

Dear Health Law Section Members,

The Health Law Section (“HLS”) website has been updated with articles on significant developments in health law that may interest you in your practice.

These summaries are presented to HLS members for general information only and are not legal advice from The Florida Bar or its Health Law Section. HLS thanks these volunteers who have generously donated their time to prepare these summaries for our members.

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We also wish to extend our thanks to Elizabeth Scarola, Esq. for her past service as Editor-in-Chief of the HLS Update.

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GENERAL TOPICS

Independent Pharmacy Landscape in 2025

In recent years, the role of Pharmacy Benefit Managers (PBMs) has come under increasing national scrutiny, particularly given their growing influence over drug pricing, pharmacy reimbursement, and patient access. Originally designed to control costs and improve efficiency within the pharmaceutical supply chain, PBMs have assumed a central role in the administration of pharmacy benefits.

I. Explaining PBMs

Pharmacy Benefit Managers (PBMs) are third-party administrators that manage prescription drug programs for health insurers, large employers, and Medicare Part D plans. PBMs claim to reduce overall drug costs,¹ but critics contend certain PBM practices undermine competition and transparency, including the following:

- (i) spread pricing, where PBMs charge insurers more than they reimburse pharmacies;
- (ii) rebate retention, where PBMs keep a portion of manufacturer rebates instead of passing them to consumers; and
- (iii) patient steering, which channels patients to PBM-affiliated pharmacies.²

II. Trump's Goals for PBMs

President Donald Trump has openly criticized PBMs, calling them “horrible middlemen” and pledging to “knock out the middleman” to lower prescription drug prices.³ The Trump Administration’s regulatory goals reflect this commitment to dismantle PBM practices that critics contend distort the pharmaceutical supply chain.

Two recent Trump Administration initiatives signal this policy shift:

- (i) Executive Order 14273, which directs the Secretary of Labor to propose regulations to improve transparency regarding PBM compensation.⁴
- (ii) Executive Order 14297, which directs the Secretary of the Department of Health and Human Services (HHS) to propose rulemaking to impose “most-favored-nation pricing” on pharmaceutical manufacturers to bring the prices Americans pay for prescription drugs in line with the prices of the same drugs in comparable countries.⁵

¹ See Pharmaceutical Care Management Association, *Stepping Toward a More Affordable Future* (Jan. 2025), <https://www.pcmanet.org/affordable-future/>.

² See Kristi Martin, *The Common Wealth Fund, What Pharmacy Benefit Managers Do, and How They Contribute to Drug Spending* (Mar. 17, 2025), <https://www.commonwealthfund.org/publications/explainer/2025/mar/what-pharmacy-benefit-managers-do-how-they-contribute-drug-spending>

³ See Reuters, *Insurer stocks fall after Trump says 'we're going to knock out the middleman'* (Dec. 16, 2024), <https://www.reuters.com/business/healthcare-pharmaceuticals/insurer-stocks-fall-after-trump-says-were-going-knock-out-middleman-2024-12-16/>.

⁴ Exec. Order No. 14,273, 90 Fed. Reg. 16,441 (Apr. 15, 2025).

⁵ Exec. Order No. 14,297, 90 Fed. Reg. 20,749 (May 12, 2025).

III. How Pharmacies Are Responding to the Uncertainty of Federal Policy Changes

While recent headlines have focused on the Trump Administration’s proposed pharmaceutical tariffs, independent pharmacies overwhelmingly report that the primary threat to their financial viability stems from PBM reimbursement practices rather than supply chain disruptions.⁶

Dr. Neal Smoller, an independent pharmacist who has spoken extensively on pharmacy policy, noted in a personal interview that independent pharmacies face greater financial pressure from reimbursement dynamics than from external economic variables such as tariffs. He observed that certain PBM practices, including data-driven reimbursement adjustments, have made it increasingly difficult for some pharmacies to maintain sustainable dispensing operations.⁷

In response to these pressures, many independent pharmacies have implemented strategic purchasing practices, working with both primary wholesalers and secondary suppliers to contain costs.⁸ Nonetheless, there is concern that reimbursement rates, particularly those set through proprietary PBM analytics, may not reflect the actual cost of dispensing, potentially affecting profitability for smaller pharmacy operators.⁹

Pharmacy Services Administrative Organizations (PSAOs) provide administrative services to independent pharmacies and assist with evaluating and negotiating contracts with PBMs.¹⁰ While PSAOs can help negotiate contracts and reduce individual burdens, their effectiveness may be limited because PBMs often ultimately control the reimbursement terms. The Federal Trade Commission (FTC) reports that PBMs excise vast bargaining leverage and often refuse to negotiate certain contract terms with PSAOs, stripping even collective groups of meaningful influence.¹¹ “Being part of a PSAO might help a little,” Dr. Smoller adds, “but it doesn’t fix the problem when the people paying you are using your own data to squeeze your margins even further.”¹²

PBMs frequently use claims data to inform reimbursement methodologies and may apply post-adjudication adjustments such as Direct and Indirect Remuneration (DIR) fees.¹³ DIR fees are typically assessed after the point of sale and may reduce the final reimbursement amount

⁶ Press Release, Nat’l Cmty. Pharmacists Ass’n, *NCPA to CMS: A Third of Independent Pharmacies Won’t Carry Drugs Negotiated in Medicare Program* (Jan. 27, 2025), <https://ncpa.org/newsroom/news-releases/2025/01/27/ncpa-cms-third-independent-pharmacies-wont-carry-drugs-negotiated>.

⁷ Interview with Dr. Neal Smoller, Pharmacist & Pharmacy Advocated in Woodstock, N.Y. (May 30,2025) (notes on file with author).

