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2019 Healthcare Law Year in Review

Welcome to the eleventh annual *Healthcare Law Year in Review* produced by the Brach Eichler Healthcare Law Practice. The goal of this publication is to highlight some of the most important issues and developments in healthcare, both nationally and in New Jersey, over the past 12 months.

The healthcare landscape in 2019 was marked by continued change—not surprisingly—with physicians and other providers/professionals subject to even greater regulation and scrutiny. This heavily regulated operating environment will continue in 2020 and into the foreseeable future.

Among the important issues covered in this year's report are:

- The amended rules regarding prescriber compensation from pharmaceutical companies
- Proposed amendments to the Stark Law and Anti-Kickback Statute
- New price transparency rules for hospitals and health plans
- DOBI's proposed out-of-network regulations.

Brach Eichler's healthcare law attorneys are always available to provide guidance and/or assist with issues related to regulatory compliance and other matters. If you have any questions or would like additional information regarding any of the articles contained in the *2019 Healthcare Law Year in Review*, please do not hesitate to contact John D. Fanburg, Esq., Chair of Brach Eichler's Healthcare Law Practice, at 973-403-3107 or jfanburg@bracheichler.com

CMS Issues New Price Transparencies Rules for Hospitals and Health Plans

On November 15, 2019, the Centers for Medicare & Medicaid Services (CMS) issued two rules advancing the Trump administration's goals of improving price and quality transparency in healthcare.

The first is a final rule implementing Section 2718(e) of the Public Health Service Act requiring each hospital operating in the United States to establish, update, and make public an annual list of the hospitals' standard charges for items and services provided by the hospital, including for diagnosis-related groups. The rule, which will be effective January 1, 2021, finalizes: the definitions of "hospital," "standard charges," and "items and services;" the requirements for making public a machine-readable file online that includes all standard charges for all hospital items and services; the requirements for making public prices for discounted cash payments, payer-specific negotiated charges, and the lowest and highest charges negotiated with all third-party payors for at least 300 "shoppable services" that are presented in a consumer-friendly manner; and the monitoring and action requirements for hospital noncompliance, including audits, corrective action plans, and penalties of $300 per day, as well as a process for hospitals to appeal these penalties.

The second rule is a proposed Transparency in Coverage rule which would require most group health plans, including self-insured plans, and health insurance issuers in the individual and group markets to disclose price and cost-sharing information to participants, beneficiaries, and enrollees. The proposed rule would not apply to grandfathered health plans that existed prior to the Affordable Care Act. The rule would give healthcare consumers real-time, personalized access to estimates of their cost-sharing liability for all covered health care items and services. The information would be provided through an online tool, and in paper form upon request, that group health plans and issuers must make available to all of their members. The goal is to enable healthcare consumers to shop and compare costs between specific providers prior to receiving care. The plans and issuers would also be required to disclose on a public website their negotiated rates for in-network providers and the allowed amounts paid for out-of-network providers. The rule would take effect for plan or policy years beginning one year after the finalization of the rule.

Compensation from Pharmaceutical Companies: The Amended Rules

On January 16, 2018, regulations limiting gifts and payments from prescription drug and biologics manufacturers to NJ 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.

CMS and OIG Proposed Amendments to Stark and Anti-Kickback Regulations

The Focus is on Value-Based and Coordinated Care

On October 17, 2019, the U.S. Department of Health & Human Services (HHS), Centers for Medicare & Medicaid Services (CMS) issued its highly anticipated proposed rule updating regulations under the federal self-referral law known as the Stark Law, titled "Medicare Program; Modernizing and Clarifying the Physician Self-Referral Regulations" (referred to in this alert as the "Stark Rule Proposal"). On the same date, the HHS, Office of Inspector General (OIG), in conjunction with the HHS's Regulatory Sprint to Coordinated Care, issued a second proposed rule to amend the safe harbors under the federal Anti-Kickback Statute, titled "Medicare and State Healthcare Programs: Fraud and Abuse; Revisions to Safe Harbors Under the Anti-Kickback Statute, and Civil Monetary Penalty Rules Regarding Beneficiary Inducements (referred to in this alert as the "AKS Rule Proposal").

