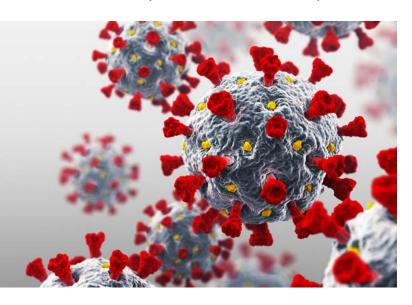
Healthcare Law UPDATE

FEDERAL UPDATE

Public Health Emergency Extended

On January 14, 2022, the Secretary of Health and Human Services (the "HHS Secretary"), Xavier Becerra, renewed the national Public Health Emergency (PHE) resulting from the COVID-19 pandemic. Pursuant to section 319 of the Public Health Service Act, the HHS Secretary may declare a PHE if he or she determines that (i) a disease or disorder presents a PHE, or (ii) a PHE such as a significant infectious disease outbreak or a bioterrorism attack exists. Former HHS Secretary, Alex M. Azar II, initially declared a PHE on January 21, 2020 in



response to the COVID-19 pandemic. Such a declaration lasts for either the duration of the emergency or ninety (90) days. Since the initial declaration, the PHE has been renewed seven times. This latest renewal by Secretary Becerra will expire on April 14, 2022, unless otherwise renewed.

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STATE UPDATE

Governor Murphy Extends the Public Health Emergency and Waivers for Temporary Emergency Healthcare Licenses

On January 11, 2022, due to the rapid and ongoing spread of the COVID-19 variants, Governor Murphy issued an Executive Order declaring a new Public Health Emergency (PHE) effective immediately. Executive Order 280 reinstates the existing State of Emergency across the State of New Jersey, allowing state agencies and departments to utilize state resources to assist the healthcare system and communities responding to and recovering from COVID-19 cases. By statute, a PHE automatically expires after thirty days, unless renewed.

The Governor also issued Executive Order 281 which extends, until revoked or modified by the Governor, numerous previously issued Executive Orders and extends various regulatory actions taken in response to COVID-19, including the following:

- Requiring healthcare facilities to report their capacity and supplies, including bed capacity ventilators, and Personal Protective Equipment on a daily basis (Executive Order 111).
- Granting the Division of Consumer Affairs (DCA) the authority to (i) temporarily reactivate certain inactive healthcare licenses and allowing 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 (Executive Order 112). Importantly, the civil and criminal immunity previously granted to healthcare professionals related to the COVID-19 response has not yet been reinstated.

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- Requiring all individuals, regardless of age, to be automatically enrolled in the New Jersey Immunization Information System upon receipt of a COVID-19 vaccination (<u>Executive Order 207</u>).
- Requiring all public, private, and parochial preschool programs and elementary and secondary schools, including charter and renaissance schools, to maintain a policy regarding mandatory use of face masks by staff, students, and visitors in the indoor portion of the school district premises, except in certain specified circumstances (Executive Order 251).
- 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 beginning September 7, 2021 (<u>Executive Order 252</u>) as subsequently revised by (<u>Executive Order 283</u>).
- Requiring school districts to maintain a policy that requires all covered workers to provide adequate proof that they have been fully vaccinated or submit to COVID-19 testing at minimum one to two times weekly beginning October 18, 2021 (Executive Order 253).
- Requiring all child care centers and other child care facilities to maintain a policy regarding mandatory use of face masks by staff, child enrollees, and visitors in the indoor portion of the child care setting premises, except in certain specified circumstances (<u>Executive</u> <u>Order 264</u>).
- Requiring all child care settings to maintain a policy that all covered workers must either provide adequate proof that they have been fully vaccinated or submit to COVID-19 testing at minimum one to two times weekly beginning November 1, 2021 (Executive Order 264).
- Requiring state government contracts to include a clause that contractors and subcontractors must have a policy that their covered workers will provide adequate proof of full vaccination or submit to COVID-19 testing at minimum one to two times weekly (Executive Order 271).

The PHE also allows the state to continue vaccine distribution, vaccination or testing requirements in certain settings, the collection of COVID-19 data, implementation of any applicable recommendations of the Centers for Disease Control and Prevention to

prevent or limit the transmission of COVID-19, staffing and resource allocation, and other components of the State's COVID-19 response.

