# HEALTH LAW CHECK-UP

The Health Law Check-Up is a newsletter brought to you by the Health Law Group at Wilentz, Goldman & Spitzer, P.A.

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## Beware of Increased Enforcement Actions Against New Jersey Medi-Spas

### by Grace D. Mack, Esq.

New Jersey has continued to see significant growth in the creation of "Medi-Spas," which are quasi-medical practices providing a variety of services ranging from those requiring the involvement of a physician or nurse practitioner (such as provision of Botox and other injectables), to those requiring an aesthetician license (such as certain skin care procedures) to everything in-between. The primary issue facing Medi-Spas in New Jersey and throughout the country is the lack of clarity as to ownership, licensure and oversight requirements.

While the New Jersey regulators have yet to issue any formal regulations or even guidance specifically addressing Medi-Spas (apart from draft Board of Medical Examiners regulations which were never formally proposed and which date back many years), 2023 and 2024 saw numerous enforcement actions taken against Medi-Spas for improper ownership and the provision of services by unlicensed individuals.

In particular, in July 2024, the New Jersey Attorney General announced that the owner of a Passaic County skin-care spa agreed to pay a $10,000 civil penalty and accept a 10-year ban on operating a skin care specialty spa in New Jersey in order to resolve allegations of unlawfully providing invasive aesthetic treatments which only licensed medical professionals are authorized to perform in New Jersey.[1] The owner of the now-defunct spa entered into a consent order with the State Board of Medical Examiners and the State Board of Cosmetology and Hairstyling that resolved allegations stemming an investigation from the Division of Consumer Affairs.

The investigation found evidence that the spa: (i) unlawfully provided cosmetic services without the requisite professional licenses, (ii) provided services that exceeded those permitted under the spa's skin care specialty shop license, and (iii) provided services that only licensed medical professionals are authorized to perform.

The unlicensed services allegedly performed included:

- Botox and dermal filler injections;
- body contouring;
- laser hair removal;
- teeth whitening;
- permanent makeup;
- microblading;
- microneedling; and
- platelet rich plasma facials, also known as "vampire facials."

New Jersey Attorney General Platkin stated "As the med-spa industry continues to grow and evolve, we will continue to investigate and hold accountable individuals providing aesthetic services they are neither licensed nor qualified to perform."

Most recently, in September 2024, a New Jersey physician had his medical license permanently revoked as a result of inappropriate provision of cosmetic injections, among other things.[2] Dr. Muhammad A. Mirza, a board-certified internist who operated "Mirza Aesthetics," was found to pose a "clear and imminent danger to the public" as a result of "off label" use of certain dermal fillers, including near patients' eyes, into their breasts and even into their penises.

The New Jersey Attorney General and the Division of Consumer Affairs have made it clear that they are increasing their efforts to halt the unlicensed and/or improper practice of medicine in medi-spa settings. With the growth of these entities showing no signs of slowing, we are likely to see more enforcement actions. To avoid scrutiny, it is important to structure medi-spas in conformance with available guidance.

Resources:

[1] https://www.njoag.gov/owner-of-passaic-county-spa-agrees-to-pay-10000-accept-10-year-ban-on-doing-business-in-nj-to-resolve-allegations-of-practicing-medicine-without-a-license/

[2] https://www.njoag.gov/state-board-of-medical-examiners-revokes-license-of-tri-state-doctor-whose-practice-of-aesthetic-medicine-allegedly-posed-grave-risk-to-public/

# The Not-So-Friendly PC Model? What Envision Healthcare's Withdrawal From California Means for the "Captive" PC Model Going Forward

## by John D. Barry, Esq.

In July 2024, Envision Healthcare, a large, nationwide provider of physician management services ("Envision"), announced that it had ceased operations in the State of California. This withdrawal stems from a lawsuit filed in December 2021 by the American Academy of Emergency Medicine Physician Group ("AAEM-PG"), whereby AAEM-PG alleged that Envision's management structure violated California's prohibition on the corporate practice of medicine due to control of clinical decisions by non-licensed individuals.

