HEALTH LAW CONNECTIONS

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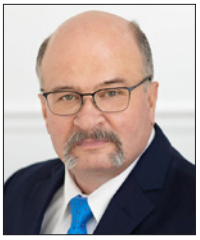

Mark S. Kopson
Plunkett Cooney

When this column is published in early November, I will have attended my first three in-person conferences as President—Tax Issues for Health Care Organizations, the Fraud and Compliance Forum, and Fundamentals of Health Law. I am thankful for the opportunity to have attended those conferences and to have met and interacted with so many members and non-member attendees. I have also gained an even deeper appreciation for our outstanding planning committee members and conference faculty who so generously give their time and talent for the benefit of our diverse health law community, all with the assistance and coordination of our incredibly talented AHLA staff members. In that spirit of gratitude, I have two requests for you.

While in-person conferences offer many benefits, one I have always enjoyed is meeting and reconnecting with our many sponsors and discussing the wide variety of services they offer to us and our clients. While you may not have realized it when passing their exhibits, sponsor support of AHLA is crucial to our ability to offer in-person and virtual conferences, webinars, on-demand programming, and our many member publications and resources. I won't bore you with mind-numbing budget details, but suffice it to say that without the generous support of our sponsors, both member dues and registration fees would have to significantly increase to potentially prohibitive levels. I am thankful for our sponsors' continuing financial support of AHLA's networking activities, keynote speakers, off-premises receptions, and a host of professional development offerings. For all of these reasons, **my first request is that you please take time to visit with and thank our sponsors.** You will not only learn about their wide range of offerings, but also enhance your professional network, and may develop some long-term friendships, as I have done.

I am also thankful for the many members who give so generously of not only their time and talent, but also their treasure. Tax-deductible contributions to AHLA play a crucial role in achieving our strategic goals: (1) provide authoritative, timely, and high-quality content that meets the needs of all health law professionals; (2) attract a diverse array of professionals to connect, learn, and support one another; and (3) optimize governance and sustainability of offerings to best position AHLA as a continual authority for health law. How so? As but one example, each year, over 1,200 students benefit from free access to AHLA's comprehensive educational resources—an investment in tomorrow's health law leaders who will carry forward our tradition of collaborative camaraderie.

What can your personal financial contribution accomplish? The choice is yours to make. Your donation to the Michael F. Anthony Health Law Scholarship Endowment Fund,[1] honoring his dedication to health law, provides scholarships for attendance at our annual Fundamentals conference. Contributions to the Anne H. Hoover Educational Fund[2] directly empower student internships, academic competitions, mentorship programs, and professional development resources that continue Anne's 36-year commitment to excellence in health law education. Your support of the IDEA Fund[3] enables resources, training, and direct assistance that removes barriers and fosters a welcoming environment for varied viewpoints at all levels of AHLA, enriching our professional community and strengthening the practice of health law. Through the Health Law Leadership & Innovation Fund[4] your contribution empowers health law professionals to become industry leaders, driving excellence through cutting-edge learning platforms, specialized expertise development, and thought leadership opportunities that advance the entire field of health law.

If you can't decide on a particular aspect of AHLA's mission to support, it's not a problem. By earmarking your contribution for Areas of Greatest Need,[5] you will empower AHLA to respond quickly to emerging opportunities and challenges, allowing us to direct resources where they can make the most significant impact on the health law community.

My second request is that you make a donation—in whatever amount is meaningful to you—to support whichever AHLA fund best advances your own passion. By leveraging our collective generosity, even the smallest donation will have a major impact on current and future health law professionals. Start now.[6]

Whether sponsor, speaker, author, leader, donor, member, or staff, I am thankful for all of you and for everything you do to support our collegial community of life-long learners. Best wishes for a healthy, safe, and peaceful holiday season.

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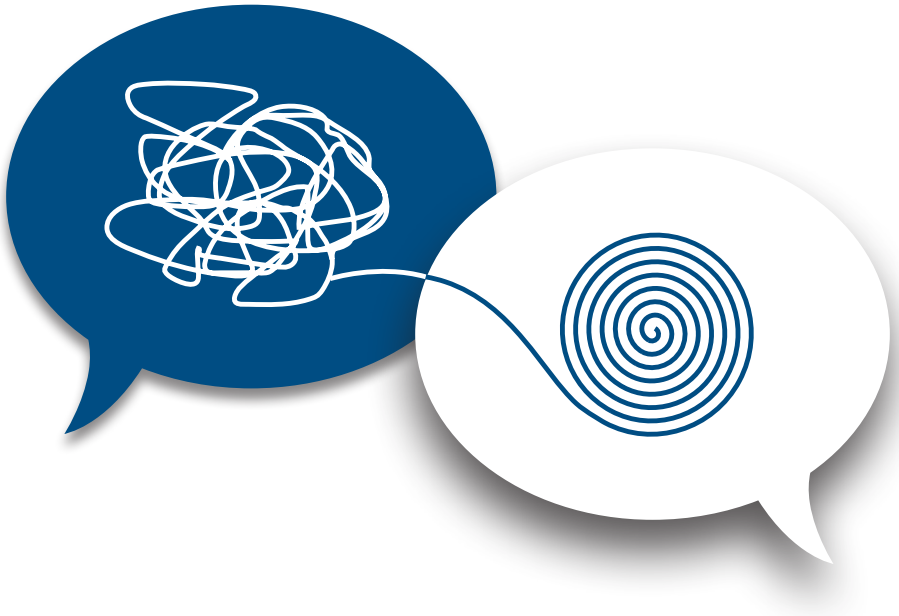

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Key Legal Issues in Academic Medical Center and Community Hospital Tie-Ups

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Affiliations between academic medical centers (AMCs) and community hospitals are a commonly sought solution to respond to a health care market characterized by significant financial pressures, as hospitals and health systems work to control costs while improving quality and access to care for patients in the communities that they serve. But these affiliations also present a variety of institutional, cultural, and legal and regulatory challenges. For example, how should the affiliation be structured to establish shared governance over the participant hospitals and their affiliated physicians? What changes may be required to align physician compensation and physician performance for faculty physicians and community physicians? If there is a desire to engage in a shared strategy to contract with payers, how will the parties implement the requisite financial or clinical integration to mitigate against potential risks under federal antitrust laws and emerging state regulatory regimes for reviewing transactions for their impacts on health care costs and market consolidation? Evaluating and addressing these issues—not only in developing and negotiating the affiliation at the outset, but also in planning for post-closing integration and implementation—is critical to the success of these affiliations.

When planning any affiliation involving an AMC, a community hospital, and their respective affiliated physicians, one of the first and most fundamental decisions is how to establish a governance structure that ensures alignment across the entire enterprise to drive improvements in quality and access while reducing costs.

Governance Structure

When planning any affiliation involving an AMC, a community hospital, and their respective affiliated physicians, one of the first and most fundamental decisions is how to establish a governance structure that ensures alignment across the entire enterprise to drive improvements in quality and access while reducing costs.

The legal structure of an AMC's faculty practice plan can vary greatly between states and institutions. Moreover, the AMC's faculty practice plan and community hospital-affiliated physician groups typically operate through distinct legal entities. To enhance collaboration and alignment between the physician affiliates, the AMC, and the community hospital, the parties may explore various joint venture or joint venture-like approaches. Service line joint ventures have largely replaced co-management joint ventures; such service line joint ventures are more efficient when at the hospital-to-hospital level, but that model doesn't help much on the physician side. Nonprofit medical foundations, where allowed by state law, can be better vehicles for incorporating community physician input into ambulatory operations and governance, although, in more mature markets like California, those foundations have developed a reputation for giving too much power to their affiliated health systems. Nonetheless, such foundations are often a useful bridge between academic and community medicine.

Moreover, the structure of affiliations among AMCs, community hospitals, and their respective affiliated physicians and the associated mechanism(s) for shared governance and decision making will have significant implications under federal antitrust laws and federal health care fraud and abuse laws.

Antitrust Considerations

The timing and nature of the antitrust considerations depend on the structure of the affiliation. On the one hand, an AMC's full acquisition of a community hospital and/or community hospital-affiliated physician groups may pose challenges during the negotiation and due diligence stage, particularly in light of a growing number of state laws requiring prior review of the cost and market impact of a proposed transaction. But once the transaction is closed, the AMC, community hospital, and affiliated physician groups can act as one. By contrast, any arrangement short of full acquisition requires ongoing antitrust compliance among the AMC, community hospital, and the community hospital's affiliated physicians.

In antitrust law, two separate economic entities generally must make their own independent decisions when it comes to competing for patients and negotiating payer contracts. The Supreme Court decision in *Copperweld,*[1] and its progeny, explains that if two entities are one economic unit, they are incapable of conspiring with each other, allowing them to coordinate how they compete and how they negotiate with payers. Some factors that address whether two entities function as one are a single governance structure, control over finances, a combination of assets, and risk allocation, among others.

Affiliations or joint venture arrangements typically do not satisfy enough of these factors for the AMC and community hospital-affiliated physician groups to be considered a single entity. However, antitrust laws recognize that affiliations can be beneficial to patients, hospitals, and physicians. Thus, guardrails for antitrust compliance among the AMC, the community hospital, and community hospital-affiliated physician groups must be set up at the outset and continue for the life of the affiliation. These guardrails must address how to appropriately share competitively sensitive information and what the AMC, community hospital, and community hospital-affiliated physician groups can do jointly versus what they must continue to do separately.

The level of financial and clinical integration between the AMC and community hospital can affect the antitrust guardrails. For example, if an AMC and community hospital enter into an affiliation agreement pursuant to which the AMC will provide neurosurgery services for the community hospital's patients, the AMC and community hospital may share patient information, may advertise the affiliation, may share strategic information about neurosurgery services, and may share information regarding recruitment of neurosurgery physicians (but not compensation). However, the AMC and community hospital may *not* share strategic information more broadly, may not allocate patients, and may *not* jointly negotiate payer reimbursement contracts.

That said, if an AMC and community hospital form a joint venture to provide neurological services,[2] including neurosurgery, and the AMC and community hospital both share upside and downside financial risk in the joint venture, and the two entities are clinically integrated, not only may the AMC and community hospital share strategic information about the joint venture and the services the joint venture provides, they may also jointly recruit and set compensation for physicians staffed with the joint venture and may jointly contract with payers for the services the joint venture offers. This is because the antitrust laws treat a sufficiently integrated joint venture as a single entity, incapable of conspiring with itself.[3] A warning, though, becoming financially and clinically integrated to the level required for antitrust purposes is often not as easy in practice as it is on paper. It requires buy-in and commitment from the AMC and community hospital, and the affiliated physicians of the AMC and community hospital. Joint ventures in name only have been successfully challenged.[4]

In some respects, from an antitrust perspective, a full acquisition where the community hospital/physician group is fully integrated with the AMC can be easier. In this situation, the AMC and community hospital/physician group are no longer considered separate economic entities and can be folded into the AMC's strategic plans, compensation structures, and payer contracting for all services.

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In some respects, from an antitrust perspective, a full acquisition where the community hospital/physician group is fully integrated with the AMC can be easier.

The challenge with a full acquisition is that, depending on the AMC and the community hospital and its affiliated physician groups, there could be a substantive antitrust issue, i.e., federal or state antitrust regulators could view the acquisition as lessening competition. Whether or not a transaction faces a substantive antitrust challenge is highly fact dependent, including whether there are other hospitals in the area and the number and complexity of overlapping services. Because of the difference in complexity and type of services offered at an AMC versus a community hospital, there may be an argument that the AMC and community hospital do not actually compete and therefore there is no lessening of competition. In addition, if the AMC is affiliated with a state-created university, it may—in certain states—benefit from the "state action immunity" doctrine, which is a court-created doctrine that immunizes political subdivisions from antitrust liability when the state authorized otherwise anticompetitive activities. A detailed analysis of all the facts surrounding an AMC and community hospital merger is necessary. But once the acquisition is complete, the AMC and community hospital are one entity and can operate in all respects as such.

Antitrust compliance, both when contemplating an affiliation or full acquisition between an AMC and a community hospital, should not be ignored. Failure to adhere to antitrust laws may lead to fines, payment of damages, and in some cases criminal liability.

Fraud and Abuse Considerations

When affiliating or integrating a community hospital with an AMC, certain high-level structural considerations can also have major implications for the Physician Self-Referral Law (PSL) or Anti-Kickback Statute (AKS) analysis that will apply.

