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2018 Health Law Year in Review

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The Brach Eichler Health Law Practice Group is pleased to provide its tenth annual *Year in Review*. The *2018 Year in Review* highlights key issues and developments at the state and federal level concerning health care providers over the past 12 months.

During 2018, the pace of change in New Jersey's health care industry was brisk and we expect a similar landscape in 2019. Many of the new laws that providers and other health care professionals must now adhere to are multidimensional and complex. This element, combined with the fact that regulatory scrutiny will continue to be ever present, will contribute to a challenging operating environment over the next year and beyond.

Some of the key issues that emerged in 2018 and that are covered in this year's report include:

- Limits on compensation, including meals, from pharmaceutical manufacturers to prescribers;
- New Jersey's Health Insurance Market Preservation Act;
- Medicaid reimbursement for emergency room visits;
- BME screening and diagnostic medical testing regulations;
- New law requiring surgical practices to apply for licensure as ambulatory care facilities; and perhaps most significantly;
- New out-of-network law that imposes significant requirements on virtually every practitioner and facility in the State of New Jersey.

As always, the attorneys at Brach Eichler are here to help decipher the law and provide guidance. If you have any questions or would like additional information regarding any of the articles contained in the *2018 Year in Review*, please do not hesitate to contact John D. Fanburg, Esq., Chair of Brach Eichler's Health Law Practice Group.

COMPENSATION FROM PHARMACEUTICAL COMPANIES: NEW LIMITATIONS AND OBLIGATIONS ON PRESCRIBERS

On January 16, 2018, new regulations limiting gifts and payments from prescription drug and biologics manufacturers to prescribers became effective in the State of New Jersey. Under the rules, payments received by physicians and other prescribers for non-clinical services rendered to the pharmaceutical industry will be capped at $10,000 per year. These rules do not apply to arrangements with prescribers entered into on or before January 15, 2018.

Limitations Imposed on Prescribers' Bona Fide Services

Under the newly revised rules, "prescribers" may not accept more than $10,000 in aggregate from all pharmaceutical manufacturers in any calendar year for "bona fide services" provided by the prescriber, including promotional speaking activities, participation on advisory boards, and other consulting arrangements. Payments for speaking at education events that are considered "bona fide services" are not subject to the cap, but must be set at fair market value and must be set forth in a written agreement and meet other specific requirements. Payments for research activities, and royalties and licensing fees are not subject to the cap, but other requirements apply. A "prescriber" is defined to mean a New Jersey-licensed physician, podiatrist, physician assistant, advanced practice nurse, dentist, or optometrist. Prescribers speaking at education events or promotional activities must directly disclose to attendees, either orally or in writing at the beginning of the presentation, that the prescriber has accepted payment for bona fide services from the sponsoring pharmaceutical manufacturer within the preceding five years. Prescribers employed by pharmaceutical manufacturers must satisfy other obligations under the rules.

Bona Fide Services

Bona fide services provided by a prescriber to a pharmaceutical manufacturer must be set forth in a written agreement, and include speaking presentations at promotional activities and education events, participation on advisory boards, and consulting arrangements. The written agreement must contain a number of detailed elements, including the specific services to be provided and the specific compensation amount based on the fair market value of the services.

Other Acceptable Items

In addition to the annual cap, prescribers are permitted to receive certain items and reimbursement from pharmaceutical manufacturers, including patient educational items of nominal or no value to the prescriber (e.g., anatomical models for patient education use); pharmaceutical manufacturer subsidized registration fees at education events that are available to all event participants; modest meals provided through event organizers at education events with certain limitations; modest meals provided

by a manufacturer to non-faculty prescribers through promotional activities; and reasonable payment or reimbursement of travel, lodging, and other personal expenses associated with the provision of bona fide services, associated with employment recruitment, or in connection with research activities.

Sample Medications

The rule does not change a prescriber's ability to accept sample medications from pharmaceutical manufacturers, so long as the samples are intended to be used exclusively for the benefit of the prescriber's patients, the prescriber does not charge patients for such samples, and the prescriber satisfies all dispensing standards set forth in the prescriber's licensing board rules.