⁸ *These Are the Top Trends in Secondary Purchasing*, PBA Health (Sept. 2021), <https://www.pbahealth.com/elements/these-are-the-top-trends-in-secondary-purchasing/>.

⁹ Fed. Trade Comm’n, *Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies*(July 2024), https://www.ftc.gov/system/files/ftc_gov/pdf/pharmacy-benefit-managers-staff-report.pdf.

¹⁰ Avalere Health, *The Role of Pharmacy Services Administrative Organizations for Independent Retail and Small Chain Pharmacies* 8 (Sept. 30, 2021), <https://www.hda.org/getmedia/9902c3e9-81ae-422c-b413-d982e995e9d4/The-Role-of-PSAOs-for-Independent-Retail-Small-Chain-Pharmacies.pdf>.

¹¹ Fed. Trade Comm’n, *Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies*(July 2024), https://www.ftc.gov/system/files/ftc_gov/pdf/pharmacy-benefit-managers-staff-report.pdf.

¹² Interview with Dr. Neal Smoller, independent pharmacist & pharmacy-reform advocate, in Hudson, N.Y. (May 30, 2025) (notes on file with author).

¹³ H. Comm. on Oversight & Accountability, 118th Cong., *The Role of Pharmacy Benefit Managers in Prescription Drug Markets* (2024), <https://oversight.house.gov/wp-content/uploads/2024/07/PBM-Report-FINAL-with-Redactions.pdf>.

previously paid to a pharmacy. Because these adjustments occur retrospectively, they can affect the predictability of reimbursement and, in some cases, may contribute to reduced profit margins on dispensed medications.¹⁴

Some independent pharmacies have reported challenges maintaining profitability under this model and have responded by expanding into ancillary services such as immunizations, dietary supplements, and point-of-care testing. While these services may help diversify revenue, stakeholders have noted that they may not fully offset the decline in revenue from traditional dispensing activities.

In addition, strategies such as inventory management, service diversification, and enhanced cash flow planning are used to respond to ongoing market uncertainty, including the potential impact of pharmaceutical tariffs. Stakeholders have observed that these efforts are largely adaptive in nature and reflect broader economic and contractual dynamics within the pharmacy reimbursement framework.¹⁵

IV. Florida's PBM Transparency and Accountability Statute (Fla. Stat. § 626.8825)

In 2023, the Florida Legislature enacted section 626.8825, Florida Statutes, as part of the broader Prescription Drug Reform Act.¹⁶ This statute establishes requirements for (i) contracts between PBMs and pharmacy benefits plans or programs and (ii) contracts between PBMs and participating pharmacies. These requirements address practices long criticized by independent pharmacies as sources of financial strain, such as spread pricing, rebate retention, and patient steering.

Indeed, the statute provides that a contract between PBMs and a pharmacy benefits plan or program must not allow for spread pricing, directly or indirectly, unless the PBM passes along the entire amount of such difference to the pharmacy benefits plan or program.¹⁷ Additionally, if a contract between a PBM and a pharmacy benefits plan or program delegates to the PBM the authority to negotiate manufacturer rebates, the contract must include a term requiring the PBM to pass through 100 percent of all rebates, including those from nonresident manufacturers, to the pharmacy benefits plan or program. These funds must be used exclusively to reduce defined cost-sharing obligations and lower premiums for covered individuals. Any remaining rebate revenue must be applied to reduce copayments and deductibles.¹⁸ Further, PBMs may not restrict pharmacy networks to include only affiliated pharmacies, a practice that could otherwise limit patient access and steer volume toward PBM-owned entities.¹⁹

Florida's PBM transparency and accountability statute also requires contracts between PBMs and participating pharmacies to include terms prohibiting financial clawbacks, reconciliation offsets, or offsets to adjudicated claims. Such terms must ensure that PBMs comply with an express prohibition against charging, withholding, or recouping DIR fees, dispensing fees, brand name or

¹⁴ Muhammad Cheema, *PBM Price Negotiations Have Unintended Consequences for Independent Pharmacies*, Pharmacy Times (June 28, 2024), <https://www.pharmacytimes.com/view/pbm-price-negotiations-have-unintended-consequences-for-independent-pharmacies>.

¹⁵ Jackie Fortiér & Arthur Allen, *Pharmacists Stockpile Most Common Drugs on Chance of Targeted Trump Tariffs*, NPR (May 13, 2025), <https://www.npr.org/sections/shots-health-news/2025/05/13/nx-s1-5395834/pharmacists-stockpile-generic-drugs-trump-tariffs>.

¹⁶ Ch. 2023-29, Laws of Florida, <https://laws.flrules.org/2023/29>

¹⁷ Fla. Stat. § 626.8825(2)(b).

¹⁸ *Id.* at § 626.8825(2)(d). This requirement does not apply to contracts involving Medicaid managed care plans. *Id.*

¹⁹ *Id.*

generic effective rate adjustments whether through reconciliation or other monetary charges, withholding, or recoupments, with limited exceptions for fraud, quality incentive payments, and audit corrections, or certain recoupments returned to the state.²⁰

V. Conclusion

The evolving role of PBMs continues to raise complex legal and regulatory questions at the intersection of reimbursement policy, data use, and provider network access. Recent federal policy developments, including executive actions and tariff discussions, have introduced new variables into the broader pharmaceutical landscape. However, independent pharmacies continue to be affected by PBM practices that influence reimbursement structures and contractual relationships.

As federal regulatory agencies, such as the FTC and HHS, continue to evaluate PBM practices, some states, including Florida, have enacted reforms addressing permissible PBM conduct, transparency in reimbursement mechanisms, and the structure of contractual relationships between payers and pharmacies. Future federal reforms, such as the rulemaking called for by President Trump's recent executive orders, will likely further shape relationships between PBMs and independent pharmacies.