Also on January 11, 2022, Governor Murphy signed into law <u>Bill S4139</u> extending to June 30, 2022 licensure



waivers previously granted to out-of-state healthcare workers practicing under a temporary emergency reciprocal license, and to certain recently graduated healthcare workers practicing under a temporary emergency graduate license. In addition, the law allows out-of-state healthcare professionals and recent healthcare graduates who have not yet applied for a waiver to now apply for such emergency temporary licenses. The waivers had been set to expire on January 11, 2022. The DCA had issued such waivers early on in the pandemic to help treat New Jersey residents during the PHE. With the PHE extended, the waivers are needed to help New Jersey's healthcare workforce meet the increased demand for healthcare services.

The types of healthcare workers permitted to practice under a temporary emergency out-of-state reciprocal license include medical doctors and doctors of osteopathy, nurses, social workers, homemaker-home health aide, licensed alcohol and drug counselors, marriage and family therapists, professional counselors, psychoanalysts, psychologists, and respiratory care practitioners. Recent graduates who may practice under a temporary emergency graduate license include nurses, physician assistants, respiratory care therapists, pharmacists, social workers, and alcohol and drug associate counselors.

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New Law Requires NJ Professional Licensing Boards to Utilize the National Practitioner Data Bank

On January 10, 2022, Governor Phil Murphy signed Bill S845 into law to require healthcare professional licensing boards to utilize the National Practitioner Data Bank (NPDB) with regard to licensing determinations. The NPDB is a web-based repository of reports containing information on medical malpractice payments and certain adverse actions related to healthcare professionals. Under the new law, professional and occupational licensing boards that regulate the practice of a healthcare professional may not issue or renew or, if renewed, must revoke or suspend a license or other authorization to practice a healthcare profession that is regulated by that board if the board determines through use of the NPDB that there is cause to refuse to issue, suspend or revoke any license or authorization of a healthcare professional.

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New Law Expands Exemptions from Codey Self-Referral Restrictions

On January 10, 2022, Governor Phil Murphy signed into law Bill S3632 to expand the exemptions from restrictions on healthcare practitioner referrals and to require certain referrals to be made in accordance with specific professional standards. Under the current New Jersey law known as the Codey Law, New Jersey's state-specific anti-referral law, a healthcare practitioner generally is not permitted to refer a patient to a healthcare service in which the practitioner, the practitioner's immediate family, or the practitioner in combination with the practitioner's immediate family, has a significant beneficial interest. One exception to the Codey Law pertains to referrals a healthcare practitioner makes to a healthcare service in which the referring practitioner has a significant beneficial interest, when participants in an alternative payment model registered with the Department of Health make a bona fide determination that the significant beneficial interest is reasonably related to the alternative payment model standards filed with the Department of Health, provided that the determination is documented and retained for a period of 10 years. The new law narrows

One exception to the Codey Law pertains to referrals a healthcare practitioner makes to a healthcare service in which the referring practitioner has a significant beneficial interest...

this exception by requiring that the referral be made in accordance with alternative payment model standards and the professional standards applicable to the healthcare service in which the referring practitioner has a significant beneficial interest. The new law also adds an exception to the Codey Law by providing that restrictions on referrals of patients do not apply to a value-based arrangement made in accordance with federal self-referral laws, a payment model authorized under a Medicare shared savings program, or a demonstration project operated by the Center for Medicare and Medicaid Innovation. The aforementioned expansions coincide with the recent federal Stark Law and Anti-Kickback Statute expansions enacted in 2020 that just took effect on January 1, 2022. Register for our upcoming webinar on March 15, 2022 at 12:00 p.m., "Federal Stark Law and Anti-Kickback Statute Changes for 2022 and Beyond" to learn more about the newly effective changes and the impact they may have on existing and new provider arrangements and transactions going forward.

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Governor Murphy Signs Law Prohibiting Invasive Examinations of Unconscious Patients Without Consent

On January 18, 2022, Governor Phil Murphy signed into law <u>Bill S1771</u> to prohibit healthcare providers from performing an invasive examination of a patient while the patient is under general anesthesia or otherwise

unconscious without the patient's prior written informed consent to the invasive examination. As used in the new law, "informed consent" means an affirmative authorization to perform an invasive examination, which authorization will not be valid unless the healthcare practitioner first provides the patient with a full description of the nature and attendant risks associated with the proposed invasive examination. "Invasive examination" include any visual, tactile, or mechanical inspection of the patient's reproductive organs, rectal cavity, or breasts.

