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Health Law UPDATE

June 2019

In This Issue:

FEDERAL UPDATE

Final Conscience Rule Brings a Spate of Lawsuits Against the Trump Administration

Last month, the Department of Health & Human Services (HHS) Office for Civil Rights released the final conscience rule that protects federally funded health care entities, professionals, and employees who have conscience or religious objections related to performing, paying for, referring for, providing coverage of, or providing certain services, including, but not limited to, abortion, sterilization, or assisted suicide. The controversial rule, scheduled to take effect on July 22, 2019, has prompted numerous lawsuits by states, municipalities, and advocacy groups.

The State of New York, joined by 22 states, cities, and municipalities, was the first to file a lawsuit against the Trump administration to prevent the rule from taking effect. A similar lawsuit was also filed by the State of California. A coalition of women's reproductive rights groups and lesbian, gay, bisexual, and transgender (LGBT) health organizations also filed suit in federal court in California to have the rule struck down as unconstitutional. The groups allege that the rule "specifically invites refusals to provide care to women seeking reproductive healthcare and transgender and gender-nonconforming patients seeking gender-affirming care, adversely affecting the healthcare entities that provide reproductive healthcare services and that serve the lesbian, gay, bisexual, and transgender ("LGBT") community." Further, the "rule stigmatizes and shames these patients, depriving them of their constitutionally protected rights of access to healthcare and their dignity and autonomy in seeking medically necessary healthcare central to their self-determination."

More recently, on June 11, 2019, two separate lawsuits brought by Planned Parenthood Federation of America and the American Civil Liberties Union (ACLU) in federal court in New York also seek to have the Rule blocked as unconstitutional. Planned Parenthood argues that the Rule "jeopardizes access to the full array of health services offered by Planned Parenthood and is antithetical to its mission to provide comprehensive and non-judgmental health care and information to all who seek care at any of its more than 600 health centers across the country." The ACLU's lawsuit claims that members of the National Family Planning and Reproduction Health Association (NFPRHA) "reasonably fear" that "failure to comply with the Rule could subject NFPRHA members to the loss of hundreds of millions of dollars of federal funding without which they cannot operate" and that "the Rule will threaten the health of the patients they serve by impeding access to comprehensive reproductive health services, other health services (e.g., LGBT-related care), and emergency care."

Court rulings have not yet been issued in any of the lawsuits.

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CMS to Introduce New Provider Payment Options

The Department of Health & Human Services (HHS) and the Centers for Medicare & Medicaid Services (CMS) announced on April 22, 2019, their new joint effort to further transform our healthcare system towards "value-based" payment for outcomes rather than payment for services. The announcement outlined the latest initiative, the CMS Primary Care Initiative, which provides for five new payment options for physicians and providers. The initiative seeks to ease the administrative burdens of primary care physicians and providers. The changes undertaken by CMS and HHS strive to allow physicians to spend more quality time with patients, which leads to better quality care and, ultimately, lower health care costs.

The new voluntary payment options will be made available in January 2020. The CMS Innovation Center will offer two payment models, with different options within each model. The Primary Care First (PCF) model offers two options, PCF General and PCF High Need Populations. PCF is a five-year model, intended for smaller primary care practices. Under the PCF model, practices will be paid on a total monthly basis, practices who chose the High Need Populations option will receive higher payments than those who opt for the PCF General. The Direct Contracting (DC) model encompasses three options: DC Global, DC Professional, and DC Geographic. This model strives to reduce spending while simultaneously improving patient care for patients of Medicare fee-for-services. The DC model is intended for larger practices and organizations, such as ACOS, Medicare, and Medicare managed care organizations. This model incorporates the concept of risk-sharing arrangements. Under this model, providers receive a fixed monthly payment; the amount will depend upon the providers share of risk. Under the DC Global and DC Geographic options, the providers bear 100% of shared savings/shared losses, while under the DC Professional option, providers only bear 50% of the shared savings/shared losses. Though the models are currently voluntary, CMS Administrator Seema Verma has stated that some of these models may become mandatory in order to understand why providers are selecting one option over another. In addition, Verma believes this data will assist in providing necessary data to further innovation.

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CDC Clarifies Guideline for Prescribing Opioids for Chronic Pain

The Centers for Disease Control and Prevention (CDC) issued a clarification letter regarding the CDC's Guideline for Prescribing Opioids for Chronic Pain. The CDC guideline, released in March 2016, states that recommendations for prescribing opioids are applicable to primary care clinicians who prescribe opioids for chronic pain outside of active cancer treatment, palliative care, and end-of-life care. However, as stated

by Clifford A. Hudis, the Chief Executive Officer of the American Society of Clinical Oncology, many payers have been inappropriately applying the guideline to make opioid coverage determinations for patients during active cancer and sickle cell disease treatment.

