deadlines for Group 1 are:

- By January 27, 2022, facilities covered under the CMS Rule must have developed and implemented policies and procedures for ensuring all facility staff (broadly defined to also include independent contractors and volunteers) are vaccinated for COVID-19, regardless of clinical responsibility or level of patient or resident contact. Also, the facility’s covered
staff must have received at least one dose of a COVID-19 vaccine, excluding federally recognized exemptions for religious belief and disability and delayed dosing recommended by the CDC; and

- By February 28, 2022, facilities covered under the CMS Rule must have ensured that 100% of their staff have received the required doses to complete the COVID-19 series (i.e., one dose of a single dose vaccine or all doses of a multiple-dose vaccine series). Again, federally recognized exemptions and CDC-related dosing recommendations do not count against the facility.

C. The Federal “No Surprises Act” and Related Regulations Prohibiting Surprise Medical Bills Came Into Effect January 1, 2022

On December 27, 2020, President Donald Trump signed into law the No Surprises Act (NSA) to protect American consumers against excessive out-of-pocket costs due to surprise medical bills and balance billing for certain out-of-network services. During 2021, multiple federal agencies published regulations to implement the new federal law. Effective January 1, 2022, the NSA provides, among other things, the following protections for insured and non-insured individuals.

For people who have health coverage through an employer, a Health Insurance Marketplace, or an individual health plan purchased directly from an insurer, the NSA:

- Bans surprise bills for emergency care services by out-of-network (OON) providers or OON emergency facilities, and requires that cost sharing for these services (e.g., co-pays) be based on in-network rates, even when care is received without prior authorization.
- Bans surprise bills for covered non-emergency care services, including post-stabilization services, by certain OON providers at in-network facilities (hospitals, hospital outpatient departments, and ambulatory surgical centers), unless notice and consent is provided.
- Bans surprise bills for air ambulance services by OON air ambulance providers.
- Requires providers and facilities to share with patients easy-to-understand notices that explain the applicable billing protections and who to contact if they have concerns that a provider or facility has violated the new surprise billing protections. Providers must use the form in its original format; no edits are permitted.
- Permits OON providers and facilities to obtain waivers from insured patients to permit balance billing under certain circumstances, but prohibits waivers for ancillary services such as anesthesia, pathology, radiology, neonatology, and the services of hospitalists, intensivists, and assistant surgeons.
- Establishes the federal independent dispute resolution (IDR) process that OON providers, facilities, providers of air ambulance services, plans, and issuers in the group and individual markets may use to determine the OON rate for applicable items or services after an unsuccessful open negotiation.

For people who do not have health insurance or those who desire to pay for care on their own, the NSA:
• Requires most providers to give a good faith estimate of costs before providing non-emergency care.
• Requires the good faith estimate to include expected charges for the primary item or service, as well as any other items or services that would reasonably be expected. For example, when getting surgery, the estimate must include the cost of the surgery, as well as any labs, tests, and anesthesia services that might be used with the procedure. However, other items or services related to the surgery that might be scheduled separately, like pre-surgery appointments or physical therapy in the weeks after the surgery, do not have to be disclosed in the good faith estimate.
• Provides a model notice, “The Right to Receive a Good Faith Estimate of Expected Charges” and a “Good Faith Estimate Template” to be provided to all uninsured and self-pay patients.
• Provides a specific timeframe for giving the good faith estimate to patients.
• Provides a process for patients to dispute final charges that exceeds the good faith estimate by $400 or more.

Interplay Between the NSA and New Jersey’s Out-of-Network Law

Implementation of the NSA is complicated in New Jersey because New Jersey has its own law governing out-of-network billing. New Jersey’s “Out-of-Network Consumer Protection, Transparency, Cost Containment and Accountability Act” (the NJ OON Law) became effective in August of 2018. Like the NSA, the NJ OON Law provides notice requirements, balance billing limitations and an arbitration procedure for out-of-network claims that are covered by the law. However, the NJ OON Law is not consistent with the NSA in all respects.

Often when federal and state law conflict, federal law preempts state law. In the interplay between the NSA and the NJ OON Law, this is not always the case. In this case, the NSA creates a “floor” of protections against surprise bills from out-of-network providers, but does not preempt state laws that provide at least the same or greater protections against surprise bills and higher cost-sharing than what is provided by the NSA. Because the NSA has, to a large extent, more stringent notice and consent requirements than the NJ OON Law, providers will be required to use the federal notice forms when applicable. However, because the NJ OON Law does require that certain disclosures be made beyond what is required in the NSA, when the NJ OON Law is applicable, providers will be required to make both federally mandated disclosures and New Jersey required disclosures.

Moreover, with respect to arbitration, so long as a state’s dispute resolution process meets or exceeds the minimum requirements under the federal IDR, the HHS will defer to the state process. New Jersey’s dispute resolution process appears to meet or exceed the federal requirements. Therefore, New Jersey’s dispute resolution process will take precedence over the federal IDR for matters that are within the jurisdiction of New Jersey’s process. This includes matters that arise from claims for services rendered to patients that are covered under New Jersey licensed health benefit plans, as well as self-funded plans (i.e., ERISA plans) that opt-in to the New Jersey process. The New Jersey process does not, however, apply to disputes that arise from claims for services rendered to patients that are covered under the Federal Employees Health Benefit Program, or ERISA plans that do not opt-in to the New Jersey process. These disputes would need to proceed under the federal IDR.