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²⁰ *Id.* at § 626.8825(2)(e).

FEDERAL ADMINISTRATIVE AGENCIES AND REGULATIONS

OIG Advisory Opinion Gives Telehealth Management Arrangement a Green Light

Big news for telemedicine physicians who own their own practices: the OIG just issued [Advisory Opinion 25-03](#), and it offers a clear green light for a common but often scrutinized management structure. In this opinion, a physician-owned professional corporation (PC) leases clinicians from a separate telehealth platform, uses its own payer contracts to bill, and pays the platform for both the clinicians' time and back-office services. The OIG concluded this arrangement does not violate the federal Anti-Kickback Statute, as long as it follows the personal services and management contracts safe harbor.

The key reasons the OIG approved the structure are worth noting. The PC's payments to the platform are set out in a written agreement that is signed and lasts for at least one year. The compensation is fixed in advance at fair market value, with separate fees for clinical time and administrative services, and there is no connection to the volume or value of referrals. The payments are made regardless of whether the PC actually gets reimbursed, which helps demonstrate that the arrangement isn't designed to drive utilization. The scope of administrative services is also limited to necessary, commercially reasonable support functions like credentialing, scheduling, IT, marketing, and accounting.

For practice owners, this opinion opens a pathway to in-network expansion. If your platform doesn't have robust payer contracts, leasing clinicians to a well-contracted PC can expand access to care without risking a compliance misstep.

The advisory opinion also offers a detailed compliance blueprint: use an independent fair market valuation, negotiate at arm's length, clearly separate clinical and administrative roles, and avoid informal or side arrangements. That said, this opinion is specific to the facts presented and doesn't address state law issues like corporate practice prohibitions or fee-splitting rules.

With careful structuring, partnering with a separate management entity to lease clinicians and support your operations can be both scalable and compliant. This OIG opinion provides a helpful playbook, but execution matters: get the details right and consult with legal counsel to ensure your version holds up under scrutiny.

Submitted and authored by Jackie Bain, Esq., Silverman Bain, LLP. *Republished with permission from* https://www.linkedin.com/posts/healthlawyerjackie_big-news-for-telemedicine-physicians-who-activity-7338656804312174592-YG2f

DOJ Takes Aim at Medicare Advantage Kickbacks and Disability-Based Steering

In *United States ex rel. Shea v. eHealth, Inc., et al.* (Shea),¹ the United States Department of Justice (DOJ) has intervened in what could become a landmark case targeting alleged systematic abuse within the Medicare Advantage Program.

Filed in the District of Massachusetts, the 217-page complaint details allegations of a five-year (2016-2021) scheme involving major insurers—Aetna, Humana, and Elevance Health (formerly Anthem) —and brokers—eHealth, GoHealth, and SelectQuote.

According to the DOJ’s complaint, the defendants allegedly conspired to inflate enrollment in certain Medicare Advantage (MA) plans using illegal kickbacks and discriminatory marketing practices. Specifically, the DOJ alleges that these defendants orchestrated a scheme whereby brokers were paid improper remuneration, disguised as “co-op,” “marketing” or “sponsorship payments,” in exchange for enrolling beneficiaries into particular MA plans. Because these payments were contingent upon enrollment targets, the DOJ contends they violated the Anti-Kickback Statute (AKS) and rendered the resulting claims to the Centers for Medicare & Medicaid Services (CMS) false under the False Claims Act (FCA).²

Legal Framework

CMS pays MA Organizations (MAOs) a fixed, risk-adjusted per-member-per-month rate, which varies depending on beneficiaries’ expected healthcare utilization.³ To ensure that brokers act in beneficiaries’ best interests, Congress directed CMS to cap broker compensation and limit incentives that could distort plan selection.⁴ These limitations, codified in 42 C.F.R. 422.2274, cap total broker compensation, including commissions, bonuses, gifts, and other remuneration, on a per-enrollment basis. Similarly, CMS regulations expressly delineate permissible payments that are not considered “compensation,” including payments for legitimate administrative services. Prior to March 22, 2021, these “administrative payments” were required to be at or below fair-market value and not exceed an amount commensurate with the amounts paid by the MA organization to a third party for similar services during each of the previous 2 years.⁵ Under the current rule, these “administrative payments” must reflect fair market value and relate to non-enrollment services, such as training or customer support.⁶

The AKS independently bars remuneration intended to induce referrals in any federal health care program.⁷ A claim that “results from” an AKS violation is automatically false under the FCA.⁸ An AKS violation can also lead to FCA liability when someone falsely represents that there is no AKS

¹*United States ex rel. Shea v. eHealth, et al.*, No. 21-cv-11777 (D. Mass. May 1, 2025) (originally filed as a *qui tam* action by a former eHealth employee).

² See 31 U.S.C. § 3729.

³ See 42 U.S.C. § 1395w-23(a)(1)(B); 42 C.F.R. §§ 422.254, 425.304.

⁴ See 42 U.S.C. § 1395w-21(j)(2)(D).

⁵ 42 C.F.R. § 422.2274(b)(1)(iv) (2020) (emphasis added).

⁶ See 42 C.F.R. § 422.2274(e)(1).

⁷ See 42 U.S.C. § 1320a-7b(b)(2).

⁸ See *id.* at § 1320a-7b(g).

violation in connection with a claim. This second pathway to FCA liability for an AKS violation does not require proof of causation.⁹

Complaint Allegations

DOJ contends that the defendant insurers funneled hundreds of millions of dollars to brokers under the guise of marketing or administrative support, when in fact, the payments were contingent in enrollment performance. The complaint illustrates allegations that the defendants knew their conduct was illegal with references to communications among eHealth executives joking about CMS's lack of scrutiny and Humana personnel discussing broker remuneration.