The lawsuit, *American Academy of Emergency Medicine Physician Group, Inc. v. Envision Healthcare Corporation, et. al.*, challenged the "friendly PC" model - also sometimes referred to as the "captive" PC model - whereby a "friendly" physician owns legal title to the equity of a professional corporation (the "PC") or other professional entity, and a separate management services organization (the "MSO") owned and controlled by non-physicians provides management services to the PC. In this model, it is common for the MSO to require the PC and its physician owner to agree to certain restrictions on the operations of the PC. In alleging that the friendly physician was not in fact the true owner of the medical group, AAEM-PG pointed to the following:

- Addresses listed for physician practices managed by Envision were actually Envision corporate locations;
- Unlicensed Envision executives acted as corporate officers for physician practices;
- Documents in the name of physician practices were signed by executives from Envision, rather than the physician owner of the practice;
- Envision had physician owners of practices signing Stock Transfer Agreements, which AAEM-PG claimed effectively prevented the physician from having "actual control" of the practice entity;
- Other than a salary via an employment agreement, the physician owner realized little to no profits from the practice, with those profits instead going to Envision; and
- Envision controlled physician hiring, schedules, compensation, the number of patient encounters, policies and protocols for physicians to follow in treating patients, and general physician working conditions.

After over 2 years of litigation, rather than continuing to the fight to uphold the legality of its "captive" PC–MSO model, Envision ceased operations in California, and the lawsuit ended, as California courts no longer had jurisdiction over the dispute. During the litigation, multiple entities, including the California Medical Association, filed amicus briefs in support of AAEM-PG's position. Many in the healthcare industry were concerned that were AAEM-PG to prevail, the healthcare industry in California (and likely beyond) would be upended, as the structure and arrangements utilized by Envision in managing affiliated medical practices are commonplace and widely used.

With the lawsuit withdrawn, some MSOs and their investors may see it as a “win,” as the legality of PC-MSO model was not formally ruled upon. Others, however, are concerned about the influence that AAEM-PG was able to exert - forcing a large management services provider to exit the most populated state in the country - and what this ultimately means for future challenges (and potentially legislative initiatives) in California and beyond. As more and more physician practices become owned or managed by corporations such as insurers, private equity firms, and large pharmacy chains, there are rising concerns about the impact this has on physician decision-making and quality & costs of care. For example, although vetoed in September 2024 by the Governor, the California legislature had proposed Assembly Bill (AB) 3129, which would have required physician management arrangements involving entities such as private equity groups to receive approval from the California Attorney General’s Office. As non-physician investment in the physician practice space shows little signs of slowing, more lawsuits and legislation aimed at curtailing private control of the practice of medicine are likely on the horizon.

## New Jersey Enacts Medical Debt Relief Act
### by Jason J. Krisza, Esq.

On July 22, 2024, New Jersey followed the lead of New York and Colorado, becoming the latest state to enact a law which limits collection abilities on medical debt with the passage of the Louisa Carman Medical Billing and Medical Debt Relief Act (the “Act”). The Act prevents a medical creditor, i.e., medical practices, or medical debt collector from:

1. Reporting a patient’s medical debt to any consumer reporting agency for health care services performed on or after the effective date of the bill, i.e., July 22, 2024;
2. Making a consumer report containing a patient’s paid medical debt or a medical debt worth less than $500, regardless of the date the medical debt was incurred;
3. Charging an interest rate on a medical debt of more than 3 percent per year;
4. Garnishing the wages of a patient with an annual income of less than 600 percent of the federal poverty level to collect medical debt owed by that patient; or
5. Engaging in any collection actions against a patient until 120 days after the first bill for a medical debt has been sent or against a patient who accepts and complies with the terms of a reasonable payment plan.

#### I. Restrictions for Consumer Reporting Agencies

The Act prohibits consumer reporting agencies from creating a consumer report for a patient’s paid medical debt or a medical debt of less than $500, regardless of the date it was incurred and prevents reporting of debt for all medical services rendered on the effective date of the law.

#### II. Restrictions for Medical Creditors and Medical Debt Collectors

Medical creditors or medical debt collectors are now prohibited from engaging in any collection efforts until the 120th day *after* the first bill for a medical debt has been sent to the patient and after the creditor has offered a reasonable payment plan.

A reasonable payment plan consists of the following: (i) monthly payment amounts shall be set at a level that the patient can reasonably afford or not more than 3 percent of the patient's monthly income, if known by the medical creditor or medical debt collector; (ii) the duration shall allow the patient to repay the debt in full within a reasonable timeframe, which shall include, but not be limited to, a timeframe that is between 6 months and 5 years in length, based on the total amount owed and the patient's financial capacity; (iii) the plan shall include provisions for adjusting the payment amounts and duration in response to significant changes in the patient's financial circumstances; (iv) the terms of the payment plan shall be clearly documented in a written agreement provided to the patient, including the total amount owed, the monthly payment amount, the payment schedule, and any interest; (v) the plan shall provide a grace period of at least 60 days for late payments; and (vi) the plan shall not charge an interest rate on a medical debt of more than 3 percent per year.