The CDC's clarification letter states, "The Guideline is not intended to deny any patients who suffer with chronic pain from opioid therapy as an option for pain management. Rather, the guideline is intended to ensure that clinicians and patients consider all safe and effective treatment options for patients."

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STATE UPDATE

New Jersey's Appellate Court Issues a Pro-Payor Decision that Could Leave Providers Out of Luck

On April 29, 2019, a New Jersey appellate court issued a ruling that is advantageous to commercial payors, but it may hurt New Jersey providers. In the underlying lawsuit, dentists challenged Aetna's recoupment practices based on the New Jersey Health Claims Authorization, Processing and Payment Act (HCAPPA). Generally, this law requires prompt payment by health insurers. However, the prompt pay requirement is conditioned on both (1) the patients' eligibility and (2) the patients' coverage at the date of service. Noncompliant health insurers face a penalty of 12% interest per annum (to be paid to providers) for failure to promptly pay claims.

Among other claims at issue in the underlying lawsuit are whether it is permissible under HCAPPA for a payor to effectuate reimbursement of an overpayment by withholding a payment due to a provider for a claim submitted on behalf of a different patient. After the lower court ruled in favor of Aetna, the plaintiffs appealed, arguing in relevant part: (1) the overpayment recovery provisions in HCAPPA do not apply to "stand-alone" or "dental-only" benefit plans; (2) the overpayment reimbursement provisions in HCAPPA do not apply to benefits paid to persons who were not covered on the date of service; (3) HCAPPA does not empower a payer to effect an overpayment reimbursement for covered services and thereafter inform the covered person that it has no obligation to pay the provider."

The dentist-plaintiffs in the underlying lawsuit provided various dental services to patients who were insured and eligible for covered dental services at one point in time but later became ineligible. Aetna made initial payments on the claims. After some time passed, Aetna notified the providers that there was an improper payment, and later recouped the monies from reimbursements on the providers' future submitted claims. Aetna determined that the patients were no longer eligible for covered services during the dates of services.

The lower court ruled that these recoupment practices are permitted under HCAPPA for such mistaken payments; the appellate court affirmed this decision. The appellate court reasoned that when prompt payments and prompt eligibility determinations are made, mistakes are bound to occur. HCAPPA does not limit the payer's ability to collect reimbursement of overpayments by offsetting "any future claims," including future claims related to patients other than the patient for whom the overpayment was made. The court further clarified that the law has broad applicability to various forms of insurance plans, including stand-alone dental plans.

Moving forward, providers should initiate procedures to verify health and dental benefits at the time services are rendered, in order to avoid clawbacks from insurers, including by offsets to payments on future claims.

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NJ Rx Monitoring Program Expanded to Bolster Prevention of Opioid Addiction and Fatalities

On May 6, 2019, amendments to New Jersey's Prescription Monitoring Program (PMP) took effect to further combat opioid addiction and fatalities. The PMP is a centralized statewide database that collects and tracks prescription sales by pharmacies of opioids and other controlled dangerous substances. The PMP is accessed by prescribers and pharmacies to identify signs that individuals are abusing or diverting these medications.

The new rules require prescribers to look up patient records on the PMP for prescriptions written in hospital emergency rooms. Practitioners are exempt from the look-up requirement if they prescribe no more than a five-day supply of a controlled dangerous substance to a patient within 24 hours after the patient has undergone an operation or treatment for acute trauma in a general hospital or a licensed ambulatory care facility, so long as the treatment was not provided in the hospital emergency department. The rules also require that the PMP be accessed for prescriptions for all opioids, not just Schedule II drugs. In addition, prescribers must also check the PMP before writing prescriptions for benzodiazepines, a class of sedatives, including Xanax and Ativan, that increases the risk of fatalities when combined with opioids.

The amended rules also broaden who may access the database. Prescribers may now delegate PMP access to a wider scope of healthcare professionals, including athletic trainers in a clinical setting, medical scribes employed by a hospital's emergency department, registered dental assistants, and licensed mental health practitioners providing treatment to substance abuse patients at licensed residential or outpatient substance abuse treatment centers.