For instance, the complaint alleges that “during the months after Humana agreed to pay GoHealth \$750,000 for 3,000 enrollments, GoHealth offered its agents monetary inducements for steering Medicare beneficiaries to Humana Medicare Advantage plans” and “paid its agents commissions that were fifty percent higher for Humana enrollments compared to those from competing carriers,” in addition to volume-based bonuses.¹⁰

DOJ alleges several theories of FCA liability, including (1) presentment of false claims resulting from AKS violations; (2) presentment of false claims that falsely represented compliance with material statutory, regulatory, or contractual requirements; (3) use of false records or statements material to false or fraudulent claims; and (4) conspiracy to violate the FCA.

Among other things, the complaint includes FCA theories of liability premised upon allegations that Aetna and Humana each conspired with defendant brokers to unlawfully discriminate against Medicare beneficiaries with disabilities¹¹ by tying broker payments not only to volume but also to the demographic mix of enrollees, instructing brokers to keep the share of disabled beneficiaries below preset thresholds. Brokers allegedly complied by filtering calls and deploying call-routing algorithms to deprioritize or reject leads from individuals with disabilities. The complaint alleges that, as a result of this tactic, the percentage of beneficiaries with disabilities among eHealth's Medicare Advantage enrollments for Humana decreased significantly between 2016 and 2021.

Because violations of the FCA are subject to per claim civil penalties, plus treble damages, the defendants' exposure to FCA liability is potentially enormous.

Looking ahead

Florida has one of the highest Medicare Advantage penetration rates in the country,¹² and many Florida-based health care entities rely on marketing-development-fund arrangements or similar support with large brokers. The complaint puts the industry on notice that payments labeled as advertising or lead-generation will be scrutinized for de-facto volume-based compensation. Local

⁹ See *United States v. Regeneron Pharms., Inc.*, 128 F.4th 324, 333, 334 (1st Cir. 2025).

¹⁰ *United States ex rel. Shea v. eHealth, et al.*, No. 21-cv-11777 (D. Mass. May 5, 2025).

¹¹ Under Section 1557 of the Affordable Care Act, MAOs and brokers are prohibited from discriminate against beneficiaries with disabilities in connection with enrollment in Medicare Advantage plans. See 42 U.S.C. § 18116; 45 C.F.R. § 92.207.

¹² See Meredith Freed et al., KFF, Medicare Advantage in 2024: Enrollment Update and Key Trends (Aug. 8, 2024), <https://www.kff.org/medicare/issue-brief/medicare-advantage-in-2024-enrollment-update-and-key-trends/>.

plans and brokers should therefore re-examine every non-commission funding stream to ensure it is anchored in documented fair-market value and unambiguously unrelated to sales volume or demographic mix.

Equally important are the DOJ's allegations with respect to discriminatory steering. Given Florida's sizeable population of Medicare beneficiaries with disabilities, local plans should verify that "phone tree" or interactive voice response systems, lead-scoring rules, and agent incentives do not tilt against customers with chronic conditions.

Counsel for MA plans, distribution partners, and whistle-blowers alike should watch *Shea* closely; its resolution may redefine how "marketing" dollars and enrollee demographics can lawfully be managed in the Medicare Advantage marketplace.

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The Times They Are A-Changing: HIPAA-Adjacent Wellness Data and Privacy Rule Modernization in the Wake of the 23andMe Bankruptcy

The bankruptcy of genetic testing giant 23andMe has exposed a critical vulnerability in America’s health privacy framework—one that leaves millions of consumers, including Florida residents, without meaningful protection for their most sensitive health information. As digital health technologies proliferate and healthcare moves toward value-based payment models, the gap between traditional protections offered under the U.S. Health Insurance Portability and Accountability Act of 1996 (as amended, “HIPAA”) and modern health data realities demands urgent attention from policymakers and practitioners alike.

The Current Privacy Patchwork

The U.S. Department of Health and Human Services (“HHS”) recently issued a notice of proposed rulemaking (“NPRM”) that would modernize the HIPAA Security Rule.¹ Referencing the Change Healthcare breach, the NPRM shifts from a risk-based approach to security to a minimum floor of acceptable standards for all covered entities and business associates. While the NPRM is pending, a parallel crisis has emerged around health data that falls outside of the scope of HIPAA. Like the Change Healthcare breach, the March 2025 collapse of 23andMe could serve as a similar impetus for reform of federal privacy law. Currently, companies like 23andMe, fitness app developers, and wellness platform providers operate in a regulatory gray zone where consumer protections vary dramatically by state—or don’t exist at all.

This patchwork approach challenges Florida residents and healthcare providers, who recommend digital and health wellness apps that may leave patients out in the HIPAA-adjacent cold. Unlike states such as Washington and Nevada,² which have enacted specific consumer health data privacy laws, or Connecticut and Maryland,³ which folded health data protections into broader consumer privacy legislation, Florida has yet to implement comprehensive consumer data privacy protections. This leaves Floridians who use genetic testing services, fitness trackers, or wellness apps largely dependent on company privacy policies and federal oversight that may prove inadequate should these companies fail.

23andMe: A \$6 Billion Privacy Lesson

The 23andMe bankruptcy illustrates these vulnerabilities in stark terms. Once valued at over \$6 billion, the company and its affiliates filed for chapter 11 bankruptcy earlier this year. A bankruptcy court in Missouri recently approved a sale of the 23andMe to a nonprofit led by the company’s co-founder and former CEO.⁴ The sale of the genetic data of approximately 13 million

¹ HIPAA Security Rule to Strengthen the Cybersecurity of Electronic Protected Health Information, 89 Fed. Reg. 898 (Jan. 6, 2025) (proposing amendments to 45 CFR Parts 160 and subparts A and C of 45 CFR part 164).

