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Healthcare Law UPDATE

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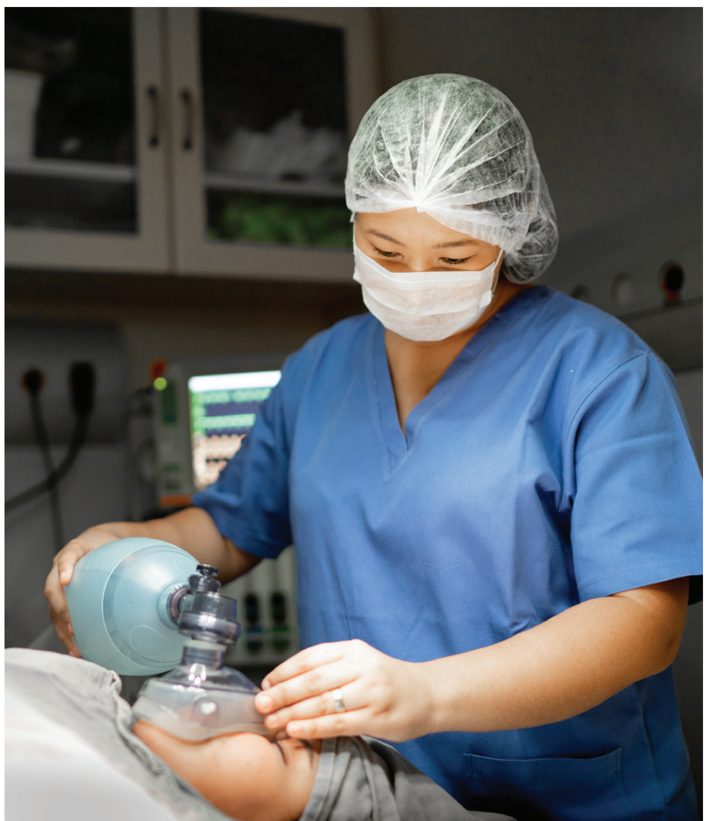
FEDERAL UPDATE

Physician Owner of ASC May Profit from Employed CRNA's Services at ASC

The Office of Inspector General (OIG) of the Department of Health & Human Services determined in recent Advisory Opinion No. 21-15 that a pain management practice solely owned by a physician and the ambulatory surgery center (ASC) at which the physician is a majority owner may profit from anesthesia services performed by the practice's employed certified registered nurse anesthetist (CRNA) in the practice office and at the ASC. The OIG concluded that it would not impose sanctions under the federal anti-kickback statute relating to the proposed arrangement.

Under the federal anti-kickback statute, it is a criminal offense to knowingly and willfully offer, pay, solicit, or receive any remuneration to induce, or in exchange for, referrals reimbursable under a federal healthcare program. "Remuneration" includes the transfer of anything of value, directly or indirectly, in cash or in kind. The statute has been interpreted to cover any arrangement where one purpose of the remuneration is to induce referrals. The statute and its regulations provide safe harbors, or exceptions, that set forth specific arrangements that do not violate the law. One safe harbor applies to compensation paid to a bona fide employee.

Under the arrangement described in the advisory opinion, the pain management practice pays a salary to the employed CRNA, who provides anesthesia services in the practice's office and at the ASC. Under the CRNA's employment agreement, the CRNA reassigned to the practice the right to receive reimbursement for the separately-billable anesthesia services performed by the CRNA, whether in the medical office or in the ASC. The practice bills for all of the CRNA's anesthesia services provided in both settings. The practice also assumes responsibility for the CRNA's performance of anesthesia services. The OIG determined that, because the CRNA is a bona fide employee of the practice, the salary to the employee is not a kickback. The OIG further found that although the reassignment of benefits flows from the employee to the employer, and technically is not protected by the anti-kickback statute's employee safe harbor, the arrangement is not a kickback scheme, because salaries to bona fide employees in exchange for reassignment



of benefits are (i) a common practice in the healthcare industry, and (ii) are explicitly authorized by the Medicare program.