Modernizing the Stark Law for Value-Based Care

According to CMS, the Stark Rule Proposal "supports the CMS 'Patients over Paperwork' initiative by reducing unnecessary regulatory burden on physicians and other healthcare providers while reinforcing the Stark Law's goal of protecting patients from unnecessary services and being steered to less convenient, lower quality, or more expensive services because of a physician's financial self-interest." The Stark Rule Proposal adds three new statutory exceptions for value-based care compensation arrangements which would permit "physicians and other healthcare providers to design and enter into these arrangements without the fear that legitimate activities to coordinate and improve quality of care and lower costs would violate the Stark Law."

Full Financial Risk Exception

The "full financial risk" exception would apply to value-based arrangements between participants that have assumed "full financial risk" for the cost of all patient care items and services covered by the applicable payor for each patient in the target patient population of the arrangement. To meet this exception, the participants must be financially responsible for the cost of all patient care items and services covered by the applicable payor for each patient in the target patient population for a specified period of time. Such an arrangement may take the form of capitation payments or global budget payment from a payor that covers a predetermined period of time.

Meaningful Downside Financial Risk Exception

The "meaningful downside financial risk" exception would protect remuneration paid under a value-based arrangement between an entity furnishing designated health services and a physician where the physician is at meaningful downside financial risk for failure to achieve the value based purposes of the arrangement, such as coordinating and managing the care of a target patient population, improving the quality of care for a target patient population, or appropriately reducing the costs to, or growth in expenditures of, payors without reducing the quality of care for a target patient population. CMS proposes to define "meaningful downside risk" to mean that the physician is responsible for paying the entity no less than 25 percent of the value of the remuneration the physician receives under the value-based arrangement.

Value-Based Arrangements Exception

The "value-based arrangements" exception would permit any value-based arrangement, regardless of risk level, so long as the requirements of the exception are satisfied.

Other Provisions of Proposed Rule

The Stark Rule Proposal contains additional provisions addressing indirect compensation arrangements to which the proposed new exceptions are applicable and price transparency in the context of the Stark Law. In addition, the proposal addresses "fundamental terminology and requirements," including a definition of "commercially reasonable," bright-line rules for the "volume and value" and "other business generated" standards, revised definitions of

"fair market value" and "general market value," and revisions to group practice rules. Finally, the proposal includes an exception for limited remuneration to a physician (less than $3,500/year), and would eliminate the sunset provision of the EHR exceptions.

Federal Anti-Kickback Statute: Focus on Value-Based and Coordinated Care

Under the AKS Rule Proposal, HHS would create three new safe harbors for certain remuneration exchanged between or among eligible participants in a value-based arrangement that fosters better care coordination and managed patient care: (i) care coordination arrangements aimed at improving quality and outcomes; (ii) value-based arrangements with substantial downside financial risk; and (iii) value-based arrangements with full financial risk. The safe harbors vary by the types of remuneration protected, level of financial risk undertaken by the parties, and types of safeguards implemented.

Similar to the Stark Rule Proposal, the AKS Rule Proposal contains new "value-based" terminology for key terms to be used in the rules, and contains specific elements that must be satisfied in order to fit within each new safe harbor.

In addition, the AKS Rule Proposal includes:

- A proposed new safe harbor for certain tools and supports furnished under patient engagement and support arrangements to improve quality, health outcomes, and efficiency
- A proposed new safe harbor for certain remuneration provided in connection with a CMS-sponsored model, which should reduce the need for OIG to issue separate and distinct fraud and abuse waivers for new CMS-sponsored models
- A proposed new safe harbor for donations of cybersecurity technology and services
- Proposed modifications to the existing safe harbor for electronic health records items and services to add protections for certain cybersecurity technology included as part of an electronic health records arrangement, to update provisions regarding interoperability, and to remove the sunset date
- Proposed modifications to the existing safe harbor for personal services and management contracts to add flexibility with respect to outcomes-based payments and part-time arrangements
- Proposed modifications to the existing safe harbor for warranties to revise the definition of "warranty" and provide protection for warranties for one or more items and related services
- Proposed modifications to the existing safe harbor for local transportation to expand and modify mileage limits for rural areas and for transportation for discharged patients
- Codification of the statutory exception to the definition of "remuneration" related to ACO Beneficiary Incentive Programs for the Medicare Shared Savings Program.