For example, will the post-affiliation physician employment vehicle(s) be a "group practice" under the PSL? If the physicians are in the same legal entity as a hospital and it is not the right time to upend this structure, then being a "group practice" under the PSL is not an option (though, notably, the PSL *bona fide* employment exception may be available to support employment-related compensation paid to employed physicians). If the physicians are not in the same legal entity as a hospital, or could readily be migrated to a different entity, it will often be possible to ensure that the employing entity is structured as a "group practice" under the PSL. When the physician employment vehicle is structured as a PSL "group practice," generally neither commercial reasonableness nor fair market value will be required from a PSL perspective with respect to physician compensation.

Structuring the physician employment vehicle as a PSL "group practice" can generally serve as an effective 'backstop' to a party's efforts to ensure physician compensation is consistent with fair market value. For example, if a community hospital's affiliated physicians were brought under a faculty practice plan entity that was structured as a PSL "group practice," and if perhaps one or two percent of physicians' compensation was arguably pushing the bounds of fair market value, it could be useful to rely on the PSL "in-office ancillary services" exception (which keys off of the physician vehicle being a "group practice") to protect the compensation arrangements with such physicians. That said, separate considerations beyond the PSL will generally limit parties' ability to rely on being a "group practice" to the same extent that a private for-profit group could. Tax-exempt considerations are one such constraint. Additionally, under the AKS' AMC framework, as is expressed in various advisory opinions, a critical factor is that downstream wages to physicians must be consistent with fair market value. Thus, if physician wages are downstream of funds flow monies that relied on the AKS' AMC framework, then such funds flow monies could potentially raise significant risk under the AKS if a significant number of physicians were compensated materially in excess of fair market value.

Another key example of how a high-level structural factor can have implications for the PSL analysis and AKS analysis is whether the AMC has an affiliated Medicare Shared Savings Program (MSSP) Accountable Care Organization (ACO) that can appropriately capitalize on the MSSP ACO Participation Waiver (Participation Waiver) with respect to physician compensation. The Participation Waiver waives the PSL and AKS requirements for any arrangement of an MSSP ACO or one or more ACO participants that is reasonably related to the purposes of the MSSP (which primarily involve the quality and efficiency of care) and that satisfies certain modest procedural hurdles. Thus, if physician compensation arrangements are brought under the Participation Waiver, the PSL is waived and other PSL considerations like whether the employer is a "group practice" are mooted. Additionally, any 'upstream' funds flow arrangements could likely be brought under the protection of the Participation Waiver as well, in which case it would not matter if the parties were outside of the AKS' AMC framework, because the AKS also would be waived by virtue of the Participation Waiver.

Physician Alignment, Culture, and Physician Compensation Considerations

When affiliating a community hospital with an AMC, a key factor in its success will be the design and execution of a strategy to integrate the community hospital-affiliated physicians. The cultural differences between academic physicians and community physicians are vast—as are the differences between their respective compensation plans and funds flow arrangements,

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which can present a barrier to physician alignment. If an AMC is new to affiliating with community physicians, it may stumble into fraught territory if it attempts to structure compensation and other arrangements with such physicians without legal oversight, particularly in the fraud and abuse arenas, but also with respect to clinic licensure and enrollment, the corporate practice of medicine, and antitrust issues, as referenced above.

Compensation

There are two primary methods to align compensation between AMC physicians and community physicians: (1) offering community physicians compensation structures that resemble the compensation plans offered to AMC faculty physicians, and (2) adjusting academic physician compensation to better reflect what community physicians typically negotiate. While differences in aggregate compensation may be narrowing, challenges remain in bridging this divide. On the academic side, faculty are not accustomed to market-level compensation or compensation disconnected from the AMC. They also may not be used to the time pressure or urgency of the clinician culture of community physicians, as well as the significant variance in the compensation earned by community physicians, particularly for high performers. On the community physician side, such physicians may expect simpler, more responsive administrations and clear compensation structures that primarily reward productivity. They also may have significant input in clinical housekeeping issues, governance, and operations, particularly regarding their own clinical space.

Any funds flow model that helps fund a physician bonus pool will require careful legal review, as subtle differences in pool structure can be the difference between a compliant compensation structure and Halifax-level financial exposure.

While academic physicians can be retained through a simple offer letter that meets regulatory requirements under the PSL, many administrators may express surprise that detailed professional services agreements (PSAs) are often necessary for an AMC to compensate community physician groups for their services. And PSAs are usually not sufficient to encourage integration—additional approaches are needed. As a result, many AMCs and their network clinical hospitals resort to one version or another of a funds flow process to guide how funds are used to pay physicians. At its best, an explicit, thoughtfully designed funds flow process enables the flow of funds and guides the funding of services among the AMC, affiliated community hospital, and their respective physician groups. At its worst, the funds flow process becomes a neglected set of legacy contracts developed over years, service by service, chaperoned on an ongoing basis by staff. Often, the biggest impediment at AMCs is the transition from academic department-specific funds fiefdoms to a system where programming, but not financing, is within the AMC's control. The shared rules regarding financing

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One of the frequent drivers for affiliations among AMCs and community hospitals and their respective affiliated physician groups is to be able to drive value for payers, achieving both cost efficiency and improved quality through an integrated care delivery model.

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are critical to the success of initiatives integrating a community hospital and its affiliated physicians.

In response to market pressures, with or without significant community physician affiliations, AMCs have developed and implemented productivity-based compensation, both at the funds flow level (i.e., calculating payments to faculty departments) and at the physician compensation level. Caution is warranted in structuring funds flows that are intended to enhance alignment with the AMC. Practitioners are wise to remember the risks posed by technical revenue-containing bonus compensation pools as documented in *United States v. Halifax Medical Center* (*Halifax*),[5] where the court found that varying the size of a bonus pool for employed physicians that contained designated health services revenues caused the arrangement to fail to qualify for the "bona fide employment" exception under the PSL. Subsequent clarifications regarding the PSL's volume or value standard provide comfort with respect to moderate tweaks to the structure of such bonus pools, but thoughtful design remains essential. Any funds flow model that helps fund a physician bonus pool will require careful legal review, as subtle differences in pool structure can be the difference between a compliant compensation structure and *Halifax*-level financial exposure.

Some AMCs have developed "non-faculty" or "staff" employment paths for community hospital-affiliated physicians. These structures require greater fraud and abuse scrutiny than the potentially available *bona fide* employment exception to the PSL, by way of comparison. Recall that referrals by a "referring physician" are only covered under the PSL AMC exception provided that the physician has a *bona fide* faculty appointment. These models may also require a deep understanding of the scope of the corporate practice of medicine doctrine in a particular state, which may have narrow exceptions with regard to academic medicine. These models will also involve compensation structures that may be more generous for the clinical services, and will require less administrative, teaching, and research burden, than faculty practice plans. As a result, this can open Pandora's box when comparing strict mission-driven faculty compensation compared to clinically driven compensation. Creating the hybrid compensation package that addresses and values various services, such as patient care, research, and teaching, is preferrable, but can be administratively burdensome and can be challenging to AMCs that have historically maintained a closed medical staff. Depending on the starting point of the different packages, the path of least resistance can be to keep the community hospital-affiliated medical groups substantially separate from the AMC faculty.

Clinical Integration and Value–Based Care

One of the frequent drivers for affiliations among AMCs and community hospitals and their respective affiliated physician groups is to be able to drive value for payers, achieving both cost efficiency and improved quality through an integrated care delivery model. In many cases, it is a first step towards readiness to take on significant and shared financial risk for the services provided to patients in the geographic areas served by the hospitals and physicians. Participation in both the MSSP and commercial ACOs presents a valuable opportunity to influence provider compensation through shared savings arrangements. The parties may also consider forming a clinically integrated network (CIN) as a strategic avenue to promote integrated care delivery. A well-structured CIN can support achievement of quality benchmarks in value-based payment models offered by managed care entities (MCEs).

Through collaboration, the parties can design a care model that reflects the unique mission of the AMC (i.e., research, teaching, and patient care), while also advancing the goals of the community hospital and its affiliated physicians (such as delivering high-quality care to underserved populations). This approach should be carefully aligned with the financial incentives offered by MCEs for meeting specific performance and quality metrics.

Additionally, establishing an ACO or CIN can mitigate certain antitrust risks associated with joint contracting and negotiation with MCEs, by demonstrating sufficient clinical and financial integration, as referenced above.[6]

Whether the parties opt to form a single contracting vehicle (e.g., a CIN, ACO, or joint venture) for value-based arrangements or prefer to contract individually, it is essential that they align on network and product participation (i.e., Medicare Advantage, Medicaid Managed Care, commercial insurance offerings, and Exchange-based plans). Failure to coordinate on MCE participation can negatively affect both the providers and patients.

Moreover, a unified contracting approach allows the parties to employ their combined geographic reach and specialty care to enhance negotiating power with MCEs. By aligning operational capabilities (such as data analytics) and care coordination, the ACO or CIN can determine the quality outcomes that the parties

can realistically influence, which is an important factor when entering into value-based contracting with MCEs. The parties must collaborate to ensure performance expectations for shared savings are achievable under the new structure. A necessary precondition to this is that in the negotiation and contracting phases, the performance expectations by the MCE need to be clearly established and quality metrics precisely defined. There may also be unique opportunities for risk adjustment within MCE contracting given the complexity of the patient populations often treated by AMCs and potentially by community-based providers. Leveraging this complexity can enhance the negotiation of benchmarks and quality targets in value-based payment arrangements.

In developing a comprehensive MCE contracting strategy, the CIN or ACO must also evaluate its risk tolerance. Generally, payer contracts offering the most upside potential also include a requirement to accept downside financial risk. Accordingly, the parties must achieve consensus on their collective risk appetite. If downside risk is accepted, the organization should assess the actuarial soundness of the proposed model and ensure that appropriate safeguards are in place, such as risk reserves and stop-loss or reinsurance coverage.

Conclusion

Affiliations between AMCs and community hospitals present strategic opportunities to enhance health care quality, access, and cost efficiencies, but they require careful navigation of complex legal, regulatory, and cultural considerations. Establishing appropriate governance structures, ensuring compliance with antitrust laws, and designing physician compensation and integration models are critical to success. Additionally, aligning clinical care and pursuing value-based arrangements through initiatives like ACOs and CINs can strengthen the affiliates' ability to deliver high-quality, cost-effective care while managing regulatory and competitive risks. Thoughtful planning and legal oversight at each stage are essential to achieving these objectives and ensuring the sustainability of these strategic collaborations.

*The Feature Article is brought to you by the **Academic Medical Centers and Teaching Hospitals Practice Group: Michelle Brennfleck**, Buchanan Ingersoll & Rooney PC (Chair); **Rudd Kierstead**, VMG Health (Vice Chair); **Allison Cohen**, Baker Donelson Bearman Caldwell & Berkowitz PC (Vice Chair); **Margia Corner**, Sheppard Mullin Richter & Hampton LLP (Vice Chair); **Tiana Korley**, DHHS Office of the Inspector General (Vice Chair); and **Elizabeth Trende**, United Network for Organ Sharing (Vice Chair).*

1 *Copperweld Corp. v. Independence Tube Corp.*, 467 U.S. 752 (1984).

2 This assumes neither the AMC nor the community hospital continue to provide neurological services on their own.

3 *See, e.g., Healthamerica Pa., Inc. v. Susquehanna Health Sys.*, 278 F. Supp. 2d 423 (M.D. Pa. 2003).

4 *See, e.g., New York ex rel. Spitzer v. Saint Francis Hosp.*, 94 F. Supp. 2d 399 (S.D.N.Y. 2000).

5 *United States v. Halifax Med. Ctr.*, Case No. 6:09-cv-01002 (M.D. Fla. 2013).

6 This said, note that in February 2023, the Justice Department withdrew its 2011 Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program (Statement). While the Justice Department indicated that such withdrawal was because of changes in the health care landscape and potentially out-of-date guidance, parties should exercise caution when reviewing and considering the Statement. *See* https://www.justice.gov/archives/opa/pr/justice-department-withdraws-outdated-enforcement-policy-statements#:~:text=Withdrawal%20therefore%20best%20serves%20the,laws%20in%20the%20healthcare%20industry (last accessed Sept. 4, 2025).