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OIG Nixes Joint Venture Between Long Term Care Owner and Therapy Provider

The Office of Inspector General (OIG) of the Department of Health & Human Services recently published Advisory Opinion No. 21-18, in which the OIG opined that a proposed joint venture arrangement (JV) between a contract therapy services company (Company) and another company (JV Partner) that directly or indirectly owns skilled nursing facilities, assisted living facilities, and full-service continuing care retirement communities (Facilities) could be subject to potential liability under the

federal anti-kickback statute (AKS). The Company provides management of day-to-day operations and therapy staffing for the Facilities.

Under the proposed arrangement, the Company would form a new entity (Newco) and would enter into a management services agreement (MSA) with Newco to provide the clinical and back-office employees, space, and equipment necessary for Newco's operations in exchange for a fee that is consistent with fair market value (FMV). Thereafter, JV Partner would purchase a 40% interest in Newco for a purchase price that would be based on a third-party valuation and consistent with FMV. The Company would retain a 60% interest in Newco. Newco would be retained to provide contract therapy services in the Facilities. Newco would not have any employees; rather, it would lease all clinical and back-office employees from the Company through the MSA. Distributions from Newco would be proportional to the Company's and JV Partner's respective ownership interests in Newco. Both parties would appoint members to Newco's board of directors, but JV Partner would not be involved in the day-to-day operations of Newco.

The OIG concluded that: (i) the proposed JV transaction does not meet the requirements of any anti-kickback statute safe harbor, and (ii) under the totality of the facts and circumstances reviewed by the OIG to assess the relative risk of fraud and abuse presented by the JV transaction, significant risks exist, including patient steering, unfair competition, inappropriate utilization, and increased costs to federal healthcare programs. In this regard, the OIG stated that the proposed transaction exhibits many attributes of the problematic contractual joint ventures identified by the OIG in its 2003 Special Advisory Bulletin on Contractual Joint Ventures. Based on this, the OIG stated it was "unable to exclude the possibility that the Proposed Arrangement is designed to permit the [Company] to do indirectly what it cannot do directly: pay the JV Partner a share of the profits from the JV Partner's referrals (whether directly or through its Affiliated Facilities) to [the Company] for therapy services that are reimbursable by a Federal health care program."

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OCR and DOJ Settle Disability Discrimination Case with Medical Center

The U.S. Department of Health & Human Services, Office for Civil Rights (OCR), along with the U.S. Department of Justice through the U.S. Attorney's Office for the District of Massachusetts (DOJ), entered into a Voluntary Resolution Agreement with Baystate Medical Center (Baystate) arising from a complaint on behalf of an individual (Complainant) who is deaf and utilizes American Sign Language (ASL) to communicate. The Complainant alleged that Baystate failed to furnish appropriate auxiliary aids and services necessary to effectively communicate with her during her hospitalization, in violation of Title III of the Americans with Disabilities Act (ADA) and its implementing regulations. The Complainant also alleged that, despite requesting a qualified ASL interpreter before her scheduled arrival to induce labor, Baystate failed to take appropriate steps to ensure that its communications with her during labor and childbirth were effective.

The OCR investigated the Complainant's allegations, in partnership with the DOJ, and reviewed Baystate's policies and procedures for effective communications with individuals who are deaf or hard of hearing, as required under Section III of the ADA, Section 504 of the Rehabilitation Act of 1973 and Section 1557 of the Affordable Care Act. During the course of the investigation, the DOJ learned of a second aggrieved party who made similar allegations.

In settlement of the allegations, Baystate agreed, among other things, to (i) pay monetary compensation to each of the Complainant and the second complainant, (ii) review and revise its policies concerning effective communications with patients who are deaf or hard of hearing and the provision of auxiliary aids, and (iii) provide training on the provision of auxiliary aids and services.

The settlement should serve as a reminder to healthcare providers of the need to ensure compliance with the ADA and other discrimination and related laws requiring the provision of auxiliary aids and services to deaf, hard of hearing, and other patients who require them.

