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Editors-In-Chief

Alexis N. Reynolds
Amanda K. Roenius
Judy C. Tsui

McGuireWoods
Chicago, Illinois

HEALTH CARE LAW MONTHLY welcomes your comments and opinions. Please direct all correspondence and editorial questions to: Adriana Sciortino, LexisNexis Matthew Bender, 230 Park Ave., 7th Floor, New York, NY 10169 (1-908-665-6768); e-mail: adriana.sciortino@lexisnexis.com. For all other questions, call 1-800-833-9844.

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A Beautiful Investment: Regulatory Considerations for Investors in Cosmetic Dermatology

By Alexis Reynolds, Kayla McCann Marty and Bart Walker¹

Cosmetic dermatology has seen exponential growth in recent years. The global dermatology market is projected to grow from \$20 billion in 2015 to \$33.7 billion by 2022, with revenue for minimally or non-invasive aesthetic procedures—such as the fat-reduction treatment CoolSculpting[®], body contouring, skin rejuvenation, and laser hair removal services—accounting for about 20% of the market.² Driving the market's growth are a few primary forces—an aging population, expanding middle-class, skin-health awareness, and the increasing concern with physical appearance.³

Several factors make dermatology practices with a cosmetic dermatology service line extremely attractive to third-party and strategic investors. First, dermatology practices offer add-on opportunities for profitable ancillary-service components, such as lab services, clinical trials, retail cosmetic products, and surgery center-eligible procedures.⁴ Second, high-margin elective procedures and retail cosmetics are generally paid out-of-pocket by individual patients and therefore are less reliant on insurance payments.⁵ Circumventing the insurance-payment system has the added benefit of avoiding several restrictive federal fraud and abuse regulations that apply only to government reimbursable goods and services. Finally, strong brand recognition and savvy marketing by cosmetic practices “lends well to physician transition, unlike

other medical specialties where the practice goodwill may reside predominantly with the physicians.”⁶

Despite the fervent acquisition and investment activity in the dermatology sector,⁷ challenges still exist for both physicians seeking to add new cosmetic products or service lines to their practice and individuals seeking to affiliate with extant cosmetic-service practices. By examining the statutes, rules, and regulations of several states and their respective medical boards, this article provides an overview of various regulatory and diligence considerations that are key for investors and dermatology providers alike.

I. Fraud and Abuse Considerations

The federal Anti-Kickback Statute and Stark Law apply to certain financial relationships that involve payments from Medicare, Medicaid, and other federally funded healthcare-payment programs. As mentioned above, cosmetic-dermatology services are predominately paid out of pocket by consumers, and therefore most federal fraud and abuse laws are not the primary fraud and abuse restrictions applicable to these procedures. But even if no federal healthcare reimbursement is involved, certain financial relationships and marketing arrangements may nonetheless implicate similar state prohibitions that apply regardless of payment source. It is also important to note that simply excluding government reimbursable goods or services does not necessarily

¹ Bart Walker is a partner in the Charlotte, North Carolina office of McGuireWoods LLP. Kayla McCann Marty and Alexis Reynolds are associates in the firm's Charlotte office.

² INDUSTRY PROFILES: DERMATOLOGISTS, FIRST RESEARCH (May 29, 2017).

³ See INDUSTRY PROFILES: DERMATOLOGISTS, FIRST RESEARCH (May 29, 2017). See also Meghan Daniels, *Dermatology in Demand in 2017*, AXIAL (Jan. 31, 2017), <http://www.axial.net/forum/dermatology-demand-2017/>.

⁴ Meghan Daniels, *Dermatology in Demand in 2017*, AXIAL (Jan. 31, 2017), <http://www.axial.net/forum/dermatology-demand-2017/>.

⁵ Patrick Krause, *Private Equity Firms Are Suddenly Buying Dermatology Practices — Here's Why*, BUSINESS INSIDER (Aug. 22, 2016, 2:54 PM), <http://www.businessinsider.com/why-private-equity-firms-buy-dermatology-practices-2016-8>.

⁶ HEALTHCARE & LIFE SCIENCES SPECIAL REPORT, SKIN IN THE GAME: GROWING PRIVATE CAPITAL INVESTMENT IN DERMATOLOGY PRACTICES (Aug. 2014); see also Elizabeth Woodcock, *Incorporate Innovative Practice Marketing Strategies That Don't Break the Bank*, DERMATOLOGY TIMES (Dec. 01, 2011), <http://dermatologytimes.modernmedicine.com/dermatology-times/news/modernmedicine/modern-medicine-feature-articles/incorporate-innovative-practi?page=full>.