² Washington My Health My Data Act, 2023 Wash. Laws 191 and Nevada Consumer Health Data Privacy Law, S.B. 370), 2023.

³ Connecticut Data Privacy Act (amended), Substitute S.B. No. 6 and Maryland Online Data Privacy Act, S.B. 541 (2024).

⁴ 23andMe, Press Release, 23andMe Receives Court Approval for Sale to TTAM Research Institute, a Nonprofit Public Benefit Corporation (June 30, 2025), <https://investors.23andme.com/news-releases/news-release-details/23andme-receives-court-approval-sale-ttam-research-institute>.

customers proceeded without restrictions on further sales and despite ongoing California litigation and reservations of various states attorneys general who continue to recommend that consumers delete their accounts.⁵ The transaction highlights several concerning realities about health data outside HIPAA’s umbrella:

1. Limited Regulatory Oversight. The entire transaction is structured to fall outside HIPAA regulation despite involving some of the most sensitive health information imaginable—genetic profiles that reveal predispositions to diseases, ancestry information, and family health patterns.
2. Vulnerable Security Standards. 23andMe’s 2023 data breach, believed by the company to be caused by a credential stuffing attack that compromised approximately 7 million records, might have been prevented or mitigated under the HIPAA Security Rule’s requirements for risk assessments, password controls, and encryption standards.⁶
3. Weak Consumer Recourse. While 23andMe settled the resulting class action for \$30 million,⁷ the bankruptcy effectively stayed the collection of that settlement, leaving impacted consumers with limited remedies. Meanwhile, a delayed report of unprocessed deletion requests and website glitches suggests compliance failures occurred at the start of the bankruptcy proceeding.⁸ As of July 1, 2025, 1.9 million users deleted their accounts, still allowing for the mid-July transfer of approximately 13 million accounts to the winning bidder, who has agreed to an independent advisory board and annual reporting to state attorneys general.⁹
4. Regulatory Gaps in Enforcement. Although the Federal Trade Commission (FTC) issued a reminder to the U.S. bankruptcy trustees in the case of its expectations that the company continue to honor privacy policies, its oversight remains limited to the agreements and policies undertaken by the winning bidder.

⁵ Geoffrey A. Fowler, The Washington Post, 23andMe is out of bankruptcy. You should still delete your DNA (July 17, 2025) <https://www.washingtonpost.com/technology/2025/07/17/23andme-bankruptcy-privacy/>; Cal. Dep’t of Justice, Press Release, Attorney General Bonta Urgently Issues Consumer Alert for 23andMe Customers (Mar. 21, 2025), <https://oag.ca.gov/news/press-releases/attorney-general-bonta-urgently-issues-consumer-alert-23andme-customers>.

⁶ Jonathan Stempel, Reuters, 23andMe settles data breach lawsuit for \$30 million (Sept. 14, 2024), <https://www.reuters.com/technology/cybersecurity/23andme-settles-data-breach-lawsuit-30-million-2024-09-13/>.

⁷ *Id.*

⁸ Kroll Docket #408, Objection to Sale First filed by Movant David S. Neal on March 24, 2025, alleging 23andMe failed for honor his deletion request with an electronic signature. Due to a technical failure to include an original signature, the pleading was returned to the movant on April 29, 2025. The movant handsigned the pleading and refiled it on May 5, 2025. More than a week later, on May 13, 2025, the objection was added to the docket.

⁹ Queenie Wong, L.A. Times, Court approves sale of 23andMe to nonprofit led by co-founder Anne Wojcicki (July 1, 2025), <https://www.latimes.com/business/story/2025-07-01/court-approves-sale-of-23andme-to-nonprofit-led-by-its-founder-anne-wojcicki>.

Implications for Florida Healthcare Practice

These developments carry significant implications for Florida healthcare providers and their legal counsel:

1. Partnership Risk Assessment. Healthcare organizations increasingly partner with digital health companies to offer wellness programs, remote monitoring, and patient engagement tools. The 23andMe situation demonstrates that these partnerships may expose patients to privacy risks that traditional HIPAA compliance programs fail to address.
2. Employee Wellness Programs. Many Florida employers and health plans offer fitness memberships, wellness apps, and wearable device programs. Legal counsel should evaluate whether these partnerships adequately protect employee health information and what exposure may exist should their partners fail.
3. Value-Based Care Initiatives. As Medicare and commercial payers push toward value-based payment arrangements, healthcare providers may increasingly rely on digital health tools for population health management and patient engagement. Understanding the privacy landscape for these tools is critical for both compliance and patient trust.
4. Patient Counseling. Healthcare providers may need to advise patients about privacy risks when recommending digital health tools, particularly given the absence of comprehensive state-level protections in Florida.

Practical Recommendations

While comprehensive federal privacy reform may take years, the following are immediate steps that can be taken to address these challenges.

- For Healthcare Providers:
 - o Conduct privacy impact assessments before partnering with digital health companies.
 - o Include specific data protection requirements in vendor agreements that go beyond minimum legal requirements.
 - o Develop patient education materials about digital health privacy risks.
 - o Consider whether business associate agreements are appropriate even when not legally required.
- For Legal Counsel:
 - o Review existing vendor agreements with digital health companies for adequate privacy protections.

- o Advise clients on state-specific privacy law requirements when operating across multiple jurisdictions.
- o Monitor proposed federal legislation and state privacy initiatives that may affect client operations.
- o Develop template contract language for digital health partnerships that addresses data portability, deletion rights and breach notification.

The Path Forward

As more companies follow 23andMe's path—whether through bankruptcy, acquisition, or simple business model changes—millions of Americans' health privacy hangs in the balance. The gaps in the current system's patchwork approach to the protection of genetic testing customers' privacy highlighted by 23andMe's bankruptcy case could foreshadow similar vulnerabilities across the expanding digital health ecosystem.