Shaping the Future of Digital Health: Technology, Regulation, and Ethics

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The high rate at which digital health technologies are growing has greatly changed how health care is offered, measured, and administered. At the core of such change is the introduction of digital health care tools, which include high-tech software programs, into the sphere of clinical practice, monitoring, diagnostics, and treatment.[1] Nonetheless, this transition comes with regulatory oversight issues, ethical considerations, data management requirements, and the need to build stakeholder trust. As new technologies, like Software as a Medical Device (SaMD), Software in a Medical Device (SiMD), and artificial intelligence (AI)-based health technology, offer the potential to improve outcomes and efficiency, they also create ambiguity concerning patient safety, algorithm responsibility, privacy, and legal conformity.[2] The main concern is that the system of regulations and ethical principles that these technologies fall under is complicated and frequently disjointed. This article explores how existing frameworks address ethical challenges in digital health, identifies remaining gaps, and highlights key studies that inform ethical progress in the field. The aim is to synthesize the existing body of knowledge to offer a basis for understanding the situation between innovation, oversight, and ethical practice in digital health.

There is an increasing interest in the complex essence of digital health, which joins the perspectives of technical, regulatory, legal, and societal standpoints.[3] Analysis reveals that SaMD and SiMD are gaining more popularity, wearable and mobile health technologies are becoming more distant, and AI is used in diagnosis and decision-support systems.[4] Regulatory authorities like the U.S. Food and Drug Administration (FDA) and the European Medicines Agency are also changing their systems to accommodate the evolution of technology, especially in adaptive and risk-based systems.[5] Nonetheless, researchers cite ongoing skepticism in global convergence, enforcement regularity, and cross-border data control.[6] Also, new bioethical discussions incorporate topics of algorithmic bias, informed consent, and decay of human agency in AI-based care.[7] These trends exemplify how digital health has become a complex field requiring cross-sector investigations to operate successfully.

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Types of Digital Health Products in Life Sciences

The environment of digital health technologies has evolved to be diverse, with software-based technology being the core of diagnostics, treatment, and health care provision. Such tools are traditionally divided into SaMD, SiMD, and other emerging digital health applications like wearable and mobile health applications.[8] SaMD is a standalone software targeting medical use but not being included in a physical device, whereas SiMD describes software as an inseparable part of a hardware-based medical device.[9] Regulations and ethics involving such tools are also changing and becoming subject to increased issues of safety, efficacy, and international harmonization.[10] Given that new technologies, such as AI and machine learning (ML), become a vital part of such digital products, it is crucial to learn about their categorizations, regulatory consequences, and implementation in practice to enhance responsible digital health innovation.[11]

Emerging digital health tools include wearables, mobile health applications, and digital therapeutics that support patient engagement and personalized care. According to one study,[12] the market for digital tools, including fitness trackers, mobile diagnostic apps, and symptom checkers, expanded considerably amid the COVID-19 pandemic as remote patient care was in higher demand. The study highlighted that such tools enabled constant observation and prevention of diseases before manifestation, mainly in the case of chronic diseases. Other researchers examined the involvement of mobile health applications in patient empowerment and reported that digital tools could potentially address voids in traditional health care, primarily in underserved markets.[13] Their analysis revealed that usability, ease of use, and access were essential considerations to adoption, especially in populations with lower health literacy. Collectively, the literature shows that these new tools are also transforming the patient-provider relationship by providing greater flexibility and autonomy to the user beyond a clinical environment.

Digital therapeutics are gaining regulatory recognition as evidence-based software interventions that address behavioral and chronic health conditions. Digital therapeutics have been defined as a type of software that provides medical treatment using devices such as smartphones or tablets.[14] Under this definition, digital therapeutics are not ordinary wellness apps and need to prove clinical significance, which is possible during randomized controlled trials and regulated. Others have justified this opinion and added that the use of digital therapeutics in the treatment pathway of diabetes, depression, and insomnia was increasing.[15] They emphasized that such tools assisted self-management and supply clinicians with timely data to make decisions. Both sets of authors implied that digital therapeutics are a proven and organized method of augmenting or superseding traditional therapy.

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Software as a Medical Device

SaMD has become central to the innovation of health care, specifically regarding software with intended use cases for diagnosis, treatment, and patient management. This trend is driven by the availability of digital tools on smartphones, which allow for continuous and remote monitoring, early detection, and prompt clinical intervention,[16] even beyond the walls of a hospital. Rapid advancements in software necessitate a highly adaptable and agile regulatory framework to maintain the assurance of patient safety and efficacy,[17] making it a unique regulatory landscape for regulatory and legal professionals.

SaMD is defined as software purposed for one or more medical applications, achieving its medical purpose independently of any hardware medical device. This definition differentiates SaMD from SiMD, as the former focuses on software with an independent medical purpose that can function autonomously. SaMD has helped transform various aspects of health care ranging across detection/diagnosis, treatment, and mental health.

SaMD has played a significant role in disease detection and diagnosis through workflow innovation and remote monitoring. For example, software that transfers MRI or x-ray images onto general-purpose devices allows clinicians to review and analyze remotely, which decouples the diagnostic review workflow from the imaging system itself, and can also facilitate telemedicine and clinical efficiencies. Detection software takes this one step further to provide analysis of medical imaging to identify anomalies like tumors or breast cancer. Other diagnostic applications include electrocardiogram analysis software to detect heart conditions, pulmonary function testing software for respiratory assessments, and sleep diagnostic software to monitor and evaluate sleep disorders.[18] Some of these software applications can analyze the data by utilizing the sensors on a patient's smartphone.[19]

SaMD has also become commonplace for the monitoring, management, and treatment of chronic conditions with scalable, data-driven solutions that allow care to extend outside the walls of the clinical environment. These applications allow for more continuous monitoring of conditions such as diabetes, hypertension, and asthma, leveraging real-world data to support clinical decision making and patient self-management.[20]

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Consistent with all medical devices, SaMD is subjected to risk classification proportionate to the potential risk to the patient. Regulatory authorities employ risk-based schemes to dictate the level of regulatory oversight required to receive clearance or approval in each respective country. SaMD classification is commonly contingent on the significance of information provided by the software and its ability to facilitate health care decision making. In the context of the Software Development Lifecycle (SDLC) standard IEC 62304, a software safety classification is assigned as Class A, B, or C based on the potential harm to the patient.

The level of clinical safety and performance data required can vary depending on the risk and might include comprehensive clinical literature reviews and real-world data to meticulously designed and executed clinical trials.[21] Most 510(k) submissions in the United States do not require clinical data to support market clearance; however, the European Union (EU) and other international markets require some level of clinical data to support market clearance. Clinical evaluation and systems for proactive post-market surveillance are critical due to the dynamic nature of software and the need to monitor and control real-world performance. Manufacturers are expected to implement robust post-market surveillance systems to monitor the device's performance, address adverse events, and manage software updates.[22] For AI/ML-driven SaMD, the ability of algorithms to learn and change over time creates unique challenges for monitoring and managing performance modifications.

The rapid evolution of SaMD, particularly those involving AI and ML, demands dynamic regulatory frameworks that can adapt to support technological advancements. Regulators are responding by releasing new guidance documents and emphasizing reliance on real-world data (RWD) and Real-World Evidence (RWE). The FDA is actively engaged in iterating on their guidance documents through initiatives such as the Predetermined Change Control Plan, updated cybersecurity guidance, and more precise definitions of the level of clinical evidence required.[23]

Software in a Medical Device

In contrast to standalone software, SiMD refers to software that is built into and operates as part of a medical device. It cannot function independently; rather, it provides functionality or supports the intended medical purpose of the parent device. SiMD can take many forms, such as firmware installed on hardware, software that manages interoperability between devices, or programs that process information collected by sensors in the parent device.

A growing number of medical devices rely on software in some capacity. For example, pacemakers contain software that regulates heart rhythm, MRI machines utilize operating systems and displays that enable technicians to control scanning and view images, robotic surgical systems depend on software to control instruments precisely, and insulin pumps include algorithms that calculate and deliver doses. Hospital monitors, which process data and send vital signs to electronic health record systems, depend on software to function.

From a regulatory perspective, SiMD is treated as part of the parent medical device submission and requires approval or clearance based on its risk profile and intended use. A single medical device may be comprised of multiple software programs, each performing a dedicated function.

In the age of open-source and third-party software, the incorporation of off-the-shelf software into medical devices to accelerate development is becoming more common and must be adequately monitored and controlled. This type of software is referred to as Software of Unknown Provenance (SOUP), which is defined as code previously developed for which detailed records of development are unavailable. SOUP should be considered early and throughout the SDLC process, including software development planning, risk management, requirements definition, configuration management, and ongoing maintenance. This ensures that potential risks arising from the use of SOUP are adequately controlled to ensure device safety and performance.

Modular software development is an increasing trend, where software is built into separate, well-defined components. For example, a surgical navigation system may have separate modules for tracking, data flow, and image display. This enables developers to update specific modules without having to update the entire system, which can lead to efficiencies in the development process. However, modularity also raises challenges in ensuring that the changes to specific modules do not introduce new questions of safety or effectiveness for the overall platform and requires manufacturers to document detailed impact assessments and conduct thorough integration testing to ensure continued functionality and performance.

Overall, SiMD plays a critical role in how digital health technology is shaping patient care and provides the backbone for devices that utilize software to diagnose, treat, and mitigate disease or injury. By applying recognized international standards—such as IEC 62304 for software development and ISO 14971 for risk management—manufacturers can balance the need for rapid innovation with the responsibility to manage risk, ensuring safe and effective devices are placed on the market.

Feature	SaMD	SiMD
Definition	Software for medical purposes, *without being part of* a hardware medical device. Operates independently.	Software that is an *integral component of* a physical medical device. Cannot function independently.
Operational Independence	High: Runs on general-purpose platforms (smartphones, PCs, cloud). Can be updated rapidly.	Low: Reliant on associated medical hardware. Performance tied to specific hardware.
Primary Function	Actively diagnoses, treats, monitors, or informs clinical decisions.	Controls the performance or provides specific functions of the hardware device it is embedded in.
Regulatory Review (General)	Often faces distinct and rigorous regulations focused on its software component.	Regulatory review typically part of the complete hardware medical device system.

Regulatory Pathways for Digital Health

When evaluating if a digital health product is subject to regulatory requirements, manufacturers must first assess whether the software meets the definition of a medical device. In the United States, Section 201(h) of the Federal Food, Drug and Cosmetic Act provides this definition, while the International Medical Device Regulators Forum (IMDRF) offers a broader, internationally recognized version. Under IMDRF, "medical devices" include instruments, machines, implants, reagents, software, and similar articles intended for one or more specific medical purposes (such as diagnosing, preventing, monitoring, or treating disease) and do not achieve their primary intended action by pharmacological, immunological, or metabolic means.

Therefore, not all digital health products are subject to medical device requirements. Software functions intended for general office operations in a health care environment or general wellness (such as an app designed for tracking metrics like sleep habits, diet, or exercise to promote general fitness, health, or wellness) are excluded from this definition.[24]

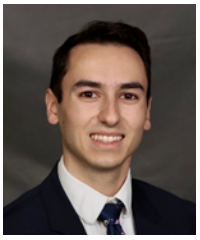
If the product does meet the definition of a medical device, manufacturers should determine the appropriate risk-based classification. The FDA maintains a Product Classification Database that can be used to help identify the appropriate regulation. The FDA classifies medical devices, including SaMD/SiMD, into three different risk classes: Class I (low risk, minimal failure impact), Class II (moderate risk, majority of SaMD, moderate failure impact), and Class III (high risk, lifesaving/sustaining, severe failure consequences).[25] Each classification has specific requirements and an associated pathway to market. For SaMD/SiMD, manufacturers should also classify their device per the international standard IEC 62304, where software is classified based on the potential risk if it fails:

- Class A: failure is unlikely to cause injury,
- Class B: failure could cause non-serious injury, and
- Class C: failure could cause serious injury or death.

When a software system is composed of multiple software modules (or units), each inherits the highest classification of the original software system unless the modules are clearly segregated and justified as lower risk. In practice, manufacturers typically must follow the strictest development and documentation requirements for the entire system to ensure safety and reliability.

Digital health technology and medical device software are constantly evolving, so manufacturers need to engage with regulatory bodies early in the development process to avoid delays and mitigate unforeseen deficiencies during the review process. The FDA provides various pathways and programs to collaborate with industry and has created a "Regulatory Accelerator" webpage under its Digital Health Center of Excellence. The aim is to provide manufacturers with a comprehensive resource index for digital health products throughout their lifecycle to accelerate innovative devices to market. Examples of early engagement are listed below:

- Early Orientation Meetings: Allows the sponsor to provide a device demonstration early in a submission review to assist the FDA's understanding of novel software functions or devices that heavily rely on SiMD to achieve their intended use.