⁷ Meghan Daniels, *Dermatology in Demand in 2017*, AXIAL (Jan. 31, 2017), <http://www.axial.net/forum/dermatology-demand-2017/>; Patrick Krause, *Private Equity Firms Are Suddenly Buying Dermatology Practices — Here's Why*, BUSINESS INSIDER (Aug. 22, 2016, 2:54 PM), <http://www.businessinsider.com/why-private-equity-firms-buy-dermatology-practices-2016-8>.

sanitize an otherwise impermissible arrangement. Examples of these state laws are discussed below.

A. Compensation of Non-Clinical Personnel and Managers. Many states prohibit physicians from splitting fees for professional services with unlicensed individuals. Typically, this prohibits payments to a person who referred patients or otherwise generated business for a physician.⁸ Yet physicians may also run afoul of fee-splitting restrictions by making payments to an entity providing business-management services that are based on a share of the physician's revenue or collections.⁹ States vary greatly with respect to circumstances or conditions that trigger the applicability of the fee-splitting statutes.

For example, Tennessee's fee-splitting prohibition applies to undisclosed split fees.¹⁰ More specifically, Tennessee law prohibits any licensed physician from dividing or agreeing to divide any fee or compensation received or charged in the practice of medicine with any person without the knowledge and consent of the person paying the fee or compensation or against whom the fee may be charged.¹¹ Not all states or professional licensing boards have enacted such fee-splitting prohibitions and the enforcement and policing practices differ dramatically. Therefore, the rules of the state in which the dermatology practice is located should be consulted before entering into any profit or fee-sharing arrangements involving clinical and non-clinical personnel. Providers should also be aware of multi-jurisdictional issues to the extent they are located near the border of a neighboring state or are marketing goods or services (especially cosmetic products) into other states.

B. Compensation of Clinical Personnel. As in any other physician specialty, investors and affiliates of dermatology practices with a cosmetic dermatology service line should also consider how clinical personnel are compensated. State anti-kickback statutes regulate referrals for professional services, and potential violations may arise when certain payments are offered or made to referral sources or others in a position to generate business for the practice.

For example, Texas law prohibits the payment or acceptance of remuneration in exchange for patient referrals, with certain exceptions (the "Texas Anti-Kickback Statute").¹² An all-payor statute, the Texas Anti-Kickback Statute permits "any payment, business arrangement, or payment practice permitted by [the Federal Anti-Kickback Statute] or any regulation adopted under that law."¹³ Even if an exception to the Texas Anti-Kickback Statute is met, however, the referring physician who receives remuneration for a referral is required to make the following disclosure to the patient: (1) the physician's affiliation with the provider the patient is being referred to, and (2) that the physician will receive remuneration for such referral.¹⁴ Thus, structuring or reviewing physician-compensation arrangements often requires tracking the physician making the referral, the final recipient of the payment, and the professional ultimately performing the services. Moreover, the conclusion that an arrangement is in fact permitted by the federal Anti-Kickback Statute is not always a settled or obvious matter.

In addition to anti-kickback statutes, some states also have self-referral laws that mirror the federal Stark Law. These laws prohibit physicians from referring a patient to a person or entity for certain services if the practitioner has either (1) an ownership or investment interest, or (2) a compensation arrangement with the person or entity. These state anti-kickback and self-referral regulations should be researched thoroughly to determine whether they apply to all services reimbursed by a commercial third-party payor or paid by the patient out of pocket, or whether they apply only to reimbursement by Medicare or Medicaid. The scope of ownership and financial relationships regulated by state law are often broader than the corresponding federal prohibitions.

C. Marketing of Cosmetic Products. While careful review of all state marketing and advertising restrictions is critical, certain marketing activities by healthcare providers are subject to heightened scrutiny.¹⁵ The Office of Inspector General of the Department of Health and Human Services (the

⁸ 3 HEALTH L. PRAC. GUIDE § 43:22 (2017).

⁹ See *id.*

¹⁰ See Tenn. Code Ann. § 63-6-225(a).

¹¹ *Id.*

¹² Tex. Occ. Code § 102.001.

¹³ Tex. Occ. Code § 102.006.

¹⁴ *Id.*

¹⁵ See, e.g., 56 Fed. Reg. 35952, 35974 (July 29, 1991); OIG Adv. Op. Nos. 99-12, 12-0, 11-0.