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Governor Murphy Signs Law Establishing Additional DOH Oversight of Nursing Homes

On January 18, 2022, Governor Phil Murphy signed into law <u>Bill A4478</u> to upgrade nursing home reporting requirements and establish additional requirements for the New Jersey Department of Health (DOH) to assess sanctions and impose penalties on nursing homes that are in violation of New Jersey and federal codes. Under



the new law, nursing homes are required to report certain financial information and quality metrics. In addition, the DOH is directed to develop a system of scaling actions and penalties for repeat violations of state and federal requirements for

nursing home administration and operations. The new law also directs the DOH to undertake further review of nursing homes reporting requirements and take substantive steps to standardize and consolidate such reporting requirements for the purpose of reducing administrative demand on nursing homes while also improving the utility of the reported data and the ability to share said data across systems.

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NJ Board of Dentistry and NJ Occupational Therapy Advisory Council Adopt New Rules on Telemedicine and Telehealth; NJ State Board of Polysomnography Proposes its Own New Rules Pertaining to Telemedicine and Telehealth

NJ State Board of Dentistry and NJ Occupational Therapy Advisory Council Adopt Rules on Telemedicine and Telehealth

On January 18, 2022, the New Jersey State Board of Dentistry adopted N.J.A.C. 13:30-9, the new Telemedicine and Telehealth rules authorizing dental providers such as licensed dentists and dental hygienists to engage in telemedicine and telehealth effective immediately. Also on January 18, 2022, the New Jersey Occupational Therapy Advisory Council adopted N.J.A.C. 13:44K-7, the new Telemedicine and Telehealth rules authorizing occupational therapy providers such as licensed occupational therapists, occupational therapy assistants, temporary occupational therapy assistants to engage in telemedicine and telehealth effective immediately.

The new rules provide detailed requirements that include, but are not limited to, the following:

- A licensee who provides healthcare services through telemedicine or telehealth will be held to the same standard of care and practice standards as are applicable when healthcare services are provided in person.
- Before a licensee can provide healthcare services through telemedicine or telehealth, the licensee must establish a licensee-patient relationship by reviewing a patient's medical history and any available records. Further, he or she must provide the patient the opportunity to sign a consent form authorizing the release of the patient's records of the encounter to the patient's primary care licensee or other healthcare provider identified by the patient.
- Further, the licensee must generally use interactive, real-time, two-way communication technologies that include a video component but if, after accessing and reviewing the patient's records, the licensee determines that he or she is able to meet the standard of care for such services as if they were being provided in-person without using the video component, he or she may use interactive, real-time,

two-way audio in combination with asynchronous store-and-forward technology without a video component.

NJ State Board of Polysomnography Proposes Rules on Telemedicine and Telehealth

On January 18, 2022, the New Jersey State Board of Polysomnography proposed N.J.A.C. 13:44L-7, Telemedicine and Telehealth, to authorize providers, including licensed polysomnographic technologists, technicians, and trainees, to engage in telemedicine and telehealth. The new rules provide detailed requirements that include, but are not limited to, the following:

- A licensee who provides healthcare 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-patient relationship by reviewing a patient's medical history and medical records.
 Further, he or she must provide a patient with the opportunity to sign a consent form authorizing the release of medical records to the patient's primary care provider or other healthcare provider identified by the patient.

Comments to the new telemedicine rules closely drafted after the New Jersey State Board of Dentistry and the New Jersey Occupational Therapy Advisory Council rules pertaining to the same topic are due by March 19, 2022.

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Governor Murphy Vetoes Update to Out-of-Network Consumer Protection Law

On January 18, 2022, Governor Murphy exercised his "pocket veto" power and failed to act on Senate Bill S3458 aimed at revising the out-of-network (OON) arbitration process of the New Jersey Out-of-Network Consumer Protection, Transparency, Cost Containment, and Accountability Act.

The bill would have expanded from 30 days to 60 days the time that insurance carriers have to negotiate with healthcare providers before beginning the OON arbitration process. The bill would also have added a minimum dispute threshold of \$1,000 to proceed to the OON arbitration process. Finally, the proposed

bill sought to enhance the requirements on the OON arbitrators. For example, the arbitrator would have been required to issue a detailed decision addressing the basis for the ruling, including documentation, database information, and previous arbitration decisions.