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- Q-Submission Program: Provides the opportunity to request feedback and meetings related to device submissions (such as Informational Meetings and Pre-Submissions).
- Breakthrough Devices Program: Provides early collaboration on novel technologies and prioritized review of marketing submissions. Devices eligible for Breakthrough status provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions.
- Safer Technologies Program (SteP): Provides early collaboration for devices that aim to improve the safety of currently available treatments/diagnostics for conditions less serious than those eligible for the Breakthrough Devices Program.
- Total Product Life Cycle (TPLC) Advisory Program (TAP) Pilot: Provides sponsors of devices with Breakthrough Designation to have early collaboration with the FDA and other key stakeholders such as physician groups, payers, and patients.

Other nontraditional methods of engagement with regulators can include participation in standards development committees and working groups for novel technologies. Groups like the Medical Device Innovation Consortium[26] bridge the gap between industry and the FDA to collaborate on the development of white papers that help inform FDA policy and future guidance documents.

The rapid pace of innovation in digital health, combined with differing international regulatory requirements, highlights the importance for global regulatory harmonization. Without it, manufacturers may face longer development timelines, duplicative work, or inconsistent expectations across markets, which could all delay patient access to safe and effective technologies. The IMDRF plays a central role in addressing this challenge. Through working groups that include regulators from the United States, EU, Japan, Canada, and Australia, IMDRF develops consensus-backed technical documents aimed at promoting consistency and transparency in regulatory review. For example, the organization has released guidance related to characterization considerations for medical device software and software-specific risk, principles of cybersecurity, and clinical evaluation. In addition, IMDRF has created a working group for AI/ML-enabled medical devices, which will continue to lay the groundwork for predictable development and requirements for this emerging technology. Continued collaboration through IMDRF and related initiatives will be key to achieving streamlined, predictable, and comprehensive pathways to market globally.

Cybersecurity considerations are critical during the initial design and post-market monitoring of SaMD/SiMD to ensure continued patient safety.[27] The FDA has urged device manufacturers to implement a Secure Product Development Framework (SPDF) to adequately manage and control cybersecurity risks, which includes following the Quality System Regulation[28] or a similar framework (such as JSP2 or IEC 81001-5-1) to develop secure and reliable connected devices. This includes separate (but interconnected) systems for safety and security risk management as a part of the total product lifecycle (described by standards such as AAMI TIR57 and ANSI/AAMI SW96). A system for security risk management aims to expose and control vulnerabilities present in connected medical devices. Regulators have begun to implement robust measures to ensure data integrity and reliability are foundationally considered in the design and development of any SaMD.[29] Additionally, devices must comply with data protection laws such as the General Data Protection Regulation (GDPR) and the United Kingdom Data Protection Act, which require consent, data subject rights, and privacy by design.[30]

Privacy Aspects of Digital Health

In addition to these key regulatory considerations, patient privacy is foundational to the development of SaMD and SiMD. However, embedding privacy controls can be a complex undertaking when considering the myriad privacy and data protection laws globally. These laws may impact not only the design of the technology but also the future uses and disclosures of any personal data collected through these digital health tools. In the United States, for example, there is no single privacy law. Rather, there is a patchwork of federal and state statutes and regulations that address both health-specific privacy as well as general consumer protection.[31] Notable U.S. federal laws in the digital health space are the Health Insurance Portability and Accountability Act of 1996 (HIPAA),[32] the Federal Trade Commission Act, and the Health Breach Notification Rule.[33] In the EU, the GDPR is the primary framework covering individual privacy and encompasses additional specific requirements for special categories of personal data, including health data. However, Member States may nevertheless apply their own interpretations and enact local rules in certain circumstances.[34] Despite the variation in privacy laws, however, there are common themes to consider when planning for deployment of digital health technologies:[35]

- Provide notice to individuals about what data is collected, why it is being collected, and how it will be used and disclosed

- Obtain freely given consent or authorization, when required
- Ensure that notices and consents are accurate and do not omit important information
- Honor the provisions of those notices and consents
- Understand any relevant exceptions to notice and consent and whether those exceptions limit the use and disclosure of the collected data
- Minimize personal data collection, use, and disclosure to that which is minimally necessary to conduct a legitimate purpose (as described in the notice, consent, or legal exception)
- Provide individuals with applicable rights to access, correct, and, in certain cases, delete their information
- Conduct risk assessments and implement appropriate privacy and security practices to address those risks
- Identify requirements for cross-border transfers
- De-identify, pseudonymize, or anonymize data, as required, prior to future or secondary uses and ensure that such uses of the data do not increase the risk of future re-identification
- Contract with third-party vendors to protect personal data and monitor their compliance

Deployment of SaMD and SiMD may involve multiple parties, such as sponsors, manufacturers, distributors, and intermediary technology providers. Recognizing which individuals and organizations in the digital health ecosystem will be responsible for implementing privacy requirements is also critical. For example, digital health manufacturers often need to understand whether their activities may qualify them as a Covered Entity or Business Associate under HIPAA, along with the legal responsibilities that attach to each role. But even if an organization is not regulated by HIPAA, it may interact with parties that are. U.S. federal law prohibits even those individuals and organizations that are not covered by HIPAA from knowingly receiving individually identifiable health information in a manner that is not authorized by HIPAA.[36] Digital health manufacturers could also be subject to concurrent requirements under the FTC Act's prohibition on unfair and deceptive trade practices,[37] the Health Breach Notification Rule,[38] and state privacy and consumer protection laws. The costs of non-compliance can negatively impact organizations and individuals who provide these health technologies. Violations may result in both civil and criminal penalties[39] as well as consent decrees lasting up to 20 years.[40]

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in which the SaMD/SiMD will be commercialized. Those plans could focus first on the common themes—namely requirements for notice, consent, data minimization, data subject rights, impact of exceptions, data de-identification/anonymization, risk assessments, data governance and security, cross-border transfers, and contracting and monitoring of third-party partners. These plans will also involve harmonizing the legal requirements both within and across countries, as well as identifying whether collaborators and partners in the digital health tool ecosystem may, and will agree, to take accountability for satisfying those obligations.

Bioethics and Future AI Impacts

AI's increased application in health care has brought many complex ethical problems that transcend usual biomedical concepts. Even though AI can effectively improve diagnostics, treatment individualization, and enhance systems efficiencies, its execution is also linked to the problem of bias, transparency, consent, and accountability.[41] These ethical aspects are core in developing fair and reliable digital health systems. Three bioethical areas of significance are discussed below.

The initial sub-theme concerns algorithmic bias and its legal implications for equity. AI models are developed using large datasets, and if these datasets are not representative of the intended patient population, the resulting algorithms have the potential of generating biased outputs. This can result in significant risk and legal ramifications. These biases might lead to a disparate impact on protected patient groups, with potential to expose the manufacturer and health care provider to claims of discrimination. The challenge is to ensure that a device's development and validation protocols are sufficient to detect and mitigate these biases, thus upholding the principles of justice and non-maleficence and hopefully minimizing legal exposure.

The second sub-theme is the topic of informed consent and patient agency in an AI-driven environment. The legal standard for informed consent requires a clear explanation of risks, benefits, and alternatives. This standard is complicated when the decisions made by AI influence clinical practice, particularly with "black box" machine learning models, where the exact rationale for a clinical recommendation may not be transparent to the clinician. This necessitates the need to adjust

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disclosure routines to meet unpredictable or obscure mechanisms. Legal counsel will have to advise on adaptive ways for disclosure and the consent process to maintain patient autonomy and agency. New forms of documentation will be necessary and communications to clarify the role of AI in the decision-making process, the limitations of the technology, and the inherent uncertainties are critical to ensuring the "informed" aspect of consent remains legally defensible.

The third, and likely the most critical sub-theme, is accountability and safety. The introduction of autonomous or semi-autonomous AI technologies in clinical practice begins to blur the traditional lines of liability. Determining who is legally responsible in the event of an adverse event or a clinical error becomes extremely complex. Does accountability fall on the AI developer, the health care institution, the clinical, or even the regulatory body? This will require proactive legal strategies to define and allocate responsibilities and liabilities through contracts, agreements, and the quality management system. This framework of accountability is crucial for managing risk, ensuring patient safety, and establishing a legal foundation for this innovative technology.

These themes describe the ethical foundations needed to establish a framework of successful AI development and AI implementation in health care.

*The Feature Article is brought to you by the **Life Sciences Practice Group: Mara Smith-Kouba**, Bristol-Myers Squibb (Chair); **Kristen Chang**, McGuireWoods LLP (Vice Chair); **Mary Kohler**, Kohler Health Law PC (Vice Chair); **James Wabby**, AbbVie Inc (Vice Chair); **Luis Lanz**, Quarles & Brady LLP (Vice Chair); and **Danielle Sloane**, Bass Berry & Sims PLC (Vice Chair).*

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31 *See, e.g.*, The Federal Trade Commission Act, 15 U.S.C. § 45 (2023) (prohibiting unfair and deceptive practices); California Consumer Privacy Act of 2018, Cal. Civ. Code §§ 1798.100–1798.199.100 (2025).

32 Pub. L. No. 104-191, 110 Stat. 1936 1996) and implementing regulations 45 C.F.R. pts. 160, 162, 164 (2024).

33 45 C.F.R. § 164.410 (2023) (regulating entities that offer personal health records, which are electronic records with "identifiable health information on an individual that has the technical capacity to draw information from multiple sources and that is managed, shared, and controlled by or primarily for the individual." 16 C.F.R. §§ 318.1–318.8 (2024)).

34 *See, e.g.*, Regulation (EU) 2016/679, arts. 9, 89 (permitting Member States to "maintain or introduce further conditions, including limitations, with regard to the processing of genetic data, biometric data or data concerning health." And permitting Member States to provide derogations of certain rights if it would "render impossible or seriously impair the achievement of the specific purposes," including research), 2016 O.J. (L 119) 1.

35 For illustrative regulatory-body-issued privacy principles, *see, e.g*, Federal Trade Commission, *Federal Trade Commission Report: Protecting Consumer Privacy in an Era of Rapid Change: Recommendations for Business and Policymakers* (Mar. 2012), https://www.ftc.gov/sites/default/files/documents/reports/federal-trade-commission-report-protecting-consumer-privacy-era-rapid-change-recommendations/120326privacyreport.pdf and European Data Protection Board, *Guidelines 4/2019 on Article 25 Data Protection by Design and by Default* (adopted Oct. 13, 2020), https://edpb.europa.eu/our-work-tools/our-documents/guidelines_en (last visited Aug. 8, 2025).

36 *See, e.g.*, 42 U.S.C. § 1320d-6 (2024) (indicating that a person (including any individual or an employee) who knowingly discloses or obtains individually identifiable health information maintained by a Covered Entity without authorization is subject to monetary and criminal penalties). *See also* Department of Justice (DOJ), News Release, *Drug Maker Aegerion Agrees to Plead Guilty; Will Pay More Than $35 Million to Resolve Criminal Charges and Civil False Claims Allegations* (Sept. 22, 2017), https://www.justice.gov/archives/opa/pr/drug-maker-aegerion-agrees-plead-guilty-will-pay-more-35-million-resolve-criminal-charges-and?utm_source=chatgpt.com; DOJ, News Release, *Warner Chilcott Sentenced to Pay $125 Million for Health Care Fraud Scheme* (Apr. 15, 2016), https://www.justice.gov/usao-ma/pr/warner-chilcott-sentenced-pay-125-million-health-care-fraud-scheme?utm_source=chatgpt.com (relating to examples of DOJ enforcement for wrongful disclosure of PHI wherein Covered Entities disclosed PHI to certain manufacturers for their commercial gain and without patient authorization).

37 *See, e.g., In the Matter of CVS Caremark Corp.*, FTC Docket No. C-425, Complaint (filed by Fed. Trade Comm'n, June 18, 2009) (illustrating that a HIPAA Covered Entity may be concurrently subject to liability for unfair and deceptive trade practices for handling patient information in a manner inconsistent with its privacy notice).

38 *See, e.g., United States v. GoodRx Holdings, Inc.*, No. 23-cv-460 (N.D. Cal. 2023) (alleging that GoodRx, a consumer digital platform providing health-related products and discounts, violated the Health Breach Notification Rule by sharing identifiable user data, including information about medications, health conditions, and advertising identifiers, with third-party advertising companies for targeting advertising).

39 42 U.S.C. § 1320d-6 (2024).

40 *See, e.g., FTC, Policy Statement Regarding Duration of Competition and Consumer Protection Orders*, 60 Fed. Reg. 42569 (Aug. 16, 1995).

