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New Jersey Enacts "One-Room" Law

By Meghan V. Hoppe, Esq.

Prior to leaving office, former New Jersey Governor Chris Christie signed the "One-Room" bill (A-4995/S-287) into law on January 12, 2018. The new law (the "One-Room Law") amends New Jersey's physician self-referral law (commonly known as the "Codey Law") and enacts certain changes for registered one-room surgical practices. Under the One-Room Law, registered surgical practices in New Jersey are now required to apply for a license with the New Jersey Department of Health ("NJDOH") as ambulatory surgical centers ("ASCs"). Existing surgical practices, which are currently regulated by the New Jersey Board of Medical Examiners ("NJBME"), will need to apply for licensure as ASCs within one year of the enactment of the One-Room Law.

In order to minimize the monetary burdens associated with ASC licensure, the one-room surgical practices will be exempt from existing facility assessments and licensing fees, including the New Jersey ASC tax assessment. The One-Room Law also provides surgical practices with an exemption from having to meet the current "physical plant standards" mandated by the NJBME. Any surgical practice that is certified by the Centers for Medicare and Medicaid Services ("CMS"), or accredited by an accrediting body recognized by CMS, will not be required to meet certain physical plant and functional requirements applicable to ASCs.

The One-Room Law brings about major benefits for existing ASCs as well. The One-Room Law has been enacted at a time when developing new multi-room ASCs is prohibited by a moratorium under the Codey Law. The One-Room Law will permit existing surgical practices to combine and apply for a single ASC license, an action that would otherwise be prohibited by the moratorium. However, combined surgical practices that become licensed ASCs will be subject to the facility assessments and licensing fees.

Further benefits of ASC licensure to existing one-room surgical practices include the ability of non-owning physicians to use the surgical practice facilities. Any physician can perform procedures at a licensed ASC, not just the physician owners of the surgical practice. Moreover, a licensed ASC can be owned by non-physicians and the new law will permit direct investment by health systems or management companies.

The new law will lessen many of the regulatory restrictions and financial burdens facing surgical centers and may make it easier to sell or expand.

For more information, contact Meghan V. Hoppe, Esq. at mvh@spsk.com or 973-540-7351.

Attorney General Adopts Regulations on Acceptance of Compensation from Pharmaceutical Manufacturers

By Deborah A. Cmielewski, Esq.

On January 16, 2018, the Attorney General adopted new regulations, codified at N.J.A.C. 13:45J, concerning the provision of items of value from pharmaceutical manufacturers to certain prescribers. The regulations aim to eliminate pharmaceutical manufacturers' influence on the treatment decisions of physicians, podiatrists, physician assistants, advanced practice nurses, dentists and optometrists, unless such prescribers are employees of a pharmaceutical manufacturer that does not render patient care. The regulations were initially proposed on October 2, 2017

and interested stakeholders participated in a public hearing that took place on October 19, 2017.

Subject to limited exceptions, the regulations prohibit the identified prescribers from accepting, directly or indirectly, any financial benefit or benefit-in-kind from a pharmaceutical manufacturer or its agent. Prohibited items include gifts, payments, stocks, stock options, grants, scholarships, subsidies and charitable contributions as well as entertainment or recreational items (such as tickets or vacations). Moreover, prescribers are prohibited from accepting items of value that fail to advance disease or treatment education, such items as pens, note pads, coffee mugs, payments in cash or equivalents (*i.e.*, gift certificates) and items intended for the prescriber or his/her staff's personal benefit, such as floral arrangements and electronic devices. The prohibitions extend to the immediate family members of prescribers, unless they are employees of a pharmaceutical manufacturer from which they receive compensation for the provision of usual and customary services.

The regulations also prohibit prescribers from receiving more than $10,000 per year from all pharmaceutical manufacturers for the provision of bona fide services, including presentations as speakers at promotional activities, participation on advisory boards and consulting arrangements. In response to a number of comments, the Attorney General clarified on adoption that research activities and certain payments for royalties and licensing fees are excluded from the cap. Likewise, payments for speaking at educational events are exempt from the cap, but they must be fair market value in nature and provided in accordance with a written agreement between the parties.

The regulations specifically identify permitted gifts and payments. These include items that are primarily designed for educational purposes and have little to no real value outside of the prescriber's professional educational use, such as anatomical models that prescribers use in their examination rooms. Other acceptable gifts and payments include such items as subsidized registration fees at educational events, if the fee is available to all event participants, certain modest meals and sample medications offered free of charge to the prescriber's patients.

The regulations became effective on January 16, 2018 and apply to conduct that occurs on or after that date.

For more information, contact Deborah A. Cmielewski, Esq. at dac@spsk.com or 973-540-7327.