Prohibited Gifts and Payments

Prescribers and their immediate family members (unless employed by the pharmaceutical manufacturer and part of regular employment benefits) are prohibited from accepting gifts and other payments from pharmaceutical manufacturers, including:

- Financial benefits (e.g., gifts, payments, stock, stock options, grants, scholarships, subsidies, and charitable contributions)
- Entertainment or recreational items (e.g., theater or sporting event tickets or leisure trips)
- Meals with a fair market value in excess of $15
- With certain exceptions, any item of value that does not advance disease or treatment education, such as:
  - Pens, note pads, clipboards, mugs, or other items with a company or product logo
  - Items intended for the personal benefit of the prescriber or staff (e.g., floral arrangements and artwork)
  - Items that may have utility in both the professional and non-professional setting (e.g., electronic devices), unless the item is used by patients and remains in a common area of the prescriber's office
  - Any payment in cash or cash equivalent (e.g., gift certificates)
  - Any payment or direct subsidy to a non-faculty prescriber to support attendance at, as remuneration for time spent attending, or for the costs of travel, lodging, or personal expenses associated with attending any education event or promotional activity.

Under the rule, "immediate family member" includes the prescriber's spouse, civil union partner, or domestic partner, as well as children and all other relatives who reside in the same household as the prescriber.

How Can We Help?

The rules contain a number of restrictions and nuances for prescribers receiving payments from pharmaceutical manufacturers. Further, the rules require specific items and provisions be set forth in written agreements between the prescriber and manufacturer. Should you need assistance regarding the permissible and restricted activities and payments under the rule, or in preparing or reviewing agreements with pharmaceutical manufacturers, please contact us.

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AMENDMENTS TO PHARMACEUTICAL MEAL LIMITS PROPOSED

On August 6, 2018, the New Jersey Attorney General officially proposed modifications to the meal limitations set forth in the recently enacted regulations limiting gifts and payments from prescription drug and biologics manufacturers to prescribers. The regulations, which became effective on January 16, 2018, imposed a limitation of $15 on the amount of a modest meal that could be provided at an educational event or promotional activity hosted by a pharmaceutical manufacturer. Due to concerns expressed by manufacturers and prescribers that the $15 limitation is unrealistic in New Jersey, the Attorney General proposed to amend the limitation. The proposed modifications to the meal limits were originally announced in a letter to the four professional boards regulating New Jersey prescribers dated May 14, 2018, in which the Attorney General provided that he will forbear from prosecuting matters during the rule-making process if a prescriber's conduct is in compliance with the proposed amendments.

Under the Attorney General's proposed modifications, the definition of "modest meal" would allow $15 for breakfast and lunch and $30 for dinner in calendar year 2018. This sum would be tied to a consumer price index, allowing for dollar increases in subsequent years. In addition, standard charges for delivery, service, facility rental, and taxes would not be included in the fair market value of a modest meal. Furthermore, the dollar limits for meals associated with educational events, even if supported by a pharmaceutical manufacturer, would not be applicable, so long as the presentations are conducive to the educational purpose and include information concerning disease states and treatment approaches. Meals provided by a pharmaceutical manufacturer to prescribers through promotional activities would remain subject to the meal limitations.

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AMENDMENTS TO SCREENING AND DIAGNOSTIC MEDICAL TESTING REGULATIONS ADOPTED

Effective January 2, 2018, the State Board of Medical Examiners (BME) adopted amendments to the regulations governing screening and diagnostic medical testing in practitioner offices (N.J.A.C. 13:35-2.6). The amendments delineate separate standards for direct requests for specific diagnostic tests and those for referrals for evaluation to determine the appropriate diagnostic tests, and clarify the respective obligations borne by the referring practitioner, the requesting practitioner, and the consulting practitioner. The amendments set forth the respective obligations for practitioners directly requesting tests or referring patients for evaluation, practitioners performing or supervising the performance of the diagnostic tests, practitioners managing diagnostic offices, and practitioners owning diagnostic or screening offices. The following are some key highlights of the amendments:

