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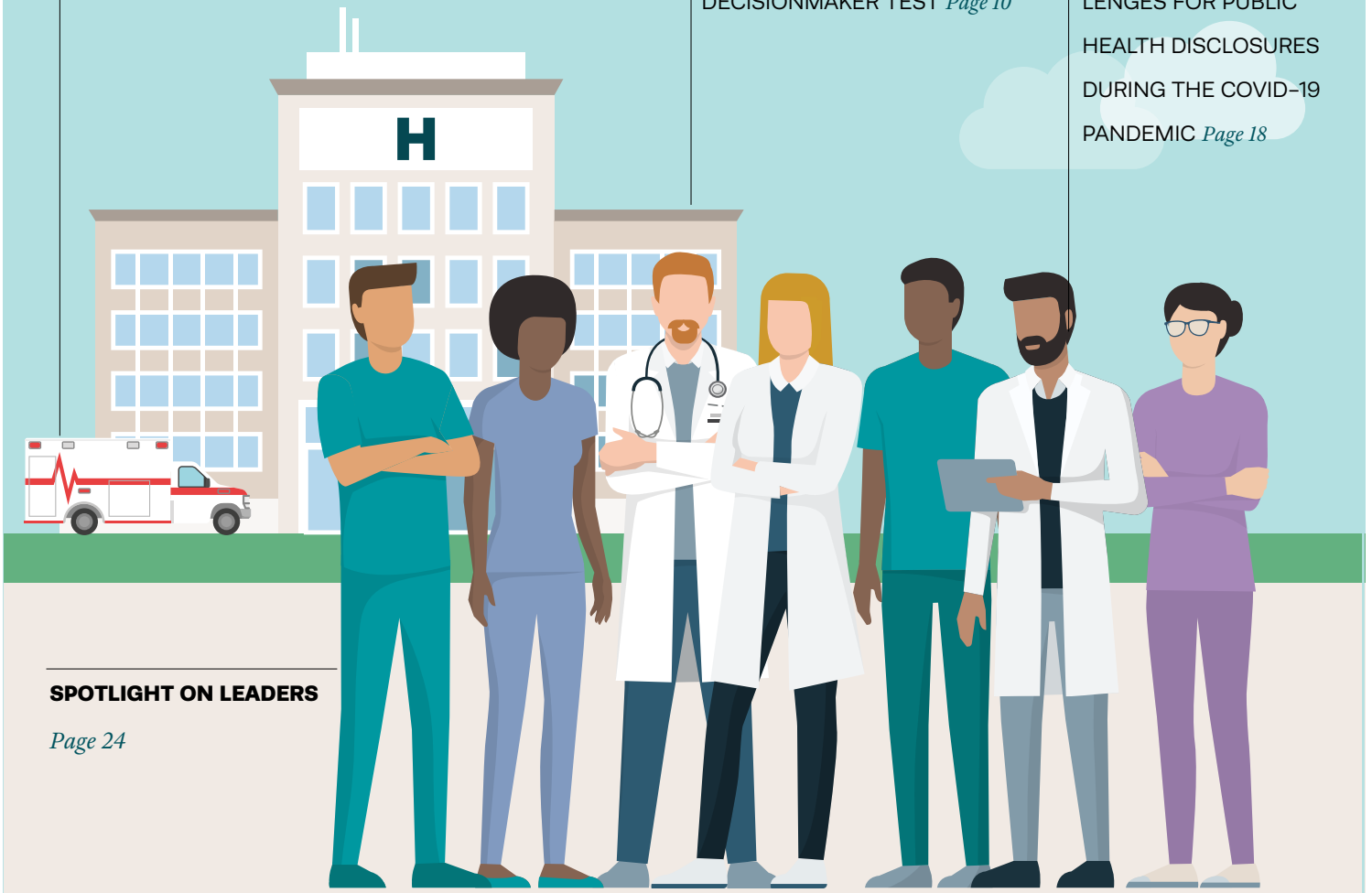