While federal reforms—such as extending meaningful privacy protections to health data regardless of its source or controller—might offer the most comprehensive solution, state-level action remains crucial tool for policymakers, particularly in states like Florida that have not enacted comprehensive consumer data privacy protections.

For Florida's healthcare community, the 23andMe bankruptcy serves as both a warning and an opportunity. By understanding these privacy gaps and taking proactive steps to address them, healthcare providers and their counsel can protect both patient interests and their own organizations while supporting the innovation necessary for improved health outcomes. Beyond legal risks, a failure to adapt privacy practices to match digital health realities can erode patient trust.

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Can a Physician Avoid Billing Medicare Directly? What All Providers Need to Know About Non-Participation and Opt-Out Status

Our clients are increasingly asking whether they can provide services to Medicare beneficiaries and avoid billing Medicare altogether. While the desire to simplify administrative burdens is understandable, federal law does not allow enrolled providers to treat Medicare patients and bypass Medicare billing (except under very specific circumstances). Whether you are employed by a hospital, operating a private practice, or splitting your time between multiple settings, here is what you need to know.

Medicare Participation Basics

Medicare classifies physicians and other eligible professionals in three ways:

1. **Participating (PAR).** Providers agree to accept Medicare's approved amount as full payment and always accept assignment. Medicare pays the provider directly, and the patient is responsible only for coinsurance and any deductible.
2. **Non-Participating (Non-PAR).** Providers are enrolled in Medicare but may choose whether to accept assignment on a case-by-case basis. If they do not, they may bill the patient directly, but only up to a limited amount known as the "limiting charge."
3. **Opted Out.** Providers who opt out of Medicare contract privately with each Medicare patient and agree not to bill Medicare for any services. Neither the provider nor the patient may submit claims to Medicare. Opting out applies across all settings and lasts for two years.

The Mandatory Claim Submission Rule

Federal law (42 U.S.C. § 1395w-4(g)(4)) requires that any provider who is enrolled in Medicare (both participating or non-participating) must submit a claim to Medicare for any covered service furnished to a beneficiary. Providers may not simply give the patient a bill and ask them to submit it to Medicare. This rule is designed to protect patients from excessive charges and ensure consistent reimbursement rules are followed.

The only lawful exception to this rule is when the provider has formally opted out of Medicare.

How Non-Participation Works

If you are non-participating and do not accept assignment:

- You may choose whether or not to accept assignment for each service.
- If you do not accept assignment, you may bill the patient directly up to 115% of the Medicare-approved amount (known as the "limiting charge").
- Medicare will reimburse the patient directly for the Medicare-approved portion.

- You are still legally required to submit the claim to Medicare, even if the patient is paying you directly.

A non-participating provider may choose to accept assignment on a claim-by-claim basis, which means agreeing to accept Medicare's approved amount (at a slightly reduced rate) as full payment for that service. When assignment is accepted, Medicare pays the provider directly, and the provider may not bill the patient more than the standard 20 percent coinsurance and any applicable deductible. Although the payment rate is slightly lower than for participating providers (95 percent of the Medicare fee schedule), accepting assignment allows for faster payment and eliminates the need for the patient to seek reimbursement. However, once a physician accepts assignment on a claim, the physician cannot charge above the approved amount or later switch the payment arrangement for that service.

Non-participation may offer some flexibility, but it does not eliminate the obligation to engage with Medicare.

What If You Do Not Want to Bill Medicare at All?

If your goal is to avoid all Medicare billing and treat Medicare patients on a cash-pay basis, you must formally opt out of Medicare. This requires:

- Submitting a written opt-out affidavit to your Medicare Administrative Contractor (MAC).
- Entering into a private contract with each Medicare patient before services are rendered.
- Acknowledging that neither you nor the patient will submit any claims to Medicare.

Once you opt out, this status applies for two years and applies universally. To be clear: you cannot be opted out in one job and opted in at another. For example, a physician cannot opt out in their private practice while continuing to bill Medicare under a hospital employer. The opt-out status follows the physician's NPI and overrides the Medicare participation status of any group or entity they work with.

Working in Multiple Roles or Entities

Many physicians work in different roles, such as hospital employment, locum tenens coverage, and private practice ownership. Medicare participation is tied to the billing entity's Tax ID, not the individual physician. This means:

- If you work for a hospital that participates in Medicare, your services will be billed as participating, even if you personally prefer non-par status.
- Separately, you can bill under a different Tax ID (such as your own practice) with a different participation status.

But again, if you have opted out of Medicare, that status applies to all services you provide, regardless of which organization bills on your behalf. It is not selective or employer-specific.

Opt-Out Rules for Nurse Practitioners and Physician Assistants

Nurse practitioners (NPs) and physician assistants (PAs) are permitted to opt out of Medicare, but only if they are authorized under state law to furnish and bill for services independently. Like physicians, opted-out NPs and PAs must submit a formal opt-out affidavit and enter into private contracts with each Medicare patient. The opt-out applies across all settings and lasts for two years. However, if a state requires physician supervision for the services in question, or if the services are billed “incident to” a supervising physician, the opt-out option may not be applicable. NPs and PAs should ensure that their employment structure and scope of practice support independent Medicare billing before proceeding with an opt-out.

What About Other Non-Physician Providers?

Certain healthcare professionals are not allowed to opt out of Medicare. This includes: Physical therapists, Occupational therapists, Speech-language pathologists, and Chiropractors. These providers are required to submit claims for covered services and may not enter into private pay arrangements that bypass Medicare rules. Chiropractors are particularly limited because Medicare only covers manual manipulation of the spine — and even for this limited scope, chiropractors must bill Medicare directly and cannot opt out. Any attempt to sidestep this requirement can trigger serious regulatory consequences, including repayment demands, audits, and exclusion from Medicare programs.