What's Next?

Comments to each of the rule proposals were due by December 31, 2019. Once the rules are finalized, it is anticipated that providers will have significant opportunities to put together new arrangements focused on value-based and coordinated care. At the same time, however, providers will need to review existing arrangements for compliance with new definitions and revisions to existing rules.

DOBI Releases Proposed Out-Of-Network Regulations

On November 4, 2019, the New Jersey Department of Banking and Insurance (DOBI) released proposed regulations to implement the Out-Of-Network Consumer Protection, Transparency, Cost Containment and Accountability Act (Act), which became effective on August 30, 2018. DOBI had previously issued guidance in the form of Bulletin No. 18-14 on November 20, 2018 to carriers, healthcare providers, and other interested parties to help those entities meet their obligations under the Act, pending the adoption of regulations. The proposed regulations are intended to codify Bulletin No. 18-14.

Key requirements of the Act addressed by the proposed regulations include the following:

- Required transparency disclosures of carriers regarding out-of-network services
- Consumer protections from billing for inadvertent and/or involuntary out-of-network services above the covered person's network level cost-sharing
- Prohibitions on the waiver of cost-sharing
- Procedures for the processing of claims for inadvertent and/or emergency out-of-network services prior to arbitration
- Procedures for the arbitration of claims for inadvertent and/or involuntary out-of-network services
- Procedures for arbitration of claims for inadvertent and/or involuntary out-of-network services where a self-funded health benefits plan does not elect to be subject to the arbitration and claims processing provisions of the Act.

Medical Aid in Dying for the Terminally Ill Act Becomes Law

On August 1, 2019, the Medical Aid in Dying for the Terminally Ill Act (Act) became effective. The Act permits a qualified terminally ill adult patient to obtain medication to self-administer in order to end the person's life. The Act contains numerous safeguards to ensure the process remains entirely voluntary and to protect the public welfare and vulnerable adults from abuse.

The Act is intended to recognize New Jersey's long-standing commitment to individual dignity, informed consent, and the fundamental right of competent adults to make health care decisions for themselves. These decisions include whether to have life-prolonging medical or surgical means or procedures provided, withheld, or withdrawn.

The Definition of Qualified Terminally Ill

The Act permits a qualified terminally ill person who is an adult resident of New Jersey and has been determined by his/her attending and consulting physicians to be terminally ill to obtain life-terminating medication for self-administration. "Terminally ill" is defined to mean that the person is in the terminal stage of an irreversible fatal illness, disease, or condition with a prognosis, based upon reasonable medical certainty, of a life expectancy of six months or less. The diagnosis of terminal illness must be made by the patient's attending physician and confirmed by a consulting physician. In order to be deemed to "qualify," among other things, the individual must be a "capable" adult, meaning the person must have the capacity to make health

care decisions and to communicate them to a health care provider, including communication through persons familiar with the patient's manner of communicating if those persons are available.

Informed and Carefully Considered Decision

The patient must make an "informed" decision, meaning that the traditional elements of the informed consent process must be satisfied. This includes that the patient's decision must be made after the patient is informed of and comprehends:

- The patient's medical diagnosis
- The patient's prognosis
- The potential risks associated with taking the medication to be prescribed
- The probable result of taking the medication to be prescribed
- The feasible alternatives to taking the medication, including additional treatment opportunities, palliative care, comfort care, hospital care, and pain control.

Once the patient has made a request for medication to terminate his/her life and before such medication is prescribed, the physician must ensure all required steps under the Act are taken, including:

- Ensuring the informed consent process has occurred
- Referring the patient to a consulting physician for medical confirmation of the diagnosis, prognosis, and patient "capability" to make the decision and confirming that the decision is being made voluntarily
- Referring the patient for counseling, if appropriate
- Recommending that the patient notify his/her next of kin of the decision
- Advising the patient of the importance of having another person present if and when the patient chooses to take the life-terminating medication, and not to take the medication in a public place
- Informing the patient of the opportunity to rescind his/her request
- Verifying that the patient is making an informed decision
- Fulfilling medical record documentation requirements and certain reporting requirements.