Additionally, a medical creditor or medical debt collector is now required to provide, at least 30 days before taking any collections actions, at least 1 additional bill and a notice to the patient that:

- Identifies that collection actions will be initiated to obtain payment, and
- Provides a deadline after which collection actions will be initiated, which date is no earlier than 30 days after the date of the notice.

Any communication made by a medical creditor or medical debt collector to a patient in the course of trying to collect a medical debt shall include a statement, in at least 14-point boldface font, that the medical creditor or medical debt collector has not reported the debt to a consumer reporting agency and that if the debt, or any part of it, has been reported to a consumer reporting agency, the portion reported is void.

### III. Restrictions Surrounding Health Insurance Reviews and Appeals

The Act also requires that if a medical creditor or medical debt collector knows about an internal review, external review or other appeal of a health insurance decision that is currently pending, then they shall not: (1) communicate with the patient regarding the unpaid charges for health care services for the purpose of seeking to collect; or (2) initiate a lawsuit or arbitration proceeding against the patient relative to the unpaid charges.

If a medical creditor or medical debt collector has previously reported a medical debt to a consumer reporting agency and *subsequently* learns of a review or appeal then currently pending, the medical creditor or medical debt collector must instruct the consumer reporting agency to delete the reported information regarding that debt.

### IV. Protection for Patients with Medical Debt

The Act provides that any portion of a patient’s medical debt that is reported to a consumer reporting agency in violation of this bill will be deemed to be void. The New Jersey Attorney General’s office is also given exclusive jurisdiction over violations of the Act and expressly prohibits a private right of action, i.e., patients cannot sue practices for violating this Act. However, if the Attorney General’s office does find a violation of this Act, the Act permits the Attorney General’s office to cause the violator of the Act to remit money or property to the impacted patient.

# Recent Healthcare Enforcement Actions: False Claims Act, Anti-Kickback Statute and Stark Law Violations & Settlements

## by Jennie M. Miller, Esq.

With the United States Department of Justice ("DOJ") estimating that upwards of 10% of all healthcare expenditures result from fraud, waste or abuse,[1] 2024 has seen the DOJ and the United States Department of Health and Human Services, Office of Inspector General ("OIG") continue their diligent efforts to combat fraud and abuse in the healthcare industry. Below is an overview of certain specific recent investigations and settlements which healthcare providers should keep in mind when evaluating their own policies, operations and proposed transactions.

### I. $5.4 Million Settlement Related to Healthcare Marketers[2]

Arrangements involving the use of commission-based marketers have consistently been scrutinized by the DOJ and OIG.[3] In keeping with that trend, in July, 2024 Admera Health LLC ("Admera"), a New Jersey-based clinical laboratory testing company, agreed to pay close to $5.4 Million to the federal government, plus an additional $147,851 to certain individual states, to settle allegations that Admera violated the federal False Claims Act ("FCA") and Anti-Kickback Statute ("AKS") by paying kickbacks in the form of commissions to third party marketers. The government alleged that kickbacks were paid in return for the marketers arranging for genetic testing services to be ordered from Admera. The investigation into Admera originated as a *qui tam* action brought by one of the very third party marketers utilized by Admera.

As part of the settlement, Admera admitted:

1. Admera made millions of dollars in commission payments to marketers to induce them to arrange for or recommend that healthcare providers order and refer clinical laboratory services to Admera that were reimbursable by Medicare and/or Medicaid;
2. Admera paid marketers through arrangements that considered the volume and value of genetic testing referrals, and in some instances paid marketers a percentage of the Medicare reimbursements received for the genetic test recommendations[4];
3. Admera was advised that the payment of commissions to independent contractors would violate AKS, but continued to enter into such contracts; and
4. Admera only terminated its contracts with the marketers after the Center for Medicare and Medicaid Services ("CMS") suspended Medicare payments to Admera in November 2020.

### II. $17.3 Million Dollar Settlement Related to Physician Compensation Structure[5]

Physician compensation arrangements have also recently been scrutinized by the DOJ and OIG in instances where physician compensation is linked to the number of referrals made by the physician for specific services. New York Presbyterian/Brooklyn Methodist Hospital (the "Hospital") agreed to pay the United States $16.41 Million, plus an additional $890,000 to the State of New York, to settle allegations that the Hospital paid unlawful kickbacks in the form of physician compensation based in whole or in part on the volume of, value for, or reimbursement for chemotherapy, infusions, and other services at an affiliated chemotherapy infusion center (the "Center"). [6] Importantly, the investigation originated from the Hospital's voluntary self-disclosure to the OIG, which ultimately mitigated damages imposed by the government.