There is no legal way for an enrolled provider to avoid Medicare billing for covered services while still treating Medicare beneficiaries — unless you formally opt out of Medicare and follow all related rules. Opting out must be done uniformly and applies to all your professional activities. Non-participation allows some flexibility, but still carries mandatory billing requirements and strict limits on what you can charge.

Submitted and authored by Jackie Bain, Esq., Silverman Bain, LLP. *Republished with permission from* <https://www.silvermanbain.com/avoid-medicare-billing-options-for-providers/>

STATE LAWS AND STATUTES

Governor DeSantis Vetoes Bill to Repeal Medical Malpractice Wrongful Death Restriction

On May 28, 2025, Governor Ron DeSantis vetoed House Bill 6017, legislation that sought to eliminate a longstanding provision in Florida law that limits recovery in certain medical malpractice wrongful death cases. The bill targeted subsection (8) of section 768.21, Florida Statutes, which prohibits adult children from recovering non-economic damages for the death of a parent due to medical negligence if the parent was unmarried at the time of death.

This statutory provision has been criticized for years by families, legislators, and advocacy groups, who argue that it unjustly denies access to legal remedies based solely on family structure. Supporters of repeal have also noted that no similar restriction applies in other types of wrongful death cases under Florida law.

Under the current statute, a surviving spouse and minor children may recover non-economic damages such as mental pain and suffering.¹ However, if a decedent has no surviving spouse and their children are adults, those individuals are precluded from recovering any non-economic damages for losses stemming from medical negligence. This limitation does not apply in wrongful death actions involving non-medical defendants, creating a distinction that applies only to healthcare-related claims.

HB 6017 passed the Florida House and Senate with broad support.² However, in his veto message, Governor DeSantis stated that he would not approve the repeal unless the legislation also imposed limits on non-economic damages and attorney fees. Without those conditions, he expressed concern that the bill could increase malpractice insurance costs and affect physician availability.³

By vetoing the bill, the Governor left intact section 768.21(8), Florida Statutes, which bars adult children from recovering non-economic damages, such as pain and suffering, when an unmarried parent dies due to medical malpractice. Unlike other wrongful death claims under Florida law, where surviving family members can typically seek compensation for emotional losses, this provision creates a specific and narrow exception that applies only in the context of medical negligence.

Moving forward, legal practitioners should continue to carefully assess eligibility for non-economic damages in medical malpractice cases involving wrongful death. Unless and until section 768.21(8) is amended, it remains a substantial barrier for adult children seeking to recover for the loss of an unmarried parent.

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¹ See Fla. Stat. § 768.21(3)–(4).

² H.B. 6017, 2025 Leg., Reg. Sess. (Fla. 2025), <https://www.flsenate.gov/Session/Bill/2025/6017>.

³ Executive Office of the Governor, Press Release, Governor Ron DeSantis Issues Veto to Safeguard Florida Against Misuse of Medical Malpractice Claims (May 29, 2025), <https://www.flgov.com/eog/news/press/2025/governor-ron-desantis-issues-veto-safeguard-florida-against-misuse-medical>.

Florida's SB 1768: A Lawyer's Roadmap to Stem Cell Therapy Regulations

As attorneys, keeping up with Florida's evolving healthcare laws is critical, especially in cutting-edge fields like stem cell therapy. Effective July 1, 2025, Florida's SB 1768 introduces a robust regulatory framework under sections 458.3245 and 459.0127, Florida Statutes.

What's in SB 1768? Ethical Innovation at the Core

Florida's legislature sees stem cell therapy as a game-changer for medical treatment but insists on ethical sourcing. The bill explicitly bans the use of cells from aborted fetuses or embryos, promoting instead adult stem cells, umbilical cord blood, and other ethically obtained human cells, tissues, or cellular/tissue-based products (HCT/Ps). It defines key terms like "stem cell therapy" (covering treatments with afterbirth placental perinatal stem cells or HCT/Ps) and "minimally manipulated" (processing that preserves tissue or cell characteristics), giving physicians a clear framework for treating patients.

Green Light for Certain Therapies

Only Physicians licensed under chapters 458 or 459, Florida Statutes, can perform FDA-unapproved stem cell therapies, but only for orthopedics, wound care, or pain management and within their scope of practice. The primary limitation is that the stem cells must come from FDA-registered facilities certified by organizations like the National Marrow Donor Program, World Marrow Donor Association, Association for the Advancement of Blood and Biotherapies, or American Association of Tissue Banks. These cells must also be viable, with a post-thaw analysis report provided to the physician before use. Additionally, the bill only references treatment provided by a medical doctor or doctor of osteopathic medicine – there is no mention of mid-level providers or delegation from a physician.

Legal Insight: When advising providers, ensure their contracts with stem cell facilities include required disclosures (e.g., facility details, certification status) and a clause for 30-day notification of any certification changes. Non-compliant sourcing could trigger legal exposure.

Strict Compliance Standards

The bill mandates adherence to current good manufacturing practices (CGMP) under the Federal Food, Drug, and Cosmetic Act and 21 C.F.R. part 1271. This ensures stem cells are collected, processed, and stored to the highest standards.

Legal Insight: Counsel clients to verify that their suppliers meet CGMP and certification requirements to avoid regulatory violations.

Protecting Patients

SB 1768 prioritizes transparency with two key consumer protections:

- **Advertising Notice:** Physicians must include a clear, legible notice in all ads stating that therapies may not be FDA-approved and urging patients to consult their primary care provider. The notice must use the ad's largest type size.
- **Informed Consent:** Before treatment, physicians must obtain an informed consent form from the patient (or their representative if not competent). The form must explain the treatment's nature, FDA approval status, anticipated results, risks, benefits, and alternatives in plain language.