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Opening Remarks

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This is my first column as president of AHLA. I am incredibly honored to have been chosen to lead what I consider to be the premier professional organization in the field. Serving in this role provides me an opportunity to give back to an organization that has given me far more than I can ever repay. My first connection was with our predecessor organization, NHLA, when I spoke at a conference in fall 1987 while still a government attorney. I joined both NHLA and the American Academy of Hospital Attorneys shortly thereafter. I have been a member of AHLA since it was created by the merger of those two entities. For more than 30 years, AHLA has been my professional home. It has given me the opportunity to speak, write, and serve in a variety of leadership roles. And, of course, it has given me access to the tremendous educational resources.

AHLA has been vital to my professional success, providing opportunities to network with and learn from the leading practitioners in the field. It has always been a wonderfully collegial organization where leading practitioners share their knowledge and insights with great generosity and candor. Even more important than the professional success are the personal relationships I have formed with so many of you. Interactions at AHLA conferences have produced friendships over many years. One of my primary goals for this year is to provide that same experience to our newest generation of health law professionals.

I come to this office during unusual times. For the first time in AHLA history, we were unable to have our Annual Meeting in person, another casualty of the COVID-19 pandemic. I greatly missed the opportunity to see so many of you in person in San Diego. That said, one of the three pillars of the AHLA strategic plan is "resilient organization." AHLA clearly showed its resilience by quickly pivoting to a very successful virtual Annual Meeting. As I write this, we have just concluded three days of our virtual Annual Meeting, which was attended by over 600 health law professionals. The attendees were treated to two excellent and thought-provoking keynote addresses. Johns Hopkins surgeon Dr. Marty Makary spoke of his vision for a new movement of relationship-based clinics that spend time with patients to address the social, economic, and lifestyle determinants of health. Harvard-based health care economist, Amitabh Chandra, PhD, discussed potential comprehensive health care reforms that could insure the uninsured, improve quality of care, and eliminate the perverse incentives that currently drive up costs.

These keynote presentations were combined with a comprehensive and entertaining summary of the year's developments in the "Year in Review," as well as many concurrent sessions covering the breadth of both substantive health law and professional development. In addition, there were numerous virtual networking events that allowed attendees to connect. The virtual platform worked flawlessly and permitted attendees to see both the speaker(s) and PowerPoint presentations, while at the same time allowed them to ask questions and give comments to the speaker(s) via a live chat function. Kudos to our talented and dedicated AHLA staff, along with our Planning Committee and speakers, for making this a successful event.

The realities of the pandemic have already caused us to convert our fall conferences to a virtual format. While we would all prefer these conferences to be in-person, our experience with the Annual Meeting has made clear that the virtual format provides an excellent vehicle to provide you with the high-quality educational content that you have come to expect from AHLA.

Finally, I want to address the other crisis now facing our country, racial injustice. On June 4, AHLA issued a strong statement reaffirming the Association's steadfast commitment to the critical importance of diversity and inclusion both within our Association and the health law community at large. The statement is posted on AHLA's website. It is only the second public policy statement in the 50 plus year history of the Association.

David Cade, AHLA's Executive Vice President and CEO, opened the Annual Meeting of our membership with a powerful and very personal statement about the impact of racial injustice. David's column in the July 2020 issue of *Health Law Connections* reiterates his thoughts. I strongly commend it to your attention.

The AHLA statement closed with this pledge: "We at AHLA welcome and pledge to help effectuate such change." My goal for this year is for AHLA to make good on this pledge by contributing to the dialogue on racial and other inequities in health care and potential solutions to them. We will do this by focusing on providing content and dialogue on topics such as social determinants of health, discriminatory health care practices, and the impact of laws and regulations on the availability of health care to underserved communities.

While the year ahead will be one with many challenges, we believe these challenges present an opportunity to further our mission. Throughout this time, AHLA will be there with you.