**III. $1.8 Million Settlement Related to Medically Unnecessary Services[7]**
The DOJ and OIG have also heavily scrutinized billing practices wherein the services provided were deemed medically unnecessary or a result of self-referrals involving designated health services. Dr. Mohammed Athari, a Houston, Texas-based physician, and his diagnostic centers will pay $1.8 Million to resolve allegations that he violated the FCA by submitting claims for services that were medically unnecessary and in violation of Physician Self-Referral Law ("Stark Law"). The investigation resulted from a *qui tam* action filed under the FCA.

According to the settlement:

1. Dr. Athari submitted false claims to Medicare for services that were not reasonable or medically necessary based on the determination that the patients' medical records did not support such services and/or such services were incorrectly or inadequately rendered by unlicensed technicians;
2. Dr. Athari referred his neurology patients to separately diagnostic centers he personally owned, in violation of Stark; and
3. Dr. Athari submitted false claims to Medicare by billing for the diagnostic imaging procedures, also in violation of the Stark Law.

Ultimately, failure to comply with fraud and abuse laws, including the FCA, AKS, and the Stark Law, can result in severe penalties, including fines, exclusion from federal programs, and potential personal liability for executives. As a result, providers should monitor their financial relationships and implement a meaningful compliance program.

Resources:
[1] https://www.justice.gov/archives/jm/criminal-resource-manual-976-health-care-fraud-generally
[2] https://www.justice.gov/opa/pr/admera-health-agrees-pay-over-5m-settle-false-claims-act-allegations-kickbacks-third-party
[3] 2 See, e.g., OIG, Advisory Op. No. 99-33 (Mar.1993), https://oig.hhs.gov/fraud/docs/advisoryopinions/1999/ao99_3.htm.
[4] https://www.justice.gov/opa/media/1361481/dl?inline
[5] https://www.justice.gov/usao-edny/pr/new-york-presbyterianbrooklyn-methodist-hospital-settles-health-care-fraud-claims-173
[6] https://www.justice.gov/usao-edny/media/1342961/dl
[7] https://www.justice.gov/usao-sdtx/pr/physician-pays-18m-settle-false-claims-act-liability

## Restriction on a Physician's Ability to Withdraw from a Medical Practice Held Unreasonable

### by Vishva Patel, Esq.

A recent New Jersey state appellate court case highlights how restrictive clauses may be scrutinized if they impose unreasonable limitations on a physician's ability to practice medicine.

The case, *Bozic v. Orthopedic Emergency Services Springdale, L.L.C.*, involved a dispute between Dr. Vladimir S. Bozic, an orthopedic surgeon, and the multi-physician medical group he formerly co-owned. Central to the dispute was a clause in the operating agreement for the group that restricted Dr. Bozic's ability to resign or withdraw from the group without majority approval from other remaining physician owners. If a physician owner were to leave the practice without this majority approval, such physician would be subject to significant financial penalties.

The dispute originally went to arbitration, as the operating agreement directed all disputes to first be arbitrated. The arbitrator ruled in favor of Dr. Bozic, determining that the withdrawal restriction “violated public policy and was the product of economic oppression,” and further “create[d] an involuntary servitude in contravention with public policy”… “[b]ecause a member could not leave the practice without the majority members’ approval.” The arbitrator relied on the New Jersey Revised Uniform Limited Liability Act (the “Act”), which “grants members of a limited liability company significant power to dissociate, which cannot be frustrated by an unenforceable agreement, which violates public policy and the law.” (citing N.J.S.A. 42:2C-45(a) and -46(a)). The arbitrator awarded Dr. Bozic damages and also ordered the Defendants to pay his attorney’s fees and costs.

Following the arbitration decision, the practice brought suit in New Jersey state court, alleging that the arbitrator exceeded his authority in finding that the operating agreement contained restrictions that ran counter to public policy. The trial court, however, upheld the arbitration decision. The practice then appealed the trial court's decision, but the Appellate Division affirmed the trial court's decision, agreeing that the arbitrator’s determinations regarding the restrictions in the operating agreement were supported by the evidence in the record and applicable law.

While these type of restrictions are somewhat common in medical group operating agreements or shareholders agreements, this case shows that, if challenged, such restrictions may be found counter to public policy and held unenforceable.

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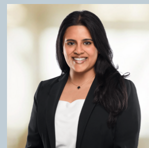

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