All prescribers and pharmacies should become familiar with the updated rules. Noncompliance with the PMP rules may be deemed professional misconduct and may result in disciplinary action

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New Jersey Legislative Update

New Jersey Board of Medical Examiners Proposes Telemedicine and Telehealth Regulations – On May 6, 2019, the New Jersey Board of Medical Examiners (BME) released proposed regulations to implement New Jersey's telemedicine and telehealth statute, which became law on July 21, 2017. The proposed regulations apply to New Jersey licensed physicians and podiatrists. Comments on the proposed regulations must be submitted to the BME by July 5, 2019. Please see Brach Eichler's Health Law Alert on the topic for a detailed summary of the proposed regulations.

New Bundled Payments for Childbirth-Related Services Law – On May 8, 2019, Governor Phil Murphy signed a new law which establishes bundled payments for childbirth-related services. The new law implements a three-year Medicaid perinatal episode of care pilot program, to be developed by the "perinatal episode of care steering committee." The steering committee will design a perinatal episode of care payment model, also known as a bundled payment model, in which provider reimbursement is based on target total cost of care for services provided within a perinatal episode

of care, rather than on individual services provided within the episode of care. A "perinatal episode of care" is defined as all pregnancy-related care including prenatal care, labor and birth, and postpartum care provided to a mother and infant, beginning 40 weeks prior to the delivery and ending 60 days after the delivery of the infant. The purpose of the new law is to improve perinatal healthcare outcomes and to reduce the cost of perinatal care.

New Law Provides Medicaid Coverage For Doula Care – On May 8, 2019, Governor Phil Murphy signed a new law for the New Jersey State Medicaid program to include coverage for doula care. To obtain federal approval for the expansion, the New Jersey Commissioner of Human Services will apply for such New Jersey State plan amendments or waivers as may be necessary to implement the provisions of the new law and to secure federal financial participation for state Medicaid expenditures under the federal Medicaid program. In addition, the new law permits the Commissioner of Human Services to establish implementation, including eligibility rules and coverage limitations.

New Law Prohibits Medicaid Coverage For Certain Early Elective Deliveries – On May 8, 2019, Governor Phil Murphy signed a new law which prohibits health benefits coverage for certain non-medically indicated early elective deliveries under the Medicaid program, the State Health Benefits Program (SHBP), and the School Employees' Health Benefits Program (SEHBP). Specifically, the law prohibits health benefits contracts which are issued or purchased pursuant to the SHBP, SEHBP, and the Medicaid program, as well as services purchased under the Medicaid fee-for-service program, from providing health benefits coverage or reimbursing a provider for a non-medically indicated early elective delivery performed at a hospital on a pregnant woman earlier than the 39th week of gestation. Non-medically indicated early elective delivery is defined as the artificial start of the birth process through medical interventions or other methods, also known as labor induction, or the surgical delivery of a baby via a Cesarean section for purposes or reasons that are not fully consistent with established standards of clinical care as provided by the American College of Obstetricians and Gynecologists. Non-medically indicated deliveries before 39 weeks of gestation are associated with an increased risk that the baby will be admitted to the neonatal intensive care unit, resulting in longer stays and higher costs, increased risk of the baby contracting pneumonia, and a higher probability that the procedure will result in the need for a Cesarean section, which carries additional risks for the mother, including infections, bleeding, and anesthesia complications.

Laws Requiring Electronic Submission of Certain Medical Bills Effective in 2019 – Two New Jersey laws regarding the electronic submission of medical bills for auto insurance and workers' compensation claims are both going into effect before the end of 2019.

Effective September 1, 2019, healthcare providers or their billing representatives will be required to submit electronic bills for payment of automobile insurance claims on standardized forms following guidelines established pursuant to the new law. Payment for a complete electronic medical bill deemed compensable by the insurance carrier will be made in accordance with current law for personal injury protection coverage benefits, provided that insurance carriers or their third-party administrators may establish shorter payment deadlines through contracts or agreements with health care providers or their billing representatives in a non-prescribed format or timeline.

Effective November 1, 2019, healthcare providers, their billing representatives, or any company that has purchased the rights to pursue their bills will be required to submit complete electronic medical bills for payment of workers' compensation claims on standardized electronic forms following the guidelines established pursuant to the new law. Payment for a complete electronic medical bill deemed by the employer, workers' compensation insurance carrier, or the workers' compensation third-party administrator to be compensable must be paid within 60 days or less.

In addition, the new law ensures that employers, workers' compensation insurance carriers for the employer, and their third-party administrators may exchange electronic data and establish payment deadlines through PPO or IPA contracts or agreements with health care providers or their billing representatives in a non-prescribed format or timeline, independent of the guidelines. The New Jersey Department of Labor and Workforce Development, Division of Workers' Compensation, adopted regulations on April 19, 2018 to effectuate this new law.