- The practitioner who makes the request for a specific diagnostic test is responsible for determining the medical necessity for the specifically requested test and the way in which the test results will inform treatment decisions.
- A practitioner with a financial interest or investment in a diagnostic or screening office must ensure that the office is wholly owned through an authorized business structure. Specifically, the regulations require that ownership must be comprised of practitioners or practitioners with closely allied health professionals, so long as the majority interest is held by practitioners who are authorized to perform and interpret all the tests offered at the diagnostic or screening office.
- A practitioner responsible for the management of a diagnostic office must ensure that timely notification is provided to a patient, or the requesting or referring health care professional, of results or the need to repeat the test.
- A trained radiologic technologist may administer a diagnostic test with contrast if a physician or physician assistant or advanced practice nurse is present in the office, except when there is a documented emergency.
- A trained radiologic technologist may administer diagnostic tests, which are not invasive, not conducted with anesthesia or contrast, or which do not require sequential analysis, such as plain film radiology, with a supervising physician immediately available by telephone or other electronic means, if not in the office suite.
- A practitioner who refers a patient for evaluation is required to provide an indication of prior testing or ancillary studies relating to the medical condition and results thereof. This facilitates the testing practitioner's ability to provide appropriate patient care.
- A practitioner who accepts a referral for the evaluation and the determination as to the appropriate diagnostic test shall institute a procedure to assure that sufficient clinical data has been provided to assist in determining the appropriateness of testing, determining which tests to perform, and generating the clinical information necessary to inform treatment decisions.

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SURGICAL PRACTICES REQUIRED TO APPLY FOR LICENSURE

On January 16, 2018, then-Governor Chris Christie, signed a law requiring surgical practices to apply for licensure as ambulatory care facilities. The new law provides that a surgical practice that is in operation on the date of enactment of the new law will be required to apply for licensure by the Department of Health as an ambulatory care facility licensed to perform surgical and related services within one year of the date of enactment of the law. Key provisions of the new law include the following:

- Facilities required to apply for licensure under the bill will be exempt from the current initial and renewal license fees.
- A surgical practice that is certified by the Centers for Medicare and Medicaid Services (CMS) will not be required to meet the physical plant and functional requirements specified in the New Jersey ambulatory care facilities regulations.
- A surgical practice that is not Medicare certified, but which has obtained accreditation from the American Association of Ambulatory Surgery Facilities or any accrediting body recognized by CMS, will not be required to meet the physical plant and functional requirements specified in the New Jersey ambulatory care facilities regulations.
- An additional exception to the prohibition against licensure of new ambulatory care facilities was included in order to permit the issuance of new licenses in the case of: two or more registered surgical practices combining to create a newly licensed ambulatory surgical facility; one or more registered surgical practices combining with a licensed ambulatory surgical facility; or two or more ambulatory surgical facilities combining. In all such cases, the exception is conditioned on the total number of operating rooms in the combined or new facility not exceeding the total number of operating rooms at the practices and facilities prior to the combination of the practices or facilities.
- A surgical practice required to be licensed pursuant to the law will be exempt from the ambulatory care facility assessment; except that, if the entity expands to include any additional room dedicated for use as an operating room, in circumstances where this is permitted by law, the entity will be subject to the assessment.
- The exception to the prohibition against physician self-referrals was revised to provide that it applies to ambulatory surgery or procedures "involving the use of any anesthesia" subject to certain conditions. The previous exception was limited to ambulatory surgery or procedures "requiring the use of anesthesia."

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NEW OUT-OF-NETWORK LAW: PRACTITIONERS AND FACILITIES FACE ONEROUS REQUIREMENTS

On April 12, 2018, the New Jersey Senate and the New Jersey Assembly passed the "Out-of-Network Consumer Protection, Transparency, Cost Containment and Accountability Act" to protect consumers from surprise medical bills. Governor Phil Murphy signed it on June 1, 2018. The intent of the new law is to increase transparency to consumers with regard to in-network and out-of-network health care services, enhance consumer protections, create an arbitration system to resolve certain health care billing disputes between insurers and providers, and contain rising costs associated with out-of-network health care services.