Additional Safeguards

The Act contains other safeguards against abuse, including that the individual must make two oral requests for life-terminating medication, with a 15-day separation between requests, followed by a written request on a form as required under the Act. The form must be signed by the individual and witnessed by at least two individuals, at least one of whom is not the patient's relative by blood, marriage, or adoption; who is entitled to any portion of the individual's estate; or in any way involved with the health care facility where the patient is receiving care or is a resident. Upon receipt of the written, signed, and witnessed request, the physician must wait at least 48 hours before writing the prescription for life-terminating medication.

Assistance

The Act contains a defined and safeguarded process to effectuate the right of a qualified terminally ill patient to obtain medication to end his/her life. The Act provides immunity to physicians and others who fully comply with the Act, and potential civil and criminal penalties for those who do not. Health care providers will need to institute detailed policies and procedures to ensure that every element of the Act is met.

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.

State Licensing Boards Propose Telemedicine and Telehealth Regulations

On June 17, 2019, the New Jersey State licensing boards that regulate physical therapists, midwives, athletic trainers, genetic counselors, psychologists, psychoanalysts, orthotists, and prosthetists, released proposed regulations to implement New Jersey's telemedicine and telehealth statute, which became law on July 21, 2017. The proposed regulations from each board were

substantially similar to one another as well as to the proposed regulations for physicians, which were released on May 6, 2019. The proposed regulations set forth requirements for the practice of telemedicine and telehealth in New Jersey by the various licensees listed above, including in the following areas:

- The required standard of care to practice telemedicine and telehealth
- The establishment of a licensee-patient relationship
- The requirements for providing services through telemedicine and telehealth
- Recordkeeping
- The prevention of fraud and abuse
- Privacy and notice to patients.

Proposed Bill to Authorize Dispensing Medical Marijuana Through Telemedicine

On November 7, 2019, Bill S4171 was introduced in the New Jersey Senate to permit dispensing medical marijuana through telemedicine and telehealth under certain circumstances. An identical bill was introduced in the New Jersey Assembly on November 25, 2019. Under the Bill, for 270 days following the date of the Bill's enactment, a healthcare practitioner may authorize a patient who is a child, resident of a long-term care facility, developmentally disabled, terminally ill, receiving hospice care, or housebound as certified by the patient's physician, for the medical use of cannabis using telemedicine and telehealth. Thereafter, a healthcare practitioner may authorize any patient for the medical use of cannabis using telemedicine and telehealth, provided that, and except in the case of a patient who is a child, developmentally disabled, terminally ill, receiving hospice care, or housebound, the patient has had at least one previous in-office visit with the practitioner prior to the patient's authorization for the medical use of cannabis.

HIPAA Highlights

Over the past year, we have seen the Department of Health & Human Services (DHHS), Office for Civil Rights (OCR) enter into settlement agreements imposing civil money penalties and corrective action plans on covered entities and their business associates. We also have seen a continued focus on cybersecurity and published guidance to assist covered entities and business associates in HIPAA compliance. Highlights of this continued focus include:

- In its Spring 2019 Cybersecurity Newsletter, the OCR warned of "advanced persistent threats" and "zero day" exploits, and provided recommendations for proactively implementing the HIPAA Security Rule's required security measures to help prevent, detect, and respond to such cybersecurity attacks.
- In April 2019, the DHHS issued a Notice of Enforcement Discretion in the Federal Register to inform the public about how it applies DHHS regulations concerning the assessment of civil monetary penalties for HIPAA violations.
- In May 2019, the DHHS published a Fact Sheet on Direct Liability of Business Associates Under HIPAA, with 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."
- In its Summer 2019 Cybersecurity Newsletter, the OCR urged healthcare organizations to safeguard sensitive information not only from external threats, but from threats within their own organizations ("malicious insiders").
- The OCR reinforced its enforcement of HIPAA's "right of access" requirement by announcing its first (and later second) enforcement action and settlement based on a violation of the right of access requirement, (i.e.,right to inspect and copy records).
- The OCR provided an Update on Preventing, Mitigating and Responding to Ransomware in its Fall 2019 Cybersecurity Newsletter.
- The OCR and the Department of Education issued Joint Guidance addressing the application of the federal Family Educational Rights and Privacy Act (FERPA) and HIPAA to records maintained on students.

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