“OIG”) has stated that marketing by healthcare professionals and medical suppliers (particularly “white coat” marketing by physicians) is subject to close scrutiny because these physicians are in a position of trust and may exert undue influence when recommending healthcare-related items or services.¹⁶ In evaluating marketing activities conducted by healthcare professionals for federally reimbursable services, the OIG looks at a number of factors, including, but not limited to, the following: (1) the identity of the party engaged in the marketing activity and that party’s relationship with its target audience; (2) the nature of the marketing activity; (3) the item or service being marketed; (4) the target population; and (5) any safeguards to prevent fraud and abuse.¹⁷ Many states also have similar marketing laws and restrictions applicable to services, regardless of whether they are reimbursable by a government payor. Promotional activities involving certain products, drugs, and devices must also conform to U.S. Food and Drug Administration (“FDA”) regulations and numerous state and federal laws, such as the federal Food Drug & Cosmetic Act (“FDCA”).¹⁸ These laws should be closely considered in any medical practice that plans to undertake any marketing or advertising to patients.

“White coat” marketing is particularly salient in the dermatology context where practices frequently possess a retail-cosmetics component. As an ancillary service, dermatologists often sell cosmetics or skincare products through their practices, offer special discounts to patients, or receive a percentage of revenue generated from cosmetic-product sales.¹⁹ Dermatologists may also bundle a regime of medical procedures and prescription medications with the retail sales.²⁰ By virtue of their position as licensed

dermatologists, such dermatologists’ actions may have the potential to influence patient decisions regarding products dispensed by the practice. The legal issues are further compounded by the physician’s overarching ethical obligations to their patients.²¹ As such, the ethical and legal restrictions on “white coat” marketing—including OIG guidance on the subject—should be researched thoroughly prior to opening a new cosmetics line and marketing these products to patients.

II. Licensing and Operational Considerations

A. Machine Licenses and Registrations.

Improvements in dermatologic-laser technology and other energy-based aesthetic devices that perform minimally or non-invasive procedures have aided the growth of cosmetic service lines in dermatology practices.²² Fractional lasers, intense pulsed light (IPL) devices, and radiofrequency and ultrasound devices are now standard equipment frequently relied on to treat cosmetic patients.²³ Lasers used for cosmetic-laser services often require specific state permits and medical director or supervising-physician registrations. For example, facilities in Arizona utilizing cosmetic lasers or lasers for hair-removal services must register each laser unit with the Arizona Radiation Regulatory Agency, meet strict requirements for operating procedures and maintenance, obtain physician attestations and acknowledgements, and have a designated Laser Safety Officer for the laser facility.²⁴ Facilities in Arizona operating the laser units must also comply with certain change-of-ownership requirements.²⁵ While some dermatologists view the innovative technology as a lucrative investment, the often annual or semi-annual state registration renewal fees, equipment maintenance, and additional compensation necessary to retain and educate the

¹⁶ *Id.*

¹⁷ See OIG Adv. Op. No. 02-12.

¹⁸ 21 U.S.C. §§ 301-399f (2012).

¹⁹ See, e.g., Cheryl Guttman Krader, *Beware The Changing Playing Field For Physician-Branded Skincare Product Lines*, DERMATOLOGY TIMES (Oct. 17, 2012), <http://dermatologytimes.modernmedicine.com/dermatology-times/news/modernmedicine/modern-medicine-feature-articles/beware-changing-playing-field>; Michael H. Gold, MD, *Ethically Dispensing Skin Care Products*, DERMATOLOGIST (Sept. 2010), <http://www.the-dermatologist.com/content/ethically-dispensing-skin-care-products>.

²⁰ See generally Leslie S. Baumann, MD, *Sell Skin Care Products to Protect Your Patients*, DERMATOLOGY NEWS (June 2, 2016), <http://www.mdedge.com/dermatologynews/article/109356/aesthetic-dermatology/sell-skin-care-products-protect-your-patients>.

²¹ *See id.*

²² Rochelle Nataloni, *Leveraging Aesthetic Devices in Your Practice*, DERMATOLOGIST (Jan. 2015), <http://www.the-dermatologist.com/content/leveraging-aesthetic-devices-your-practice>.

²³ *Id.*

²⁴ See *Cosmetic Laser*, ARIZONA RADIATION REG. AGENCY, <https://arra.az.gov/nonionizing-facility/facility-registration-instructions/medical-laser-facilities/cosmetic-laser> (last visited Aug. 15, 2017); *Laser Hair Removal Registration*, ARIZONA RADIATION REG. AGENCY, <https://arra.az.gov/nonionizing-facility/facility-registration-instructions/medical-laser-facilities/laser-hair-removal> (last visited Aug. 15, 2017).