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STATE UPDATE

NJ BME Proposes New Rule for Radiologist Assistants

On December 6, 2021, the New Jersey State Board of Medical Examiners (BME) published a proposed rule to set forth procedures the BME believes are appropriate for licensed radiologist assistants (RAs) to perform, as well as the level of supervision licensed radiologists must provide when RAs are performing such procedures and other related tasks. Highlights of the proposed rule include the following:

- Certain fluoroscopic procedures should not be performed by RAs, as these procedures require either specialized education or the experience of a physician
- Certain tasks must be performed by an RA under the direct supervision, general supervision, or personal supervision of a radiologist:
    - Direct supervision requires a radiologist to be on-site (present in the office suite or department) and be immediately available to provide assistance and direction, but does not require the radiologist to be present in the room when a procedure is performed

    - General supervision means that a procedure is performed under an radiologist's direction and control, but does not require a radiologist's presence on-site when a procedure is performed
    - Personal supervision requires a radiologist to be present in the room when a procedure is performed
- Certain tasks may be delegated to an RA, provided that certain conditions are met, including:

    - The radiologist or other licensed physician in the practice or facility has personally certified and documented the RA's training and ability to perform the task
    - The radiologist is responsible for choosing and ordering pharmaceuticals and contrast materials and for determining the dosage and route of administration
    - For pediatric patients, the radiologist has experience in the performance of the pertinent procedures with such patients
    - The radiologist and RA each has current certification in Advanced Cardiovascular Life Support
- If a radiologist seeks to direct an RA to perform certain delineated procedures (lower extremity venography, non-tunneled venous central line placement in the femoral vein, venous catheter placement for dialysis, breast needle localization, and ductogram), the radiologist must provide written notification to the BME and receive written notification from the BME that it has reviewed the submitted information.

Comments to the proposed rule must be submitted by February 4, 2022.

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NJ BME Adopts Final Rule On Provision of Abortion Procedures

The New Jersey State Board of Medical Examiners (BME) has adopted final new rules affecting the provision of abortion procedures, effective December 6, 2021. The rules, which were first proposed in January 2021, are intended to expand access to reproductive healthcare and repeal outdated rules that place medically unwarranted restrictions on abortion in New Jersey. In response to the proposed rules, the BME accepted written comments from 1,769 individuals and groups. The BME incorporated several of the comments into the final adopted rules, including important definition changes, but left intact the key substantive changes to the rules concerning where and by whom abortion procedures may be performed.

The previous BME rules provided that after 14 weeks of gestation, abortions were restricted to Department of Health-licensed ambulatory care facilities or hospitals. The prior rules also allowed only licensed physicians to perform abortion procedures in New Jersey (the "physician-only" rule), except for medication-based abortion, which was not considered a procedure subject to the physician-only rule. Highlights of the newly-adopted rules include:

- Repeal of the requirement that all abortions be performed only by a physician (i.e., repeal of the physician-only rule)
- Repeal of the rule barring office-based terminations beyond 14 weeks of gestation
- Permitting advanced practice nurses, physician assistants, certified nurse midwives, and certified midwives (advanced practice clinicians, or APCs) to perform early aspiration abortions (in addition to medication-based termination of pregnancy, which was already permitted)
    - Note, however, that the rule does not alter existing collaborating, supervisory or privileging rules for APCs; to the extent consultation with or referral to a physician or another provider is required to meet the current standard of care; those obligations remain unchanged
- Including early aspiration abortions within the definition of "minor procedures" that are low-risk services and do not require compliance with the heightened regulatory requirements of privileging process requirements, patient selection standards, recovery requirements, discharge protocol requirements, and heightened equipment mandates
- Clarifying that the definition of "special procedures" includes later abortions, but excludes early aspiration abortions, and such procedures are subject to the heightened safety requirements of the rules
- Clarifying that certified registered nurse anesthetists (CRNAs) (now licensed in New Jersey as Advance Practice Nurses specializing in anesthesia services) are not permitted to administer anesthesia for special

procedures, including post-first trimester abortions, without the presence of the supervising physician

- Permitting practitioners who perform special procedures or surgeries to obtain privileging by an ambulatory surgery center, in addition to privileging by a hospital or the BME
- Permitting all APCs to administer minor conduction blocks, including paracervical blocks, a type of local anesthesia frequently used in early aspiration abortion for pain management.