41 Victoria Hood-Wells, *Telehealth Acceptance and Medical Mistrust Among the Elderly of Rural Appalachia: A Correlational Study Using the Medical Mistrust Index and Technology Acceptance Model* (Doctoral dissertation, East Tennessee State University 2024), https://dc.etsu.edu/cgi/viewcontent.cgi?params=/context/etd/article/5918/&path_info=Hood_WellsV042524f.pdf.

Feature

Understanding the Physician Associate Licensure Compact

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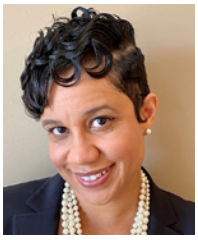

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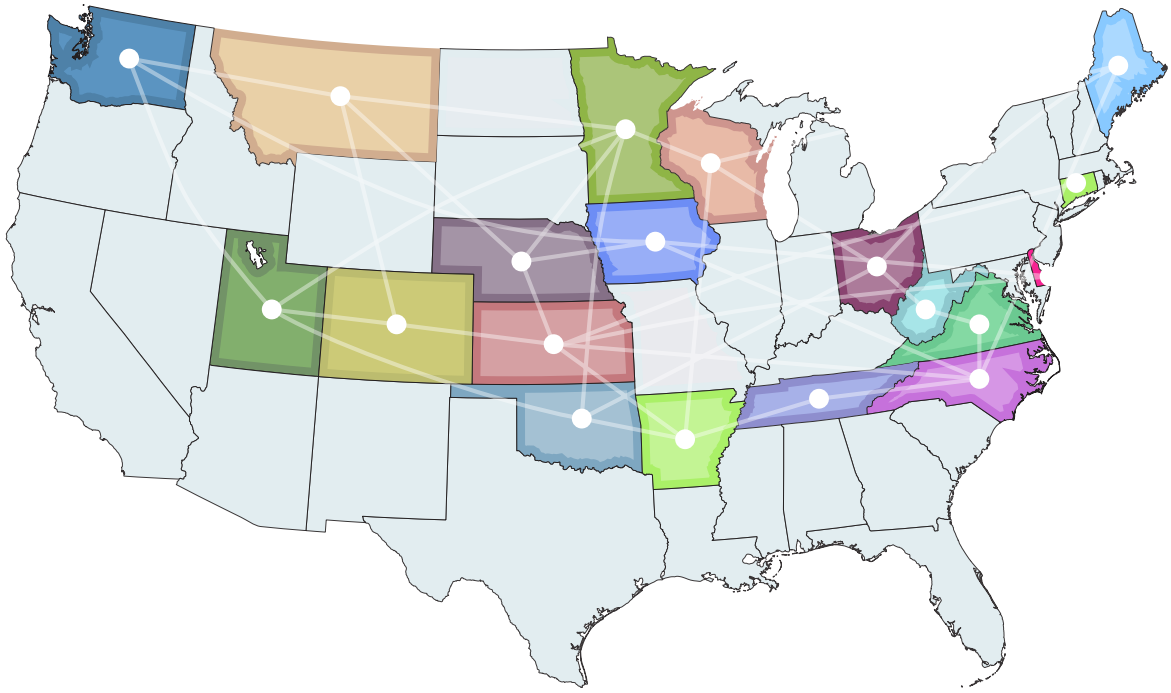

Like so much of what drives state interests, a driving force of their interest in health-related license portability is rooted in a desire to maintain autonomy from the federal government. While it may be an oversimplification, states have long feared federal overreach in the form of federally issued licenses for certain professions to address delays in licensure and provider shortages.[1] Maintaining this autonomy over health care practitioners allows states to dictate scope of practice, discipline, and, not unimportantly, to set and collect revenue that is generated by the issuance of licenses.

Compacts are created when states agree upon a uniform set of standards to allow licensed professionals to enter the compact and then the states enact near-identical legislation to commit to join and participate in the compact.

Compacts Become the Vehicle of Choice for License Portability

In the last 20 to 30 years, the preferred method for states and professions to pursue license portability has been through state licensure compacts. Interstate compacts are legally binding agreements between states that address common issues, such as licensure portability. Compacts are created when states agree upon a uniform set of standards to allow licensed professionals to enter the compact and then the states enact near-identical legislation to commit to join and participate in the compact.

What started as a slow trickle in the 1990s with the initial Nurse Licensure Compact (NLC), interstate licensure compacts have exploded in the last five to ten years. Most professions that have a licensure compact or are in the process of pursuing one are health care professions. Currently, there are 17 professional licensure compacts that are either activated or are working to achieve the minimum number of states necessary to activate.[2] Many of these compacts have seen wide adoption; for example, the NLC has 43 participating jurisdictions[3] and the Interstate Medical Licensure Compact (IMLC) has more than 40 jurisdictions with at least partial adoption or participation (more than 35 are full participants).[4]

Despite this expansion, not all states have joined these compacts for a number of reasons. State legislators and regulators in particular frequently cite concerns about patient safety, threats to state sovereignty, scope of practice changes for licensees, costs, and potential lost revenue. States also may be skeptical about the actual potential of compacts to ease health care workforce shortage.

Compacts Generally: Commonly Recognized Benefits and Support

Compacts have many goals, both for the professions that pursue them, and the states that adopt them. For health care professionals, licensure compacts enhance providers' ability to practice across state lines; standardize and streamline the licensure process; and offer a swifter path to interstate telemedicine practice. For states, compacts may help increase access to providers, particularly in rural and underserved areas, and promote competition within their health care markets, potentially improving the quality of care. Compacts achieve these benefits by establishing uniform standards to multi-state practice while simultaneously upholding a state's practice act and initial licensure process. Additionally, licensure compacts, like the physician associate/physician assistant (PA) compact, allow each state to set a fee for a compact privilege. Each member state has a seat at the table to develop rules, bylaws, and other administrative functions of the compact. Rules written by the compact commission only apply to the specific compact procedures implementing the interstate extension of member state authority across state lines without taking over individual state regulatory authority. Licensure compacts also create an interstate data system that is specifically designed to improve information sharing among compact member states, including investigative and disciplinary information, which can advance patient safety.

Physician Associate Licensure Compact—The Long and Winding Road

The history of the PA licensure compact dates to early discussions regarding the physician licensure compact. In 2013, the Federation of State Medical Boards (FSMB) began working on what would eventually become the IMLC, the licensure compact for physicians. From the beginning, the PA profession strongly advocated for PA inclusion within the physician compact. However, it was thought that setting up one compact for two distinct professions would not be possible for a variety of reasons, including, but certainly not limited to, licensure requirements and the fact that while there is some overlap, not all states license PAs and physicians through the same regulatory entity.

Not discouraged, the American Academy of Physician Associates (AAPA) continued to follow the development and eventual launch of the IMLC and stayed engaged with FSMB on other projects related to license portability behind the scenes. In early 2019, with the IMLC up and running, FSMB approached AAPA and the sole certifying organization for the profession, the National Commission on Certification of Physician Assistants (NCCPA), to write letters of support for a Health Resources and Services Administration (HRSA) grant that FSMB was applying for that would include supporting license portability for PAs. The Licensure Portability Grant Program is only eligible to state professional licensing boards, including but not limited to, organizations that are in consortia with or associations of state licensing boards. In August of 2019, FSMB was awarded the grant.[5] Work began in earnest and AAPA, FSMB, and NCCPA, together with the guidance and expertise of The Council of State Governments' National Center for Interstate Compacts (CSG), developed a compact that was activated in April 2024 when Virginia became the seventh state to enact the model compact legislation.[6] To date, 19 states have joined the PA Licensure Compact.[7]

Current Status of Efforts

The first step that is required for states that wish to join the compact (and become "compact member states") is the enactment of the model compact legislation. AAPA has been working closely with state PA chapters to advocate for the PA Compact. As of this writing, 19 states (Arkansas, Colorado, Connecticut, Delaware, Iowa, Kansas, Maine, Minnesota, Montana, Nebraska, North Carolina, Ohio, Oklahoma, Tennessee, Utah, Washington, West Virginia, Wisconsin, and Virginia) have enacted compact legislation thereby joining the PA Compact, and legislation is being considered in four states, with more expected for introduction when the 2026 legislative session begins.

The PA licensure compact required seven states to enact the model legislation for it to become activated. Upon activation, the PA Compact Commission, a joint government agency and national administrative body, was formed to begin to operationalize the compact. The PA Compact Commission is an instrumentality of the compact states acting jointly and not an instrumentality of any one state. The PA Commission creates and administers the compact's rules, policies, and procedures. Each state that joins the compact must have one delegate, who is either a current PA, physician, or public member of a licensing board or PA council/committee or an administrator of a licensing board.

The PA Compact Commission met for the first time September 24-25, 2024, during which it elected members of the executive committee and adopted bylaws and rulemaking protocols. Its executive, finance, and rules committees have been meeting monthly to work on the details of implementation. It typically takes 18-24 months from the initial meeting of the commission for a compact to be operational upon activation.

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The current expectation is that PAs may receive privileges to practice in early 2027. Throughout the next year, the PA Commission will continue to meet to hire an Executive Director and Secretariat to run the Commission's operations and create a shared database for verification of licensing and disciplinary information.

Features of the PA Licensure Compact

The operationalization of occupational licensure compacts is usually achieved by one of two approaches: expedited licensure or mutual recognition. The PA licensure compact is a mutual recognition model. Compact member states agree to mutually recognize a valid, unencumbered license from other compact member states via a compact privilege. A compact privilege is equivalent to a license and is the authorization for a PA to practice in another compact member state. Licensed PAs utilizing the compact can obtain a privilege to practice in each compact member state where they want to practice, adhering to each state's practice laws while maintaining their primary residence in their home state.

The mutual recognition model of licensure compacts is utilized by other professions, such as physical therapy, occupational therapy, audiology and speech language pathology, social work, and teaching. This model differs from the IMLC for physicians, which utilizes an expedited licensure model. The primary difference between these types of licensure compact models is in how they handle license recognition. With the mutual recognition model, the practitioner's qualifying license is accepted across all compact states, with an applicant applying and receiving their privilege to practice through the IMLC Commission. The IMLC expedited licensure model allows eligible physicians to complete a single application within the Compact and receive separate licenses from each state in which they intend to practice. This expedited licensure model requires individuals to apply for a license in each state in which they wish to practice; however, the application process is streamlined through the centralized data and standardized requirements.

The PA Compact also differs slightly from the NLC. The NLC also uses a mutual recognition model; however, nurses receive a multistate license that is issued by their primary state of residence, whereas with the PA Compact, the license is issued by the PA Compact Commission. During initial stakeholder meetings, it was quickly decided that a mutual recognition model was preferable to the expedited licensure model. Not only is the mutual recognition model less cumbersome for the licensee, but states were more familiar with it because of the various other professions that were working on similar compacts at the time.

The PA Compact is optional for PAs and can be used in addition to the "traditional" licensure route. Here are a few examples of how the PA Compact can work for a PA. In these examples, states A and B are compact members; however, state C has not joined the compact:

- A PA is licensed in state A but is not interested in practicing in other states through the compact, even though they hold a license in another compact member state. This PA can continue to seek a license in the states in which they wish to practice through the traditional method.
- A PA is licensed in state A and wishes to provide telehealth services in state B. The PA can use their qualifying license of state A to apply for a privilege to practice in state B. The PA must abide by all laws and regulations of states A and B when providing services in those states.
- A PA lives in state C, is licensed in state A, and now also wishes to provide services in state B. The PA may use their qualifying license in state A to apply for a privilege to practice in state B, and may maintain their license through the traditional licensure process in state C.
- A PA is licensed in state C and wishes to practice in state B. The PA cannot access the compact for licensure in state B because state C is not a member of the compact. The state in which they are licensed, the qualifying state, must be a member. They may, however, receive a license in state B through the traditional method, and utilize that license in a qualifying state to access the compact and apply for privileges to practice in other compact member states, while still holding their license in state C.

The PA Compact has requirements for both states to join and for individuals who wish to participate. As a condition of joining the PA compact, states must meet certain initial licensure and public protection requirements, as well as requirements to participate after they join. States must license PAs, utilize passage of a recognized national exam such as the NCCPA's Physician Assistant National Certifying Examination (PANCE), and grant the compact privilege to a holder of a qualifying license in another state participating in the compact. States must also fully implement a criminal background check, have a mechanism in place for receiving and investigating complaints against licensees and license applicants, and notify the PA Compact Commission of any adverse actions against or significant investigation information of a licensee or license applicant. Lastly, states must participate in the PA Compact Commission, the intergovernmental agency responsible for the administration of the compact and comply with its rules.