The proponents of the law claim that it will protect patients from the financial responsibility of paying the balance of out-of-network

medical bills in excess of in-network copayments and deductibles, unless the patient knowingly and voluntarily chooses to engage an out-of-network provider for a particular service. By limiting patient responsibility for out-of-network charges, however, the law provides a huge benefit to insurance carriers who typically negotiate with out-of-network providers the amount of reimbursement for out-of-network charges. Meanwhile, health care facilities and providers will be negatively impacted due to a decrease in their ability to balance bill patients. Most importantly, as more providers choose to become in-network due to their inability to balance bill for out-of-network charges, insurance carriers will have further leverage to negotiate lower in-network rates with providers.

The law may result in physicians, particularly specialists, leaving or not coming to New Jersey because they will not be able to maintain the reimbursement rates necessary to do business in the state.

The law imposes onerous disclosure requirements on health care facilities, such as hospitals and ambulatory surgery centers, as well as health care professionals. For example, prior to scheduling an appointment for a non-emergency or elective procedure, a health care facility will be required to disclose to the patient whether the facility is in-network or out-of-network. Unless the patient knowingly, voluntarily, and specifically selects an out-of-network provider, the patient cannot be charged any costs in excess of the charges applicable to an in-network procedure. Furthermore, facilities will be required to make available lists of their standard charges for items and services. In addition, facilities will be required to post on their websites the health benefits plans that they participate in and the fact that the providers who provide services at the facility may not participate in the same health benefits plans.

Health care professionals will be subject to similar disclosure requirements. For example, prior to the provision of non-emergency services, professionals will be required to disclose to the patient the health benefits plans that they participate in. If a professional does not participate in the network of a patient, the professional must, upon the patient's request for health care services, disclose to the patient an estimated cost for the services to be provided and explain to the patient that the patient will have a financial responsibility for those costs. In addition, if a patient inadvertently receives out-of-network services, including out-of-network laboratory testing ordered by an in-network health care provider, or emergency or urgent services from an out-of-network provider, the patient will only be financially responsible for the patient's copayment or deductible.

The most controversial provisions in the law relate to the binding arbitration process to resolve disputes between out-of-network providers and insurance carriers. If attempts to negotiate reimbursement for services provided by an out-of-network provider do not result in a resolution of the dispute, and the difference between the carrier's and the provider's final offers is $1,000 or more, the carrier or out-of-network provider may initiate binding arbitration to determine payment for the services. The arbitrator's decision will be one of the two amounts submitted by the parties as their final offers and will be binding on both parties.

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GOVERNOR MURPHY SIGNS NEW JERSEY HEALTH INSURANCE MARKET PRESERVATION ACT

On May 30, 2018, Governor Murphy signed into law the "New Jersey Health Insurance Market Preservation Act." The Act restores, at the State level, the repealed shared responsibility tax provided under the Affordable Care Act (ACA), which required most individuals, other than those who qualify for certain exemptions, to obtain health insurance or pay a penalty. Specifically, the Act requires that every resident taxpayer obtain health insurance coverage that qualifies as minimum essential coverage under the Act. If a taxpayer does not obtain coverage, the Act imposes a State shared responsibility tax equal to a taxpayer's federal penalty under the ACA prior to the repeal of that provision. The Act applies to tax years beginning January 1, 2019.

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BILL TO CAP MEDICAID REIMBURSEMENT FOR EMERGENCY ROOM ENCOUNTERS SIGNED INTO LAW

On July 1, 2018, Governor Phil Murphy signed into law Bill A4207 which establishes a Medicaid emergency room triage reimbursement fee for low acuity emergency room encounters. Under the new law, a hospital in New Jersey providing emergency services to patients enrolled in the New Jersey Medicaid fee-for-service program must accept as final payment an emergency room triage reimbursement fee of $140 when the emergency services provided are for low acuity emergency room encounters. Acuity is defined as the measurement of the intensity of nursing care required by a patient. The law requires the Commissioner of Human Services to publish a list of diagnostic codes that would be considered low acuity emergency room encounters for the purpose of applying the $140 fee. Critics of the new law are concerned that hospitals will be penalized for treating patients who have nowhere else to go. Furthermore, critics contend that the new law does not solve the problem that people will continue to go to the ER if they cannot get access to a Medicaid health provider.

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