Aetna Customers Settle for $17 Million in HIV Privacy Breach Case

By Sharmila D. Jaipersaud, Esq.

In January 2018, Aetna reached a settlement of $17 million after a lawsuit was filed against it for breach of privacy when thousands of customers' HIV statuses were compromised by the insurance giant. The privacy breach affected as many as 12,000 patients nationwide. The lawsuit was filed after Aetna mailed letters revealing that certain customers were taking HIV drugs; the confidential information was visible through the clear address window of the mailing envelope. The envelopes caused family members, roommates, neighbors and others to learn of the customers' HIV statuses. The initial lawsuit was filed as a class action suit by a Pennsylvania man who claimed that his sister saw the letter and discovered his HIV status.

Ironically, the letters were submitted to the customers in response to a separate privacy violation concern. In addition to the settlement payment, Aetna was imposed civil fines of $1.15 million in New York for the leak of the HIV-positive status of 2,460 New York members.

Despite the settlement, legal issues arising from this matter have continued. Aetna recently filed suit against Kurtzman Carson Consultants ("KCC"), blaming the claims administrator for the problematic mailings. Aetna has alleged that KCC performed the mailings without appropriate approval and it seeks indemnification from KCC for the incident. KCC has likewise filed a corresponding suit against Aetna, claiming that the health insurance company and its legal counsel, Gibson, Dunn & Crutcher, approved the form and content of the letters and should therefore be held responsible for the incident.

For more information, contact Sharmila D. Jaipersaud, Esq. at sdj@spsk.com or 973-631-7845.

Third Circuit Determines AKS Violation Not Automatic Violation of False Claims Act

By Divya Srivastav-Seth, Esq.

In a recent decision, the United States Third Circuit Court of Appeals held in favor of the defendants, Accredo Health Group and its affiliates, Hemophilia Health Services and Medco Health Solutions, Inc. (collectively "Accredo"), who were accused by an ex-employee of violating the False Claims Act, 31 U.S.C. § 3729(a)(1)(A)-(B) ("FCA"), under the FCA's whistleblower provisions. The FCA claim was based on Accredo's alleged participation in an illegal patient referral scheme in violation of the Federal anti-kickback statute, 42 U.S.C. § 1320a-7b (b) ("AKS"). See United States ex rel. Greenfield v. Medco Health Sols., Inc., 880 F.3d 89 (3d Cir. 2018).

Accredo is a specialty pharmacy that provides home care and specializes in medications for patients with hemophilia. Over several years, Accredo made significant annual donations to Hemophilia Services, Inc. ("HSI") and Hemophilia Association of New Jersey ("HANJ"), two charities that assisted the hemophilia patient population in a variety of ways, including the funding of outpatient treatment centers and the provision of insurance coverage for patients ineligible for Medicare or Medicaid. HSI allegedly recognized the donations when it identified Accredo on its website as an approved vendor. HSI and HANJ also provided the treatment centers with lists that identified specialty pharmacies designated as approved providers. Accredo was included on this list.

After several years of regularly donating to HSI and HANJ, Accredo advised the charities of its intent to reduce its donations. At the alleged direction of HSI and HANJ, several patients contacted Accredo and requested that funding be restored. Following a market analysis, Accredo determined that it would lose significant revenue if donations to the charities were decreased. Plaintiff alleged that this resulted in Accredo's decision to continue its usual donations in support of the charities.

The District Court ruled in favor of the defendants, holding that the plaintiff had failed to provide evidence that Federal beneficiaries chose Accredo because of its donations to the charities. Plaintiff appealed and stated that he was not required to establish causality because an automatic violation of the FCA occurred when Accredo falsely certified its compliance on claims for reimbursement. Under the AKS, a claim for reimbursement filed with the Federal government that includes items or services resulting from a violation of the AKS constitutes a false or fraudulent claim under the FCA. All claims filed for reimbursement contain a certification of compliance with the AKS. The plaintiff argued that Accredo had falsely certified its compliance with the AKS, which automatically rendered its claims for reimbursement legally false. Accordingly, plaintiff took the position that it was unnecessary to identify specific claims related to the alleged scheme.

On appeal, the Third Circuit examined the District Court's ruling and found that, although the FCA did not require proof that the donations had caused the patient member to seek out Accredo's services, the establishment of the illegal referral scheme, even if true, was not sufficient basis for the FCA claim. The Third Circuit ruled that the plaintiff still needed to prove a link between the alleged kickback and the submission of the false claim. The Third Circuit noted that the plaintiff had failed to demonstrate that the patients on the submitted claims were members of HSI or HANJ, had viewed the website or were recipients of the referral information provided. Accordingly, the Third Circuit ruled in favor of the defendants.

For more information, contact Divya Srivastav-Seth, Esq. at dss@spsk.com or 973-631-7855.