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An individual wishing to obtain a compact privilege must first meet license, certification, and education qualifications such as holding an unrestricted license issued by a participating compact state to provide medical services as a PA, graduation from an accredited PA program, and current NCCPA certification. Not every state requires current and maintenance of NCCPA certification; this is a higher bar of entry for the licensure compact. PAs must also have no felony or misdemeanor convictions; have never had a controlled substance license or permit suspended or revoked; have no limitation or restriction on any state license or compact privilege; and have no permit or registration suspended or revoked by a state or by the U.S. Drug Enforcement Administration. Lastly, PAs must notify the PA Compact Commission of their intent to seek a compact privilege in a remote state (a state participating in the PA Compact, where a licensee is seeking to exercise the compact privilege), meet any jurisprudence requirements of the remote state, and report to the Commission any adverse action taken by a non-member state within 30 days after the action is taken.

Benefits of the PA Compact for PAs, Regulators, and Health Systems

There are many benefits for PAs who wish to utilize the licensure compact. First, it reduces the time and effort needed to receive authorization for licensure. In addition, privileges to practice renew at the same time as a PA's qualifying state license, which makes it easy to keep track of renewal periods. Lastly, a PA is only required to meet continuing medical education (CME) requirements for the state in which they have their qualifying license, not in every state in which they hold a privilege. The PA Compact will charge a nominal compact fee, determined by the PA Compact Commission, and states can set fees for the privilege to practice for their state. While utilizing the licensure compact will likely not be more than receiving a license from each state, there may not be significant cost savings; however, a PA may save some money as they will not have to complete CME in every state.

The compact also has benefits for regulators since it facilitates the exchange of licensure and disciplinary information, which improves cooperation across states in regulating the profession and ensuring public safety. States still retain control of scope of practice and the initial licensure process, while also being able to set a fee for privileges to practice and renewals of those privileges.

The PA Compact—by extension—may also be advantageous for hospitals and health systems, including by simplifying access to a wider pool of qualified PAs for rapid deployment in emergencies; reducing administrative burdens and improving efficiency; enhancing patient continuity, particularly in areas where patients are likely to seek care across state lines; and facilitating telehealth access and delivery.

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How the PA Compact Addresses Concerns and Misconceptions About Interstate Licensure

Despite the benefits considered above, apprehensions around and misconceptions about interstate occupational licensure compacts are commonplace. Much of the apprehension results from misconceptions, and similar to other newer policy ideas, many states prefer to take a wait and see approach. While the PA Compact does allow states to retain their initial licensure requirements and requires those seeking a compact privilege in their state to meet specific requirements (e.g., jurisprudence exam), states are still hesitant to give up some control over their licensing process. States also worry about potential revenue loss from practitioners who will be utilizing the compact as opposed to obtaining a separate license to practice in their states despite having the ability to set a fee for a compact privilege to make up for the anticipated loss. There is also concern that implementing the necessary technology and administrative changes to join the compact will be costly to states—especially to connect to the compact database. Some states also express apprehension that joining a compact could lead to an influx of out-of-state practitioners, potentially impacting the job market of those based in the state.

While licensure compacts can exist alongside other approaches (e.g. reciprocity and endorsement), states that have already taken steps to improve licensure portability may prefer to see how these changes improve licensure portability before introducing the licensure compact, or they may see these as preferable, given the other concerns outlined above.

Patient Safety

It is well understood that in the United States, the licensing, regulation, and oversight of professions are accomplished by the states.[8] Each jurisdiction adopts

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rules by which individuals within a profession must comply, including the qualifications, responsibilities, and ethical obligations licensees must meet. Today, all states, the District of Columbia, and all U.S. territories have passed laws to authorize and regulate the practice of medicine by PAs.

The board or agency responsible for regulating the PA profession varies from state to state. PAs practice medicine, so when the profession started, PA regulation was almost always delegated only to a medical/multidisciplinary "healing arts" board. Such sole regulatory authority of PAs continues present-day, except in nine states that have established separate state PA boards.[9] No matter what the designated board for PA regulation may be, ensuring patient safety is a paramount responsibility it shares with other health care regulators throughout the country. It is therefore not surprising for officials to have questions about how interstate licensure compacts governing health care providers aim to maintain or improve public health and safety; a failure to have satisfactory safeguards in place can thwart a compact's enactment. For example, the power to prevent a reduction in competency standards and review a licensee's criminal history were cited as the rationale by some Oregon officials for their inability to support the NLC and the United States Emergency Medical Services Compacts.[10]

To counter these competency and safety concerns, the PA Compact imposes requirements on individual licensees and the state. As noted above, individuals must possess and maintain current NCCPA certification—a higher standard of entry. Again, for states, participation in the PA Compact is contingent on full implementation of a criminal background check requirement and the establishment, maintenance, and utilization of a coordinated data and reporting system (Data System) containing licensure, adverse action, and investigative information on all licensed PAs in participating states. If any participating state takes adverse action, it must notify the administrator of the Data System. The administrator is responsible for subsequently notifying other participating states of adverse actions taken by a participating state. As a result, the PA Compact creates a licensure Data System designed to improve information sharing between compact member states, including disciplinary information.

State Sovereignty

A misconception about interstate compacts is that they have the potential to invade state sovereignty, thereby invalidating state laws. On the contrary, one of the benefits of interstate compacts is their ability to permit states to preserve sovereignty in matters customarily reserved for the states with regional or national implications. The PA Compact has no impact on a state's laws and regulations except as defined within the compact—there is no invalidation, preemption, or appropriation of state regulatory authority. In short, states cannot specify the laws and regulations a PA must follow in a remote state. Thus, the compact works to respect the PA laws and regulations of each individual state. States maintain their regulation of the PA profession, including, but not limited to matters pertaining to:

- Collaboration/supervision requirements
- Prescriptive authority
- Ratios
- Title change

PA Compact privilege holders must always abide by the laws and regulations of the state in which they are practicing at the time they deliver patient care. This extends to providing telehealth services. PAs using the compact privilege may render telehealth services in accordance with the law and regulations of the state in which the patient is located.

As it pertains to disciplinary action and investigations, pursuant to the PA Compact, states can:

- Investigate compact privilege holders for action taken in their state; states do not lose the right to enforce compliance with state laws and regulations and can take action, as long as the action is taken in their state
- Act on a license or privilege issued by their state
- Participate in joint investigations with other compact member states if they are also included

States cannot:

- Act on a license or privilege issued by another member state
- Deny a privilege or investigate a PA for lawful action/lawful facet of scope of practice in another state

Scope of Practice

"Scope of practice" refers to the services a health care professional may provide and includes two subcategories: professional scope of practice and legal scope of practice.

The former encompasses services that members are educated, trained, and competent to provide. The latter refers to state laws and regulations that define the services and procedures an occupation may or may not provide by law. States are not uniform in their laws regarding PA practice. Nevertheless, all 50 states, the District of Columbia, and all U.S. territories authorize PAs to be licensed to practice medicine as members of the health care team with physicians, prescribe non-controlled and/or controlled medications,[11] and engage in a wide range of medical diagnostic and treatment services. Each PA's scope of practice is determined by the PA's education and experience, state law, employer and facility policies, and the needs of the patients.

Often coupled with matters pertaining to state sovereignty, another point of contention concerns the assumption that all compacts are an attempt to expand a profession's scope of practice. For example, some groups who oppose the PA Compact view it as a system through which PAs will be permitted to attain independent practice or prescriptive authority that does not currently exist, akin to efforts to enact a multistate licensing compact for advanced practice registered nurses.[12] However, pursuant to the PA Compact, PAs must follow the laws and regulations of the state in which the care will be provided, including those provisions governing the prescribing of medications. The PA Compact cannot be used as a mechanism to change PA scope of practice, grant independent practice to PAs, or confer/remove limitations on prescriptive authority.

Costs/Potential Lost Revenue

Compacts require funding for development, administration, and maintenance. States must be thoughtful in how they will achieve these goals. While some compacts, like the PA Compact, have initially benefited from seed funding through grants from HRSA, those monies are not provided in perpetuity. Developmental costs can vary depending on a myriad of factors. For example, since each compact is unique in how it addresses different professions and issues associated with them, some may warrant more complex and expensive developmental considerations than others. Costs may also differ due to the extent of stakeholder involvement during the compact's initial developmental phase when they examine issues, current policy, best practices, alternate structures, and establish recommendations for a compact's content prior to and post-drafting for incorporation into the final product. Lastly, the level of onsite education and technical assistance each state desires to provide fluctuates. While costs for developing the compact are not usually passed on to states, there is concern from states around the cost to connect to the Data System to share information, implementing criminal background checks, and any expenses associated with sending a delegate to in-person compact commission meetings. With regards to the Data System, the compact commission will likely look at the systems states already have in place to ensure it is not overly cumbersome or costly to the state. States also will have a bit of time to ensure they are doing criminal background checks for those wishing to join the compact, and those costs are often passed on to applicants. Lastly, most compact commission meetings will be virtual, and

in-person engagements may be supplemented by the HRSA grant and the compact budget.

States also are concerned that by joining a compact, they will lose revenue from both licensing and application fees. To address this concern, while there is no fee for states to join the PA Compact, the Compact Commission has the authority to generate revenues through the establishment of fees, including through a compact privilege fee, paid by applicants. Participating states may also assess fees to PAs applying for a compact privilege (including renewals).

Looking Ahead: The Future Is Bright

The future is bright for licensure compacts, including the PA Compact. As stated, there are 17 professions with available occupational licensure compacts, with two more in development. Over 350 pieces of legislation to enact licensure compacts have been passed by the states since 2016.[13] The PA Compact Commission continues to meet, with the database expected to be up and running by the end of the year and the hope that PAs will be able to apply for privileges to practice through the compact by early 2027.

*The Feature Article is brought to you by the **Medical Staff, Credentialing, and Peer Review Practice Group: Tim Cahill**, Dinsmore & Shohl LLP (Chair); **Laura Alfredo**, Greater New York Hospital Association (Vice Chair); **Robert Blaisdell**, Husch Blackwell LLP (Vice Chair); **William George**, CommonSpirit Health (Vice Chair); **Richard Barton**, Procopio Cory Hargreaves & Savitch LLP (Vice Chair); and **Amy Shulman**, Outten & Golden LLP (Vice Chair).*

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8 *See* U.S. Const. amend. X.

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What the Health Care and Life Sciences Industry Should Know About the DOJ's False Claims Act Working Group

Jason P. Bologna and Mark A. Kasten, Buchanan Ingersoll & Rooney

With any new presidential administration, businesses across industries must assess how shifts in regulation and enforcement priorities impact the way their organization operates. While fiscal year 2024 saw settlements and judgments under the False Claims Act (FCA) exceed $2.9 billion—the highest number of qui tam actions filed in history—the second Trump administration is looking to double down on fighting fraud through the FCA.

In July 2025, the Department of Justice (DOJ), alongside the U.S. Department of Health and Human Services (HHS), announced[1] the formation of a working group to leverage the FCA to better combat health care fraud. The DOJ listed six priority areas targeted for FCA enforcement, all intensely focusing on the health care and life sciences sectors, including:

- Medicare Advantage
- Drug, device or biologics pricing, including arrangements for discounts, rebates, service fees and formulary placement and price reporting
- Barriers to patient access to care, including violations of network adequacy requirements
- Kickbacks related to drugs, medical devices, durable medical equipment and other products paid for by federal healthcare programs
- Materially defective medical devices that impact patient safety
- Manipulation of Electronic Health Records systems to drive inappropriate utilization of Medicare covered products and services.

During Buchanan's Life Sciences + Healthcare Summit this October, we shared key insights on how this new working group, and other new regulatory priorities, would affect organizations in the sectors.

Higher likelihood for civil and criminal penalties

While the FCA has traditionally been used mostly to secure civil penalties from violators, recent trends show that the DOJ is increasingly seeking criminal penalties for defendants as well. Typically, these criminal charges are pursued in matters involving allegations of bribery and/or kickbacks.

Further complicating matters is the fact that the DOJ can begin an FCA investigation as a civil case, take testimony, and later use those statements as evidence in a criminal case. As with any investigation, having experienced legal representation in these matters is essential.

Leveraging FCA to crack down on cybersecurity customs violations

The DOJ has, in recent years, expanded the use of the FCA beyond traditional healthcare fraud. That includes increasing enforcement on companies with government contracts who fail to comply with their contractual cybersecurity regulations. These DOJ lawsuits have ramped up in the past 18 months and are expected to continue under this administration.