²⁵ *Id.*

supervising and operating personnel must be tracked by dermatology practices.²⁶ Investors and affiliates of laser-oriented cosmetic-dermatology practices should consider these requirements in connection with such an investment. They should also closely monitor all necessary state licenses and permits required for the operation of the equipment and staff, registration expiration dates, and consider implementing a license-renewal plan.

B. Provider Licensing and Supervision. Investments in cosmetic service lines are also appealing because non-physicians may perform several services offered to patients (e.g., simple skincare therapy). While some states may require direct on-site supervision of non-physician providers, this model provides dermatology practices with greater flexibility regarding patient scheduling and permits practices to retain a greater portion of their revenue as compared to other specialty physician practices. As the market for aesthetic services grows, so too has a focus on supervision of individuals who administer these cosmetic procedures.²⁷ In fact, some dermatologists have elected either to avoid delegating procedures to non-dermatologists or have become exceedingly selective about which patients are treated by the non-physician staff.²⁸ Furthermore, states have responded by establishing standards of practice for the performance, delegation, assignment, and supervision of medical and surgical procedures performed at a medical-spa facility or dermatology practice. As with other physician practices, careful review of state laws and regulations is essential prior to providing patient services.

For example, Virginia law (like many states) governs the prescribing, ordering and administration of controlled substances. Under Virginia law, only a physician, physician assistant (“PA”), or nurse practitioner (“NP”) may prescribe or order the administration of a controlled substance (drug or device) under Virginia law²⁹—including prescription Botox, prescription

chemical peels, and the use of prescription-only devices such as CoolSculpting®.³⁰ Further, such an authorized prescriber can direct others, such as nurses, to administer the controlled substances or devices only under the direction and supervision of the prescriber.³¹ Additionally, Virginia PAs and NPs must meet specific requirements—including having a practice agreement with at least one physician—to engage in independent functions.³²

Some states or state medical-licensing boards have also issued guidance specific to cosmetic-surgery procedures, such as teeth whitening and laser-hair and tattoo removal. For example, the North Carolina Medical Board has issued guidance indicating that hair and tattoo-removal procedures using certain devices³³ should be performed only by a physician or by an individual designated as having adequate training and experience by a physician who bears full responsibility for the procedure.³⁴ Additionally, North Carolina electrologists, who are licensed as laser-hair practitioners, may perform laser-hair removal (but not tattoo removal) under the supervision of a physician.³⁵ The North Carolina Medical Board views good medical practice as requiring that each patient be examined by a physician, PA or NP prior to receiving the first laser-hair and tattoo-removal treatment and at other times as medically indicated.³⁶ To aid their practice, dermatologists may also be able to take advantage of little-known equipment and

²⁶ Ted Pigeon, *Choosing the Right Laser: Expert Tips for Decision Making*, PRACTICAL DERMATOLOGY (Dec 2009), http://practicaldermatology.com/2009/12/1109_03.php/.

²⁷ Bill Gillette, *Derms Concerned About Level Of Medical Supervision At Medspas*, DERMATOLOGY TIMES (Aug. 1, 2007), <http://dermatologytimes.modernmedicine.com/dermatology-times/content/derms-concerned-about-level-medical-supervision-medspas>.

²⁸ Bonnie Darves, *Delegating Laser Hair Removal*, DERMATOLOGIST (July 2008), <http://www.the-dermatologist.com/article/8970>.

²⁹ Va. Code § 54.1-3401.

³⁰ Unlike Federal law, Virginia law classifies all drugs in Schedules II-VI as controlled substances. Va. Code § 54.1-3401. Therefore, Virginia requirements for writing prescriptions or ordering the administration of a controlled substance or device apply to Schedule VI controlled substances, such as prescriptions and other drugs not classified into one of the other schedules of controlled substances. Va. Code § 54.1-3455; see Class II Special Controls Guidance Document: Contact Cooling System for Aesthetic Use, FDA, February 7, 2011 (noting that such devices are prescription devices); see, e.g., FDA 510(k) Premarket Notification for CoolSculpting Devices (noting such CoolSculpting devices are categorized as prescription use only).

³¹ Va. Code § 54.1-2901(4); Va. Code § 54.1-3408(U).

³² Va. Code §§ 54.1-2952.1; 54.1-2957.01.

³³ Specifically, devices that (1) manipulate and/or pulse light causing it to penetrate human tissue and (2) are classified as “prescription” by the U.S. Food and Drug Administration.