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New Jersey Legislative Update

New Law Revises Requirements for Insurers to Cover Telemedicine Services – On December 21, 2021, Governor Murphy signed into law former Bill S2559, which revises certain requirements for health insurance providers covering telemedicine and telehealth. Carriers offering health benefit plans in New Jersey, the State Medicaid and NJ FamilyCare programs, the State Health Benefits Program, and the School Employees' Health Benefits Program (Programs), are now prohibited from imposing any restrictions on the location or setting used by a healthcare provider to provide services using telemedicine and telehealth or on the location or setting of where the patient is located when receiving services using telemedicine and telehealth, so long as the services provided using telemedicine and telehealth meet the same standard of care as if the services were provided in person. In addition, such Programs are now prohibited from restricting the ability of a provider to use any electronic or technological platform to provide services using telemedicine or telehealth, provided that the platform allows the provider to meet the same standard of care as would be provided if the services were provided in person.

Bill to Prohibit State Healthcare Boards from Granting Licenses to Sex Offenders Awaits Governor Murphy's Signature – On December 20, 2021, the New Jersey Assembly passed Bill S3494 which, if signed into law, will prohibit New Jersey professional licensing boards from granting licenses to individuals convicted of certain offenses, including certain sex offenses. The New Jersey Senate had previously passed the Bill on June 3, 2021, and it now awaits Governor Murphy's signature. The Bill was introduced after the State Board of Chiropractic Examiners in February 2021 reinstated the license of a chiropractor who is a registered sex offender in Florida and is on lifetime parole. The Bill would require that all New Jersey State entities which license and regulate a healthcare profession or occupation must deny an initial license certification or registration, or a renewal, reactivation, or reinstatement of a license, certification, or registration if the review of an individual's criminal history records or records with the National Practitioner Data Bank demonstrate the individual has been convicted of certain offenses, including sexual assault, criminal sexual contact or lewdness, endangering the welfare of a child, attempting to lure or entice a child, or equivalent offenses in another jurisdiction.

Bill Introduced to Limit Fees Charged to Patients for Medical Records – On December 6, 2021, Bill S4233 was introduced in the New Jersey Senate to limit fees charged to patients and authorized third parties for copies of medical and billing records. An identical bill was introduced in the New Jersey Assembly on December 13, 2021. The Bill 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. Total costs for copies of a medical record, whether the record is stored electronically, on microfilm or microfiche, or paper, would be capped at $50, inclusive of any additional administrative fees charged by the hospital or healthcare professional for reproducing the requested records. Presently, regulations of the New Jersey State Board of Medical Examiners limit the fee for such records to $100, but the regulations are generally pre-empted by HIPAA's "reasonable, cost-based fee" requirements. The Bill also would prohibit hospitals and healthcare professionals from assessing a fee for copies of a patient's billing record if the record is requested by the patient, the patient's legally authorized representative, or an authorized third party.

Bill Introduced to Require DOH Approval for Adverse Possessory Actions Against Hospitals – On December 13, 2021, Bill A6223 was introduced in the New Jersey Assembly which would require New Jersey Department of Health (DOH) approval for adverse possessory actions against hospitals. An identical bill was introduced in the New Jersey Senate on November 22, 2021. The Bill would prohibit landlords from initiating adverse possessory actions against an operator of a hospital, or a successor to the operator, without first obtaining written approval for the action from the DOH. An adverse possessory action initiated without the written approval of the DOH would be deemed invalid. The DOH would establish a process for landlords to submit requests to initiate adverse possessory actions, and would have the authority to approve requests upon finding that just cause exists for the adverse possessory action.