BME Proposes Regulations Recognizing Volunteer Medical Services for Continuing Medical Education Credits – In 2010, an amendment to New Jersey law granted the Board of Medical Examiners (BME) the authority to recognize volunteer medical services as satisfying up to 10 percent of a licensee's continuing medical education (CME) hours requirement. "Volunteer medical services" is defined as medical care provided without charge to low-income patients for health care services for which the patient is not covered by any public or private third-party payer. On May 20, 2019, the BME published proposed regulations to effectuate this law. Existing BME regulations require licensees to complete 100 CME credits every biennial renewal period. The proposed regulations would permit licensees to obtain up to 10 hours of CME credits by providing free medical care outside of their offices to low-income patients for health care services for which the patients are not covered by any public or private third-party payer. One CME credit would be granted for every two hours spent providing volunteer medical services. Comments on the proposed regulations must be submitted to the BME by July 19, 2019.

Bill Introduced to Revise Assessments on Ambulatory Care Facilities – On June 17, 2019, Bill A5605 was introduced in the New Jersey Assembly to revise the ambulatory care facility (ACF) assessment and levy the assessment on additional types of healthcare facilities beginning in fiscal year 2020. New Jersey currently imposes an annual ACF assessment of 2.95 percent of gross receipts over $300,000, with a cap currently set at $350,000. The assessment is levied on all Department of Health (DOH) licensed ACFs with the exception of one-room surgical practices. Surgical practices that have more than one operating room are required to pay the fee. The Bill proposes to remove the $350,000 cap and apply the 2.95 percent assessment to the full amount of an ACF's annual gross receipts beginning in 2020. In addition, the Bill proposes to levy the assessment on all DOH-licensed ACFs, including one-room surgical practices. ACF assessment revenues are deposited in the Health Care Subsidy Fund, which supports various health care initiatives throughout the state.

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Brach Eichler In The News

Managing Member and Healthcare Law Chair **John D. Fanburg** was named to the *NJBIZ* Power 50 Law List on June 24.

Brach Eichler released two new videos showcasing the thought leadership of our Cannabis Law Co-Chairs **John D. Fanburg** and **Charles X. Gormally** and Real Estate Member **Susan R. Rubright**. The objective of the videos is to provide resources to New Jersey and out-of-state businesses as they contemplate wide-ranging new opportunities to enter the cannabis business here. Have a look at "A Primer on NJ's Business Landscape for Out-of-State Marijuana Businesses" and "Legislative Landscape for NJ's Expanded Medical Marijuana Bill."

Managing Member and Healthcare Law Chair **John D. Fanburg** advises on selling your practice to a private equity firm in *Medical Economics*.

Lani M. Dornfeld will speak to attendees at the Home Care Association of Florida's 30th Annual "Home Care Con" on July 31, on "HIPAA Breach Response, Investigation and Reporting: How to Follow the Rules to Reduce Fines and Penalties (and What the Rules Don't Say, But You Need to Know)."

John D. Fanburg spoke on May 31 on "What's In It For Me? Tips on How to Get the Best Employment Contract." at the annual meeting of the New Jersey Obstetrical & Gynecological Society.

Register Now! Our tenth annual New Jersey Healthcare Market Review (NJHMR) will be held on September 18 - September 19 at the Borgata in Atlantic City. Visit www.njhmr.com for more information

To view a full listing of recent news items and to read the articles mentioned above, please click here.

HIPAA CORNER

New HHS Fact Sheet on Business Associate Liability Under HIPAA

On May 24, 2019, the U.S. Department of Health & Human Services (HHS) published a new Fact Sheet on Direct Liability of Business Associates under HIPAA. In the Fact Sheet, DHHS "provides a clear compilation of all provisions through which a business associate can be held directly liable for compliance with certain provisions of the HIPAA Privacy, Security, Breach Notification, and Enforcement Rules." The list includes the following:

- Failure to provide the Secretary with records and compliance reports; cooperate with complaint investigations and compliance reviews; and permit access by the Secretary to information, including protected health information (PHI), pertinent to determining compliance.
- Taking any retaliatory action against any individual or other person for filing a HIPAA complaint, participating in an investigation or other enforcement process, or opposing an act or practice that is unlawful under the HIPAA Rules.
- Failure to comply with the requirements of the Security Rule.
- Failure to provide breach notification to a covered entity or another business associate.
- Impermissible uses and disclosures of PHI.
- Failure to disclose a copy of electronic PHI to either the covered entity, the individual, or the individual's designee (whichever is specified in the business associate agreement) to satisfy a covered entity's obligations regarding the form and format, and the time and manner of access under 45 C.F.R. §§ 164.524(c)(2)(ii) and 3(ii), respectively.
- Failure to make reasonable efforts to limit PHI to the minimum necessary to accomplish the intended purpose of the use, disclosure, or request.
- Failure, in certain circumstances, to provide an accounting of disclosures.
- Failure to enter into business associate agreements with subcontractors that create or receive PHI on their behalf, and failure to comply with the implementation specifications for such agreements.
- Failure to take reasonable steps to address a material breach or violation of the subcontractor's business associate agreement.