³⁴ See North Carolina Medical Board Position Statement, Laser Surgery, Adopted July 1999, Amended Feb 2012, https://www.ncmedboard.org/resources-information/professional-resources/laws-rules-position-statements/position-statements/laser_surgery.

³⁵ *Id.*

³⁶ *Id.*

cosmetic-training events. For instance, laser manufacturers may offer training workshops and educational webinars (as part of a promotional event or purchased service) for their equipment systems.³⁷ Allergan, Inc., the makers of Botox, offer injection training, including the assistance of an injection simulator, injection safety information, muscle localization, and patient assessment from an expert injector.³⁸ Dermatology practices should be aware of the training and educational resources available from the cosmetic-product manufacturers and state licensing boards.

C. Reporting of Adverse Outcomes. Aesthetic treatments performed at dermatology practices with cosmetic service lines often are not classified as “pseudomedicine.” According to one North Carolina licensed dermatologist, “cosmetic dermatology requires a detailed understanding of the skin and its underlying anatomy as well as pharmacology and the tools required to safely carry out these procedures. It also requires critical analysis of newer procedures for safety and efficacy. Failure in these areas can result in scarring, unwanted muscle weakness, poor results and even blindness.”³⁹

Like all healthcare practices, cosmetic procedures and dermatology procedures pose some risk of malpractice litigation. According to Alex R. Thiersch, JD, the founder and director of the American Med Spa Association (“AmSpa”), laser burns are one of the fastest growing source of lawsuits brought against aesthetic practices;⁴⁰ so too is cancer misdiagnosis.⁴¹ As such, dermatologists should consider obtaining professional

liability insurance to mitigate the risk of medical-negligence allegations and related consequences.⁴²

Furthermore, in the event of medical complications or errors by the physician or equipment, dermatologists should closely review their agreements with equipment manufacturers to ensure that they comply with all necessary reporting requirements. Similarly, depending on the severity of the outcome and the equipment involved in the procedure, physicians and manufacturers may have an obligation to report adverse and critical outcomes to the FDA. Dermatologists should familiarize themselves with this mandatory reporting process, and practices should implement procedures to educate personnel on reporting compliance.

Before an adverse event occurs, dermatology practices should ensure they have the proper operating protocols and procedures in place (e.g., charting and informed consent), provide professional training and certification for personnel, obtain appropriate liability insurance, and comply with state and federal reporting requirements. Simply stated, cosmetic services like laser-hair removal or CoolSculpting® are real medical procedures that pose real risk considerations.

Conclusion

Cosmetic dermatology practices have become an increasingly popular investment opportunity. Despite this growth, both dermatologists and potential investors must be cognizant of expanded efforts to combat healthcare fraud and abuse, and the variation among state and federal rules and regulations governing physicians and mid-level providers, the surgical and aesthetic equipment, and patient safety. These developments are worth monitoring to ensure that cosmetic dermatology practices comply with all applicable laws and regulations.

³⁷ See, e.g., *Webinars*, SYNERON CANDELA, <http://syneron-candela.com/na/webinars> (last visited Aug. 15, 2017); *Webinars*, LUMENIS, <http://www.lumenis.com/webinars-surgical> (last visited Aug. 15, 2017).

³⁸ See *Peer-To-Peer Training*, BOTOX, <https://www.botoxmedical.com/Academy/Training> (last visited Aug. 15, 2017).

³⁹ Seth Cohen, *Will The Real Dermatologist Please Stand Up*, HENDERSONVILLE DERMATOLOGY (Apr. 5, 2017), <http://www.hendersonvilledermatology.com/will-real-dermatologist-please-stand/>; John Jesitus, *Avoiding, Treating Fractional Laser Complications*, DERMATOLOGY TIMES (Jan. 14, 2015), <http://dermatologytimes.modernmedicine.com/dermatology-times/news/avoiding-treating-fractional-laser-complications?page=full>.

⁴⁰ Denise Mann, *Device Delegation: Don't Get Burned*, PRACTICAL DERMATOLOGY (Mar. 2016), <http://practicaldermatology.com/2016/03/device-delegation-dont-get-burned/>.

⁴¹ Sarvajnamurthy A Sacchidanand and Shilpa Bhat, *Safe Practice of Cosmetic Dermatology: Avoiding Legal Tangles*, 5 J. CUTANEOUS AND AESTHETIC SURGERY, no. 3, 2012, at 170, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3483572/>.

⁴² *Id.*