Bill Introduced to Expedite Process for Out-of-State Mental Health Professionals to Provide Telemedicine Services in New Jersey – On December 16, 2021, Bill S4283 was introduced in the New Jersey Senate to establish an expedited process by which a person who is licensed in a mental health profession in another jurisdiction in the United States or in another country could become licensed in New Jersey to provide services using telehealth and telemedicine. An identical bill was introduced in the New Jersey Assembly on November 15, 2021. The individual would be required to have practiced in the mental health profession for at least 10 years to qualify for

the expedited process. “Mental health professionals” covered by the Bill would include professionals licensed by the Alcohol and Drug Counselor Committee, the State Board of Creative Arts and Activities Therapies, the State Board of Marriage and Family Therapy Examiners, the State Board of Medical Examiners, the Professional Counselor Examiners Committee, the Certified Psychoanalysts Advisory Committee, the State Board of Psychological Examiners, the State Board of Social Work Examiners, and the New Jersey Board of Nursing. The expedited process would permit the out-of-State professional to be licensed in New Jersey without sitting for an online course in jurisprudence or an orientation, which a board can require under current law, and would grant the professional up to one year to designate an agent in New Jersey and to submit documentation verifying the professional’s education, experience, and examination results.

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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.

Join us for a webinar on Wednesday, January 12 at 10:00 a.m. as Healthcare Law Members **John D. Fanburg**, **Isabelle Bibet-Kalinyak**, **Carol Grelecki**, and **Keith J. Roberts** discuss the federal No Surprises Act and what providers need to know as they navigate this new law. Register today!

On December 21, Healthcare Law Member **Lani M. Dornfeld** issued a Healthcare Law Alert entitled “CMS COVID-19 Vaccine Mandate in Flux.”

On December 2, Healthcare Law Member **Lani M. Dornfeld** issued a Healthcare Law Alert entitled “CMS COVID-19 Healthcare Staff Vaccination Interim Final Rule on Hold.”

On November 30, Healthcare Law Member **Lani M. Dornfeld** issued a Healthcare Law Alert entitled “Highlights of CY2022 Medicare Physician Fee Schedule (MPFS).”

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 Erika R. Marshall and Associate Paul J. DeMartino, Jr.

Erika R. Marshall

Erika Marshall provides legal counsel to medical professionals and healthcare entities in the area of healthcare business transactions and related matters.

Outside of the office, Erika enjoys cooking, trying out new restaurants, and spending time with her family, including her “pup,” Monte.

Paul J. DeMartino, Jr.

Paul J. DeMartino, Jr. is an associate specializing in assisting business and healthcare clients in complex contractual and corporate disputes involving minority oppression, LLC and partnership divorces, business dissolutions, restrictive covenants, fraud, and contractual disputes of all kinds.

In his spare time, Paul enjoys playing golf and spending time at the Jersey Shore.

HIPAA CORNER

On December 20, 2021, the U.S. Department of Health & Human Services, Office for Civil Rights (OCR) announced the OCR's issuance of guidance to help clarify that the HIPAA Privacy Rule permits covered healthcare providers to disclose protected health information (PHI) to support applications for extreme risk protection orders (ERPO) that temporarily prevent a person in crisis, who poses a danger to the person in crisis or to others, from accessing firearms. According to the OCR:

This guidance helps implement the U.S. Department of Justice's model extreme risk protection order legislation that provides a framework for states to consider in creating laws allowing law enforcement, concerned family members, or others to seek these orders and to intervene in an effort to save lives. These orders can be an important step toward improving the public's safety by helping to prevent firearm injuries and deaths.

The guidance explains the circumstances in which a covered healthcare provider may disclose a patient's PHI in support of an ERPO application by the provider or another person and otherwise to support state ERPO laws. Providers should be cautioned, however, that notwithstanding the ability to disclose PHI under ERPO laws, certain HIPAA protections, including the "minimum necessary standard" apply to such disclosures.

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