Additionally, the DOJ is leveraging the FCA to target companies seeking to dodge customs or duties for imported goods. With most durable medical equipment and medical consumables being manufactured overseas, those in the health care and life sciences sectors must ensure their practices are in full compliance with all customs requirements to avoid potential penalties under the FCA.

The Need for Experienced Legal Counsel

With a White House seeking to affect how the DOJ operates more than previous administrations and significant turnover happening at all levels of the DOJ, government enforcement is as unpredictable as ever. At Buchanan, our experienced attorneys can assess your risk potential, address compliance issues, and support you through any investigation or litigation you may face.

[1]https://www.justice.gov/opa/pr/doj-hhs-false-claims-act-working-group

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Jason is a shareholder in the firm's White Collar Defense, Compliance & Investigations group. He routinely handles FCA investigations and trials, federal and state grand jury investigations, and a myriad of internal investigations. jason.bologna@bipc.com

Mark A. Kasten
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Day in the Life: Jessica Alsop

Jessica Alsop
Senior Vice President and Chief Legal Officer, WVU Health System

Alaina N. Crislip
Jackson Kelly PLLC

Alaina N. Crislip is a Vice Chair of AHLA's Women's Leadership Council. She brings over 20 years of health care experience, including service as in-house counsel and senior administration at a health system. She provides strategic, regulatory, and operational advice to health systems, hospitals, academic medical centers, and physician organizations on health information technology, HIPAA, 340B, compliance, behavioral health, fraud and abuse, and clinical research.

When you consider Jessica Alsop's fearlessness in tackling the complex challenges of the modern health care system, her sensitivity and clear communication to her team, and her quick reflexes to address emergencies with a cool and calm demeanor, it's not hard to picture her as a champion barrel racer with an opportunity to join the rodeo circuit as a teenager. Fortunately for the West Virginia University (WVU) Health System, she chose law school instead.

Jessica does not have a normal daily routine. The Senior Vice President and Chief Legal Officer of the WVU Health System, a private nonprofit with 25 hospitals, 3,260 beds, and more than 35,000 employees in a four-state footprint, shoulders massive responsibilities in both business development and legal responsibilities. Describing a day, Jessica offers a masterclass in leadership, excellence, and communication delivered with her characteristic thoughtful discourse.

A recent day started with meetings at 8:00 am. Jessica does not waste mornings. Raised in rural West Virginia surrounded by close family who worked hard and found joy in what they were doing, Jessica absorbed that work ethic, and it is a part of her innate character.

Bob O'Neill, her predecessor, lured Jessica away from an in-house position with an energy company to be the eighth to join the WVU Health System legal department. With three young daughters and a husband with a demanding career, Jessica carefully thought through the ramifications. She knew the switch would require her to learn a whole new industry, in addition to handling what landed on her desk. That, she explains, is not a "9 to 5" exercise. She committed herself to learning the health care industry at night and on weekends, spending her days learning the legal issues from Bob. Her solid advice: learn your industry and learn from your colleagues. The WVU Health System legal department now numbers 40 lawyers.

Around lunch, Jessica takes a break to have her daughter's homecoming dress altered. How did Jessica tackle this role with a trio of active girls? She and her husband, Rob, worked together to figure out duties and schedules. They leaned on others and family members, hiring a "family." The unique work/life balance that Jessica and Rob create plays out during the day by, as Jessica puts it, "piecing together the different portions of your life." Then she was right back at it, dropping back into her schedule.

Her role as a member of the WVU Health System leadership team prompts Jessica to be more visible to the public. These obligations include events outside of the office, accompanying her CEO, Albert Wright, to meetings and functions and depositions. This wreaks havoc on her daily schedule. Travel and meetings do not stem the tide of emails, emergencies, and regular check-ins with her key team members. Does Jessica have a secret weapon to meet her obligations, stay on track, and thrive? As it happens, she does.

"I have a wonderful executive assistant who helps remind me that I need space," she explains. She plans 30 minutes a day for Jessica to eat lunch. She is adept at making sure that she is not overbooking Jessica or infringing on a family commitment. Most importantly, she finds open days for remote work or simply blocks of empty time on her calendar. These blocks are critical, Jessica advises, in thinking through solutions to problems so that she can get out of a reactive mode and into an analytical, proactive mode. The hospitals' general counsels report directly to Jessica. That gives her a granular, boots-on-the-ground view of what is going on across the entire health care system. Jessica can spot patterns or common problems and having blocks of time helps her to both define the challenge and craft the solution.

Her approach to scheduling also helps her to execute another tip: embrace surprise. Sometimes the surprises are schedule hogs that upend the flow to a day.

Other surprises allow Jessica to offer her favorite response: "that's not a big deal, don't worry about that." That reassurance underscores the responsibilities attendant to her dual role with the WVU Health System.

The workday might be winding down, but Jessica's day is still going strong: she has a board meeting to attend this evening.

A key part of Jessica's job is assimilating a great deal of information, sorting it by importance, and diving deep where warranted. Jessica characterizes herself as a high communication, low touch leader. She accepts updates in the form of texts, calls, emails, and memos—just do not put her in the position of being surprised by a question from a board member or her CEO. There are between five and ten priority items set by Albert Wright, and on those issues, Jessica is in the trenches with her team. The bottom line is that Jessica trusts her team to make really good decisions. So why is her favorite response "that's not a big deal, don't worry about it"? Because that is an indication that everything is working. The general counsels are spotting issues, and Jessica's experience and the communication from her team help her to assess and assuage instantly. She quickly offers grace to the unnamed general counsel, explaining that it takes time to understand what is important and what is less so; you must be patient with yourself as you sort that out.

And now she's at the board meeting, during which she is responsible for giving solid advice. Again, we are treated to a primer on professionalism. Jessica carefully digs into issues to prepare. Then she crafts her language to give the salient information to the board and to her CEO without bogging down in legal explanation so that she does not risk losing her audience. The board and her CEO trust her implicitly, and she guards her reputation to maintain her effectiveness. Part of this reputation is her excellent advice, and the other part is that her board and CEO know that she is not afraid to be candid with them always. She understands that her advice is not always going to be the path taken, but she wisely points out that once advice is given, "sometimes you have to stay silent instead of being right."

Her preparation involves her senior attorneys, from whom she requests input on both business and legal matters. These trusted advisors are her resources. If she's considering a business initiative, she will actively solicit feedback—and push back—to make sure that she's weighing all appropriate legal considerations in conjunction with the business considerations. She's clear that her team can be comfortable telling her things she might not want to know or want to hear. When the process is over, ultimately, it is Jessica's call, but she will both explain her reasons and take responsibility.

When the board meeting ends, Jessica takes a moment to walk her dog and regroup for the evening.

The work culture Jessica creates is one in which she knows each of her team personally and has created a work family for her team. She repeatedly speaks of the importance of trust amongst her team. This work culture creates an inclusive environment that allows smart, hardworking lawyers to thrive. She credits her early law firm experience for surrounding her with leadership, who just happened to be women, and showing her that inclusivity thrives where people are judged on talent and merits. Jessica's approach creates a naturally level playing field that means that she has no trouble attracting talent.

So, as Jessica's day ends, around 10 pm, the final piece of her day falls into place—self care. She takes a phone call from her daughter in college to walk her through her own stressful day. She prioritizes sleep, good nutrition, and movement. She takes mindful breaks. She is fearless enough to admit when she is not operating optimally so that she is not making a decision from a weakened position. And then she spends time with her family unplugging, laughing, sharing a meal, and hearing about their days.

Jessica's career and leadership success shines forth, a modest and profound role model who advises aspirants to be comfortable with yourself, work hard, and take care of your health.

AHLA's Women's Leadership Council is excited to present "A Day in the Life," where featured health law professionals walk you through their day: the good, the bad, the mundane, and the inspiring. We hope that this reflection offers some insight into the busy lives of our members. If you'd like to contribute to "A Day in the Life," please email tbirts@americanhealthlaw.org.

Understanding False Claims Act Enforcement in 2025: Trends, Takedowns, and New Priorities

Bailey Cremeans
Epstein Becker Green

As an early career health care attorney, staying informed about enforcement trends in health law, such as enforcement of the False Claims Act (FCA), is essential.

The FCA is a federal law that imposes liability on individuals and organizations that knowingly submit false or fraudulent claims for payment to the U.S. government. Combating health care fraud through the FCA has long been a top priority for the Department of Justice (DOJ).[1] In Fiscal Year 2024, DOJ recovered more than $2.9 billion under the FCA, with over half stemming from health care-related enforcement.[2]

FCA Enforcement Trends in 2025

In 2025 so far, DOJ has intensified its focus on FCA enforcement, especially as it pertains to health care fraud schemes. Most notably, in June, the DOJ announced a record-setting National Health Care Fraud takedown, resulting in criminal charges against 324 defendants, including 96 licensed health care professionals.[3] This operation uncovered nearly $13 billion in fraud, more than double the previous record of $6 billion.[4]

In addition to this takedown, several other high-value FCA settlements have been reached this year. For instance:

- In early 2025, Pfizer, on behalf of its subsidiary Biohaven Pharmaceutical Holding Company Ltd, agreed to pay nearly $60 million to resolve FCA and Anti-Kickback Statute (AKS) violations related to providing remuneration to induce prescriptions of its migraine medicine.[5]
- In April, Walgreens agreed to pay a $300 million settlement to resolve allegations that it filled invalid prescriptions for opioids and other controlled substances, in violation of the FCA.[6]
- In June, a substance use disorder treatment provider agreed to pay $18.5 million to resolve claims it paid Medicaid patients to seek its treatment and engaged in double billing.[7]

These settlements underscore the government's ongoing commitment to pursuing FCA violations tied to fraud and kickbacks. This focus is expected to intensify under the current administration, which has taken steps to prioritize and broaden the scope of health care-related FCA enforcement by re-establishing the FCA Working Group.

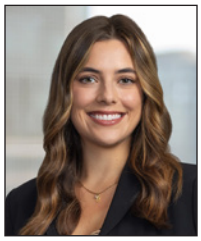
Re–Establishment of the FCA Working Group

In July 2025, DOJ and the Department of Health and Human Services (HHS) announced a re-launch of the joint FCA Working Group, originally established in 2020 to address fraud related to the COVID-19 pandemic.[8] The renewed group aims to strengthen enforcement against health care fraud by leveraging interagency collaboration and data analytics.[9] It is comprised of senior leaders from HHS' Office of General Counsel, the Centers for Medicare & Medicaid Services (CMS), the HHS Office of Inspector General, and DOJ's Civil Division. Its mission includes coordinating investigations, accelerating enforcement actions, and targeting fraud that undermines federal health care programs.[10]

The FCA Working Group has identified six key **priority areas** for enforcement:

1. Medicare Advantage fraud;
2. Drug and device pricing abuses;
3. Barriers to patient access to care;
4. Kickbacks related to drugs, medical devices, and durable medical equipment;
5. Defective medical devices affecting patient safety; and
6. Manipulation of electronic health records to inflate Medicare utilization.[11]

While certain areas, like fraud, kickbacks, and drug pricing abuses, have been long-standing priorities for enforcement—others, like barriers to patient access to care, reflect new enforcement priorities. The specific contours of how DOJ will pursue these new priorities remain to be seen. However, in May 2025, DOJ filed a FCA complaint against three of the nation's largest health insurance companies, alleging unlawful kickbacks totaling hundreds of millions of dollars paid



Bailey Cremeans is an associate in the health care and life sciences practice of the Columbus, Ohio office of Epstein Becker Green. Bailey helps health care organizations navigate the legal complexities of today's health care landscape. Hospitals, health systems, and other health care providers count on Bailey for assistance with health care fraud and abuse, reimbursement, health policy, medical staffing, and other regulatory compliance matters.

to brokers in exchange for enrollments into the insurer's Medicare Advantage plans.[12] The complaint alleges that the insurers conspired with brokers to discriminate against beneficiaries with disabilities, who they deemed to be less profitable.[13] This represents an example of the type of enforcement that might fall under "barriers to patient access to care."

The July announcement of the FCA Working Group's reestablishment also referenced high-priority FCA enforcement areas outlined in a June 11, 2025 memorandum from Assistant Attorney General Brett Shumate to DOJ Civil Division staff,[14] such as combatting discrimination and protecting women and children through the FCA.[15] Specifically, the administration promises to pursue investigations involving claims submitted to federal health care programs for non-covered services related to gender affirming care.[16] According to the memorandum, DOJ will "aggressively pursue claims under the False Claims Act against health care providers that bill the federal government for impermissible services," including "those who attempt to evade state bans on gender dysphoria treatments by submitting claims with false diagnosis codes."[17]

Looking Ahead

The first half of 2025 has seen significant FCA enforcement, particularly within the health care sector. With the re-establishment of the DOJ-HHS FCA Working Group, this trend is expected to continue and expand throughout the end of the year, targeting new areas of focus. As enforcement evolves, entities participating in health care programs and early health care legal professionals must stay informed and vigilant to ensure compliance with the expanding scope of FCA priorities.