If you need assistance in managing a breach incident or making any required reporting, please contact:

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HEALTH LAW ALERT JUNE 2019

COMPENSATION FROM PHARMACEUTICAL COMPANIES: THE AMENDED RULES

On January 16, 2018, regulations limiting gifts and payments from prescription drug and biologics manufacturers to prescribers went into effect in the State of New Jersey. The rules were established to minimize conflicts of interest between health care prescribers and pharmaceutical manufacturers and to ensure prescribers use best judgment when treating patients. In August 2018, the Attorney General, Gurbir S. Grewal, proposed amendments to the rules in an effort to increase clarity and, in particular, to address concerns related to the modest meal limit and the rules' impact on educational events. After a notice and comment period, the amended rules went into effect on May 6, 2019. The key changes are briefly summarized below.

The Scope of the Rules and "Prescribers"

The revised rules make it clear that they do not apply to prescribers' interactions with pharmaceutical manufacturers concerning medical devices. Therefore, if a manufacturer manufactures pharmaceuticals and/or biologics as well as medical devices and the interactions between the manufacturer and the prescriber are devoted solely to medical devices, the rules do not apply to such interactions.

Additionally, the rules now specify that they apply only to a prescriber who holds an active New Jersey license and who: (1) practices in New Jersey; or (2) has New Jersey patients regardless of the prescriber's practice site. Accordingly, the definition for "prescriber" was amended to mirror this change. When concerns were raised about whether this criteria was too broad, the Attorney General stated, "[T]he rules should apply equally to all prescribers licensed by the State" no matter where they regularly practice.

"Modest Meals" and the "Consumer Price Index"

In response to concerns about the $15 meal limit being untenable, the limit was reformulated to allow for a $15 limit for breakfast and lunch and a $30 limit for dinner. These limits were set for 2018, and the rules provide for adjustments in line with the Consumer Price Index. A definition for "Consumer Price Index" was incorporated into the rules, which indicates that adjustments should be made in dollar increments to reflect the Consumer Price Index annual average.

Meals provided at education events are no longer subject to the "modest meal" limits, even if the event is supported by a manufacturer. In addition, neither modest meals nor meals provided at education events are subject to the bona fide services cap, and fair market value does not include the cost of standard delivery, service, facility rental fee charges, or tax.

"Education Events"

Under the amended rules, the definition of "education event" was changed to specify that so long as a program is not classified as promotional by the Food and Drug Administration (FDA), the event is considered an "education event" if it meets the definition set forth in the rules.

Moreover, the Attorney General explicitly shared his support for educational activities and discourse. As such, he altered the definition of "education event" to include events where information about disease states and treatment approaches are discussed.

Additional Insight from the Attorney General

- The bona fide services cap remains in effect and is still set at $10,000. According to the Attorney General, the cap is a necessary component for minimizing conflicts of interest and promoting unbiased patient care. The Attorney General further reaffirmed that payments for research activities and payments for speaking at education events are not subject to the cap.
- When asked to include a safe harbor provision, the Attorney General declined. The inclusion of a safe harbor provision would have offered protection from liability under specific situations or if certain conditions were met.
- The Attorney General stated that the rules were never intended, nor should they be interpreted, to impact public health initiatives or financial assistance, scholarships, or charitable contributions that are made to, and controlled by, an educational institution.
- When met with concerns regarding whether the definition for "immediate family" is overly broad, the Attorney General disagreed and declined to amend.
- The Attorney General refused to repeal the rules. He also refused to delay the implementation of the amended rules, which are currently in effect. Similarly, a suggestion to limit the rules' applicability to only opioids was denied. The Attorney General explained that while the original motivation for the rules was to address the state's opioid crisis, the protections offered reach further than just opioids and instead speak to improved patient care overall. Conversely, the Attorney General recognized that the rules alone do not fix the opioid epidemic, but they do offer an additional safeguard.

You can find our Health Law Alert discussing the original rules in our January 2018 Health Law Update.

For more information about these new rules or any other Healthcare Law policies or procedures, feel free to contact **Lani M. Dornfeld, CHPC,** *or another member of our Healthcare Law Practice group below.*

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