Opponents of the bill criticized its failure to create uniformity with the federal No Surprises Act.

Specifically, the NJ for Healthcare Coalition argued that "[t]his is not the time to amend New Jersey's current surprise billing law. Doing so is ill-timed, ill-advised and illogical and creates unnecessary differences between the New Jersey law and the federal law that make it less protective and more complex for all involved."

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New Jersey Boards of Dentistry, Nursing, and Optometrists Propose Amended Rules Regarding Opioid Antidotes

On January 19, 2022, the New Jersey State <u>Board of Dentistry</u>, <u>Board of Nursing</u>, and <u>Board of Optometrists</u> each proposed to amend the current regulations to require the co-prescribing of an opioid antidote like naloxone when one of their respective licensees prescribes an opioid drug as required under the <u>N.J.S.A. 24:21-15.2</u>, <u>New Jersey Controlled Dangerous Substances Law</u> which was revised in April 2021.

In accordance with N.J.S.A. 24:21-15.2, a licensed dentist, certified advance practice nurse, or licensed optometrist must co-prescribe an opioid antidote whenever the licensee issues a prescription for an opioid drug that is a controlled dangerous substance and one of the following conditions exists: (i) the patient has a history of substance use disorder; (ii) the prescription for the opioid drug is for a daily dose of more than 90 morphine milligram equivalents; or (iii) the patient holds a current, valid prescription for a benzodiazepine that is a Schedule III or Schedule IV controlled dangerous substance.

Written comments to each of the board's rule proposals are due by March 19, 2022.

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Bill Introduced to Eliminate Certain Practice Restrictions for Advanced Practice Nurses

On February 10, 2022, New Jersey Senators Joseph F. Vitale (District 19, Middlesex) and Troy Singleton (District 7, Burlington) introduced **Bill S1522** in the New Jersey Senate that would eliminate certain practice restrictions for advanced practice nurses (APNs). An identical bill was introduced in the New Jersey Assembly on February 7, 2022. The bill would permit an APN with greater than 24 months or 2,400 hours of licensed, active, advanced nursing practice to be authorized to practice without a joint protocol with a collaborating provider. The bill would also permit an APN who is an APN-Anesthesia and who has completed 24 months or 2,400 hours of licensed, active, advanced nursing practice in an initial role to be authorized to practice as an APN-Anesthesia to the full scope of practice for APNs-Anesthesia, without any requirement for supervision by a licensed physician and without any requirement that the APN-Anesthesia enter into a joint protocol with a licensed physician.

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Bill Reintroduced to Revise Emergency Care Services Referral Standards for Telemedicine Providers

On February 7, 2022, <u>Bill A2193</u> was reintroduced in the New Jersey Assembly to revise emergency care services referral standards for providers of telemedicine and telehealth. An identical bill was reintroduced in the New Jersey Senate on January 11, 2022. This bill had previously been introduced in the spring of 2021. Under current law, a healthcare provider engaging in telemedicine or telehealth is required to make appropriate referrals for emergency care, if needed. The bill would revise this provision to require a healthcare provider engaged in telemedicine or telehealth to make a good faith effort to directly activate and coordinate with emergency care services in accordance with the standard of care upon determining the patient's needs for emergency services. Specifically, the healthcare provider would be required to make a good faith effort to (i) provide the name and location of the patient to emergency services in oral and written form, (ii) determine the location of the patient if a patient is unaware of his or her location, and (iii) provide his or her contact information to

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 Associate Emily J. Harris and Associate Caroline J. Patterson.



EMILY J. HARRIS

Emily Harris focuses her practice on New Jersey No-Fault PIP Arbitrations where she represents ambulatory care facilities, hospitals, chiropractors, physicians, and other healthcare providers. She is responsible for managing files, drafting arbitration statements, and assisting clients with

their cases from start to finish.

Outside of the office, Emily enjoys kickboxing, indoor rock climbing, and going to the park with her dog, Archie.



CAROLINE J. PATTERSON

Caroline Patterson concentrates her practice on the representation of healthcare providers and other business organizations in a wide variety of transactional and corporate matters, including acquisitions and sales, mergers, strategic partnerships, private equity investments, HIPAA compliance,

ownership and compensation arrangements, and employment negotiations. Caroline also has extensive experience advising investigators and clinical institutions on clinical trial agreements and clinical research law.