1 Nicole M. Argentieri, Principal Dep. Ass't Att'y Gen., *Combating Health Care Fraud: 2024 National Enforcement Action*, U.S. Dep't of Justice (July 1, 2024), https://www.justice.gov/opa/blog/combating-health-care-fraud-2024-national-enforcement-action.

2 U.S. Dep't of Justice, *Fraud Statistics – Overview* (Sept. 30, 2024), https://www.justice.gov/archives/opa/media/1384546/dl.

3 U.S. Dep't of Justice, *National Health Care Fraud Takedown Results in 324 Defendants Charged in Connection with Over $14.6 Billion in Alleged Fraud*, June 30, 2025, https://www.justice.gov/opa/pr/national-health-care-fraud-takedown-results-324-defendants-charged-connection-over-146.

4 *Id.*

5 U.S. Dep't of Justice, Press Release, *Pfizer Agrees to Pay Nearly 60M to Resolve False Claims Allegations Relating to Improper Physician Payments by Subsidiary* (Jan. 24, 2025), https://www.justice.gov/opa/pr/pfizer-agrees-pay-nearly-60m-resolve-false-claims-allegations-relating-improper-physician.

6 U.S. Atty's Office for the Northern Dist. of Ill., Press Release, *Walgreens Agrees to Pay Up to $350M for Illegally Filling Unlawful Opioid Prescriptions and Submitting False Claims* (Apr. 21, 2025), https://www.justice.gov/usao-mdfl/pr/walgreens-agrees-pay-350m-illegally-filling-unlawful-opioid-prescriptions-and.

7 U.S. Atty's Office for the Dist. of Minn., Press Release, *NUWAY Alliance Agrees to Pay $18,500,000 Settlement in Medicaid Kickbacks Scheme, False Claims Act Violations* (June 26, 2025), https://www.justice.gov/usao-mn/pr/nuway-alliance-agrees-pay-18500000-settlement-medicaid-kickbacks-scheme-false-claims-act.

8 U.S. Dep't of Justice, Press Release, *DOJ-HHS False Claims Act Working Group* (July 2, 2025), https://www.justice.gov/opa/pr/doj-hhs-false-claims-act-working-group.

9 *Id.*

10 *Id.*

11 *Id.*

12 U.S. Dep't of Justice, Press Release, *The United States Files False Claims Act Complaint Against Three National Health Insurance Companies and Three Brokers Alleging Unlawful Kickbacks and Discrimination Against Disabled Americans* (May 1, 2025), https://www.justice.gov/opa/pr/united-states-files-false-claims-act-complaint-against-three-national-health-insurance.

13 *Id.*

14 *Id.*

15 Memorandum from Assistant Attorney General, Civil Division Enforcement Priorities, (June 11, 2025), https://www.justice.gov/civil/media/1404046/dl?inline.

16 *Id; see also* Memorandum from Attorney General, Preventing the Mutilation of American Children, at 4 (Apr. 22, 2025).

17 *Id.* at 3.

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Member News

Member Spotlight

Jamie McIntyre
Stout
Lake Worth, Fl
jmcintyre@stout.com

What skill would you most like to learn?

Two: fly fishing and car restoration. I do a fair bit of fishing, but not on fly. I am also completing my second vintage car restoration—a 1956 Mercedes 190SL. The first was a 1956 Ford Thunderbird—same color, model, and options as the one Suzanne Somers drove in "American Graffiti." It was a gorgeous car, and ended up being featured in *Hemmings Magazine*. While I did some detailing, interior work, and chrome, I didn't do any of the mechanical restoration myself.

Where is the coolest place you traveled?

In 2017, I fulfilled a lifelong dream of going to the Galapagos. I started my trip in Quito, touring monasteries and the old city before heading to the edge of the Andes Mountains where I got to view Andean condors and dozens of species of hummingbirds in the wild. I also visited Pululahua, a village situated in the caldera of an inactive volcano. In the Galapagos, every minute was incredible. From thousands of flying fish being chased by sharks, to the blue-footed boobies, marine iguanas, newborn sea lions, the albatross doing their "courtship dance," and of course, the tortoises, there wasn't a dull moment. I don't usually have a voice in my head, but for that week, it was definitely David Attenborough.

What is your favorite random fact?

Wombats poop cubes. They are also nocturnal—which pretty much means they sleep all day and shoot dice all night.

What does your average weekend look like?

I have a knack for avoiding whatever strikes me as "average." A seemingly endless stream of hobbies helps with that: antiquing, SCUBA

diving, fossiling, day trips, photography, hiking, birding, fishing, car shows, thrifting, trying new restaurants, scoping out the best happy hours, and exchanging loving glances with my dog, a rescue pit-lab. That is to say, when I'm not spoiling the tiny humans in my life.

Who is the smartest person you ever met?

I don't know that I'd say any one person is smarter than the next. That said, I met Donna Shalala at the NIH in Washington when I was 15 and immediately wanted her job. That probably isn't in the cards, but I did go on to do a lot of things I could say she partially inspired: I worked on both the yearbook and newspaper, studied politics and international relations, and completed a year of public service in the National Health Corps.

What is one thing that instantly makes your day better?

A FaceTime with any of my nieces and/or nephews. Two girls, who are five and six, and three boys, all of whom are three. In order: Isla, Harper, Havok, Luca, and Nolan. Our calls are always full of silly faces, laughter (real and conjured, for all of the mutually unintelligible jokes), and lots of discussion about superheroes, art projects, kid philosophy, and Kindergarten/Pre-K.

Member News

What songs are on the soundtrack to your life?

Anything sentimental about the Carolinas—think Kenny Chesney crooning "I go back to the smell of an old gym floor and the taste of salt on the Carolina shore." As a proud Gamecock, I'm also obligated to admit that "2001 Space Odyssey," "Step to the Rear," and the "Carolina Fight Song" always get me. The one that's on loop is Lee Ann Womack's "I Hope You Dance"—my dad, a weight lifter and blue collar "guy's guy" heard it on the radio and it immediately became his song for me. When my family dropped me off at college, he gave me a book of the lyrics with the CD single and a hand-written note tucked inside. He died unexpectedly when I was 21, six weeks before I'd become the first person in his family to ever attend or graduate college. That song will always be a reminder of how proud he was, how much he loved his family, and what his dreams were for my sisters and I.

Would you like to be featured in our Member Spotlight section? Please contact agreene@americanhealthlaw.org. We'd love to hear from you!

Mark S. Kopson, the leader of Plunkett Cooney's Health Care Industry Group, was recently selected by Michigan Lawyers Weekly (MiLW) as a member of its 2025 Class of Leaders in the Law. According to MiLW, Kopson and this year's other honorees were selected for, among other things, their significant contributions to the practice of law in Michigan, their experience and expertise as practitioners, and their leadership efforts within the bar and community.

Holland & Knight is pleased to announce that **Michelle Huntsman** has joined as a partner in the firm's Houston office. Ms. Huntsman focuses her practice on the representation of health care industry clients in mergers and acquisitions and other transactional matters. Through her work on numerous health care transactions, she has significant experience in health care due diligence, as well as regulatory and reimbursement implications of changes of ownership.

Doug Mancino: In Memoriam

It is with deep sadness that we inform you of the passing of a longstanding AHLA colleague and friend, Douglas M. Mancino, on Wednesday, September 10, 2025.

Doug was a partner at Seyfarth in Los Angeles, CA. For over four decades, he represented all types of health care and nonprofit organizations on tax, business, and financial matters. He served as counsel to health care clients in a case that defined the limits of tax-exempt organizations participating in health care joint ventures and represents tax-exempt health plans throughout the United States. Doug authored or co-authored five books and treatises including AHLA's authoritative "Taxation of Hospitals and Health Care Organizations," and more than 110 articles concerning tax-exempt organizations and health care issues.

Doug served as President of the American Health Lawyers Association from 1993–1994 and was inducted as a Fellow in 2005. He was a frequent lecturer/speaker on many legal, tax, and health care subjects, and distinguished himself as one of the country's top health care and tax-exempt organization lawyers.

Beyond his legal practice, Doug was deeply committed to civic and charitable activities, serving as Chairman of the Board of Trustees of the Children's Burn Foundation and on the boards of various organizations including the Irvine Health Foundation, The Center on Philanthropy & Public Policy, Health Net, Inc., the Music Center Leadership Council, the Kent State University Foundation, and the National Center on Philanthropy and the Law. His dedication to both the legal profession and community service exemplified the values that AHLA holds dear.

Volunteer Recognition

August and September 2025

2025 Tax Issues for Health Care Organizations

Edward Berkovitz, NYU Langone Health System
Catherine Bernard, Sanford Health
David Biller, Northwestern Memorial HealthCare
Justin Caltabiano, HonorHealth
Robert J. Cepielik, Berkeley Research Group LLC
Amy Ciminello, Plante Moran, PLLC
John Crawford, Ernst & Young LLP
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Thought Leader Webinar: AI for Health Care Contract Review: Improving Speed and Compliance

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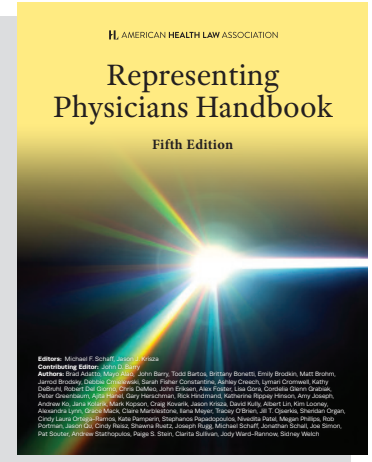

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Our consultants have extensive experience assisting complex health care organizations with design of contract management processes and implementation of contract management systems. We have worked with multiple health systems and other provider organizations to implement compliance programs that, in concert with their contract management systems and processes, help ensure compliance with the Stark and Anti-Kickback legal and regulatory requirements

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Cybersecurity

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StoneTurn partners with counsel and health care organizations on liability and litigation matters, offering expertise in compliance reviews, damages analysis, and statistical evaluations. Our experts provide consulting and testimony in disputes involving billing, reimbursement, fraud, and regulatory issues, delivering practical, data-driven solutions to complex challenges across the health care sector.

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We regularly serve as an Independent Review Organization (IRO) for clients subject to Corporate Integrity Agreement (CIA) requirements. We have substantial experience with IRO requirements for both claims review and focus arrangements CIAs. We can also provide "mock" IRO reviews to help your client ensure readiness for an upcoming IRO engagement by another IRO service provider.

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We regularly fill Compliance Officer and other related roles (e.g., Privacy Officer, Compliance Director, Compliance Auditor, Compliance Audit Director) on an interim basis. We are able as interim managers to evaluate compliance program structures and operation, and to provide feedback and make recommendations for improving the effectiveness of the compliance program.

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Upcoming Events

2025

November 2-4

Fundamentals of Health Law
Chicago, IL

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November 11

The One Big Beautiful Bill Act Explained: Provider Taxes and More

November 12

State Health Care Transaction Review Laws: Practical Guidance

November 18

Unique Challenges Impacting Smaller Health System Transactions in the Current Market – How to Survive and Thrive

December 2

State Perspectives on Health Care Data Privacy: Insights from State Attorneys General

December 4

How to Make a Group Practice Perfect: From Formation to Termination

December 9-12

Health Care Arbitration Training
Virtual

December 11

Navigating Billing and Compliance Issues for Advance Practice Professionals

2026

February 4

Optimizing Investigations in Peer Review and Legal Considerations

February 11-13

Winter Institute: Advising Providers & AI in Health Care Conferences
Las Vegas, NV and Virtual

February 23-25

Long Term and Post-Acute Care Law and Compliance
Nashville, TN

March 18-20

Institute on Medicare and Medicaid Payment Issues
Baltimore, MD

April 13-15

Health Care Transactions
Nashville, TN

June 28

In-House Counsel Program
New York, NY

29-July 1

Annual Meeting
New York, NY

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AHLA Names the 2025

Michael F. Anthony Health Law Scholarship Recipients

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Learn more about this year's scholarship recipients:
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Jahnavi Arun, University of Houston Law Center &
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