Legal Insight: Review clients' advertising materials and consent forms to ensure compliance. Non-compliant ads or inadequate consent could lead to disciplinary action or tort claims like fraud or negligence.

Exemptions to Know

The bill doesn't apply to physicians with FDA approval for investigational drugs/devices or those working under contracts with institutions accredited by entities like the Foundation for the Accreditation of Cellular Therapy or the Blood and Marrow Transplant Clinical Trials Network.

Legal Insight: For clients at accredited institutions, confirm their exemption status to streamline compliance efforts.

Enforcement with Teeth

Violations can lead to disciplinary action by the Board of Medicine and the FDA. Willfully using cells from aborted fetuses/embryos or selling/manufacturing computer products with HCT/Ps is a third-degree felony, punishable under sections 775.082, 775.083, or 775, Florida Statutes.

How Lawyers Can Guide Clients

- **For Physicians and Clinics**
 - **Compliance Planning:** Help clients secure stem cell sources from certified, FDA-registered facilities by July 2025. Draft contracts with mandatory disclosure clauses and review supplier certifications.
 - **Advertising Audits:** Scrutinize all marketing—websites, brochures, social media—for the required notice and to eliminate misleading claims. Non-compliance risks DOH sanctions or patient lawsuits.
 - **Consent Protocols:** Design consent forms that meet the bill's requirements, ensuring clarity and defensibility. Include all mandated disclosures to reduce liability.

- **Risk Management:** Advice on systems for tracking stem cell sourcing and patient outcomes to satisfy DOH inspections. Ensure CGMP compliance to avoid penalties.
- **For Businesses and Investors**
 - **Due Diligence:** Confirm that stem cell clinics or suppliers comply with SB 1768 to protect investments. Non-compliance could disrupt operations or lead to legal liability.
 - **Contract Protections:** Include clauses in agreements requiring adherence to the bill's standards, shielding clients from risks tied to non-compliant partners.
- **Strategic Considerations**
 - **Rulemaking Watch:** The Board of Medicine's rulemaking authority means new guidelines could emerge. Stay updated to keep clients compliant.
 - **Federal Overlap:** For clients operating across states, assess how SB 1768 aligns with FDA regulations to avoid conflicts.
 - **Litigation Risks:** Non-compliance may spark tort claims under existing laws.

Conclusion

SB 1768 positions Florida as a leader in ethical stem cell therapy regulation, balancing innovation with patient safety. For lawyers, it's a chance to guide clients through a complex landscape of compliance, transparency, and enforcement. Start by reviewing the [full text of the statute](#), which took effect July 1, 2025.

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New Florida Law Requires Licensed Health Care Facilities, Providers, and Practitioners to Promptly Refund Patient Overpayments

Don't sit on those patient credits. Effective January 1, 2026, a new Florida law ([CS/CS/SB 1808](#)) requires licensed health care facilities, providers, and practitioners (each, a "Licensed Provider") to refund any overpayment made by a patient no later than 30 days after the Licensed Provider determines that the patient made an overpayment.

AHCA

For Licensed Providers who are licensed by AHCA, a violation of the requirement to timely refund a patient's overpayment is subject to an administrative fine of up to \$500 per violation. Under pre-existing law (section 408.813, Florida Statutes), each day of violation constitutes a separate violation and is subject to a separate fine. As such, large administrative fines could accrue each day that overpayments are not timely repaid to patients.

DOH

For Licensed Providers who are licensed by the Department of Health ("DOH") or one of the licensing boards within the DOH, a violation of the requirement to timely refund a patient's overpayment is grounds for disciplinary action (e.g., administrative fines or the restriction, probation, suspension, or revocation of a license) by the applicable board or the DOH when there is no board.

Entities Associated With Licensed Providers

This requirement also applies to any billing department, management company, or group practice (each, a "Billing Entity") that accepts payment for services rendered by the Licensed Provider. While a Billing Entity itself may not be subject to the jurisdiction of the DOH or the applicable board, the treating Licensed Provider would be subject to discipline. It will be interesting to see how the DOH implements this power with respect to Licensed Providers employed by large Billing Entities when they have little to no control over processes and procedures for patient billing and collection.

Limitations

It is important to note the limitations of this new law. For example:

- There is no private right of action, so patients cannot sue Licensed Providers for violations. However, a patient could file a complaint with AHCA or the DOH about an overdue refund from a Licensed Provider. In turn, AHCA or the DOH could investigate the complaint and impose fines or disciplinary action.
- The new law does not apply to overpayments made by a health insurer or health maintenance organization ("Payor") to a Licensed Provider for services rendered to an insured or subscriber. Florida's insurance laws govern those payments (sections 627.6131 and 641.3155, Florida Statutes, respectively).

- The new law closes the loophole left by the insurance laws referenced above that protect Payors from overpayments, but not the patients who often pay a portion of the bill as part of their deductible, copay, or coinsurance. The new law only applies when a patient is due a refund from a Licensed Provider who filed a claim with a Payor or government-sponsored program (e.g., Medicaid, Medicare, and TRICARE) for reimbursement for the services rendered to the patient. So, while the new law does not protect the Payor or government program, their involvement is required to the extent the claim for the service for which the patient overpaid must have been submitted by the Licensed Provider for reimbursement by such Payor or government program. The law does not apply, however, to overpayments made by uninsured, self-pay, or cash pay patients.

Licensed Providers (and their Billing Entities) should review their revenue cycle management processes and procedures to ensure that overpayments made by patients are consistently repaid within the 30-day period.

Submitted and authored by Marcy Hahn-Saperstein, Esq. & John C. Hood, Esq., Akerman
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