In her free time, Caroline enjoys reading, biking, playing golf, travel and spending time her husband and two daughters. She also serves on the Alumni Board of Directors of her alma mater, Cabrini University.

emergency services. In addition, a healthcare provider engaging in telemedicine or telehealth would be required to report a suicide attempt by a patient during a telehealth or telemedicine visit to the Department of Health in a manner that is consistent with federal and state privacy laws and document emergencies which occur during a telehealth or telemedicine visit in the medical records.

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Bill Reintroduced to Provide Civil Immunity for Healthcare Professionals Providing Services for No Compensation

On February 7, 2022, Bill A2072 was reintroduced in the New Jersey Assembly to provide civil immunity to licensed healthcare professionals who provide free care at healthcare facilities. The bill which had previously been introduced in prior legislative sessions would provide immunity from civil liability for any personal injury that is a result of uncompensated care or treatment provided by a licensed healthcare professional who: (i) cares for or treats a patient at a licensed healthcare facility, including a federally qualified healthcare center, or a nonprofit freestanding clinic that is not owned or controlled by a licensed healthcare facility; and (ii) does not bill for, otherwise receive any compensation for, or have any expectation to receive compensation for, the care or treatment provided. The immunity would not extend to an act or omission that was the result of gross negligence or willful or wanton misconduct.

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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.

On March 1, Healthcare Law Member **Lani Dornfeld** was quoted in *Hospital / Healthcare Risk Management* "<u>HIPAA Safe Harbor Offers Limited But Important Protection</u>."

Register today for two upcoming Healthcare Law Practice webinars, "PART 2: The No Surprises Act: What Providers Need to Know - Practical Takeaways for Implementation" on March 2 at 12:00 p.m. and "Federal Stark Law and Anti-Kickback Statute Changes for 2022 and Beyond" on March 15 at 12:00 p.m.

On February 16, Healthcare Law Member **Isabelle Bibet-Kalinyak** authored an article in *NJBIZ*,

"Payment Pulses A Bundaya of 2022 Medicare Physicians

"Payment Rules: A Rundown of 2022 Medicare Physician Fee Schedule."

On January 25, Litigation Co-Chair and Healthcare Law Member **Keith Roberts** opined in *Medical Economics*, "Dealing with medical board complaints."

On January 21, Healthcare Law Member Lani Dornfeld issued a Healthcare Law Alert entitled "Governor Murphy Signs Executive Order 283, Drops COVID Test Option from Executive Order 252, Requires Vaccines and Booster for Healthcare Workers."

On January 14, Healthcare Law Member **Lani Dornfeld** issued a Healthcare Law Alert entitled
"SCOTUS Blocks Enforcement of OSHA Vaccine-or-Test
Mandate, Gives Temporary Green Light to CMS Vaccine
Rule – at Least for Now."

HIPAA CORNER

EHR Vendor Sued After Data Breach

ast month, electronic health record vendor, QRS, Inc. (QRS) was served with a class action lawsuit after a data breach last year. The complaint in the lawsuit alleges that approximately 319,000 current and former patients of healthcare providers that utilized QRS's services were injured in the form of identity theft and other misuse of their sensitive and highly personal information. The suit comes after QRS discovered on August 26, 2021 that an unauthorized actor had accessed a patient portal server and, by extension, personal information including names, addresses, dates of birth, Social Security numbers, and other personal information stored on the server. The plaintiffs in the lawsuit allege that QSR waited roughly two months to notify the affected persons of the data breach and inform them that their sensitive information was compromised, during which time they were not aware that their information had been breached or that their information was at significant

risk. On February 7, 2022, the parties jointly requested a brief stay of the litigation to pursue a potential settlement through mediation.

This case is an important reminder to healthcare providers of the need to take HIPAA privacy and security compliance seriously, especially in this era of rampant cyber threat actors. The case demonstrates the layers of potential liability that may result from a large security incident—not only will providers have potential liability to federal and state regulators, but also potentially to individuals impacted by such events who may institute lawsuits similar to this one. In addition, although HIPAA permits up to 60 days to notify affected individuals of a security breach, such notice must be given "without unreasonable delay." As such, advance planning and rapid response are imperative.

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