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Feature

The Coming Wave of Physician-Hospital Alignment: What the Antitrust Laws Have to Say About It

Herbert F. Allen and **Matthew C. Hans**, Polsinelli PC

A great realignment is underway among America's doctors. Over the last decade, physicians have been moving in ever-greater numbers away from independent practice towards full hospital employment or affiliation with a hospital system.

The shift has been motivated by several national trends. Independent physician practices have faced growing administrative and staffing costs, as well as new demands for capital investment in things like electronic medical records systems. A physician shortage has pushed physician salaries higher, making it increasingly difficult for independent practices to recruit and retain physicians. By 2033, the United States is expected to have an unmet need for between 54,100 and 139,000 physicians.[1] In the face of these rising costs, reimbursement rates have declined or remained flat. An aging population and the expansion of Medicaid under the Affordable Care Act has led to a lower-reimbursing payer mix for many practices.

Recent statistics show the scope of the transformation:

- Last year, for the first time ever, more physicians worked as employees than worked independently or for practices they own.[2]
- Another study last year found that the percentage of hospital-employed physicians increased from 25.8% in July 2012 to 44% in January 2018—an increase of more than 70% in just 5.5 years.[3]
- Between July 2012 and January 2018, the percentage of physician practices owned by hospitals more than doubled from 14% to 31%.[4]

COVID-19 is likely to accelerate these trends. The pandemic has already caused a 55% decline in revenue and a 60% decrease in patient volume for independent physician practices, according to one study.[5] This decline in revenue could push many independent practices over the edge.

"Most independent medical groups lack significant reserves and therefore are not in a good position to remain solvent in an atmosphere where elective surgeries have been canceled and patients are avoiding clinic visits," said Leonard Henzke, who works on physician-hospital alignment strategies at ECG Management Consultants.[6] According to Henzke, COVID-19 could represent a "tipping point" towards even greater hospital-physician partnership.

Antitrust Laws and Hospital–Physician Alignment

If we are indeed facing a new wave of alignment between the country's hospitals and physicians, then the antitrust laws will play an important role in determining how this alignment plays out.

This article examines how antitrust principles have and will continue to impact the various forms of physician-hospital alignments—starting with full mergers where hospitals acquire physician practices, then looking at contractual arrangements (like professional service agreements), and lastly considering clinical integration efforts.

Hospital Acquisition of Physician Practice—Reduction in Competition?

When a hospital acquires an independent physician practice or employs its doctors directly, the antitrust laws treat the transaction as a merger between the hospital and the physician practice. Antitrust concern about a horizontal merger arises when the combination of the newly hired physicians with physicians already employed by the hospital creates new market power that may "substantially . . . lessen competition, or tend to create a monopoly" in violation of Section 7 of the Clayton Act. Vertical mergers also may cause competitive concerns, as when a hospital employs all the surgeons in town, making them unavailable to a competing hospital.

But how do courts and agencies determine whether a merger that has not yet occurred *may* substantially lessen competition at some point in the future? At a very high level, the analysis of a horizontal merger includes the following steps:

First, courts will define a geographic market for each physician specialty for which there is an overlap between the acquiring and acquired physician groups. The analysis focuses on patients' willingness to travel for particular services, as well as the degree to which health plans need certain physicians in a particular geographic area to market a successful plan to employers. As a general matter, the geographic markets for primary care doctors may be narrower than the market for specialists who perform elective procedures, since patients may be willing to travel for elective procedures, while many patients prefer local access to a primary care service. Geographic market definition can be outcome-determinative in many antitrust cases, since it determines how many physicians are included in the denominator when calculating market shares.

Second, courts will look to market shares before and after the acquisition as an approximation of the likely competitive effects of a transaction. Transactions that result in market shares of less than 30% have been held not to present competition concerns. On the other hand, very high market shares can be sufficient for a plaintiff to make out a prima facie case that the transaction will probably lead to anticompetitive effects. For a more precise measure of concentration, courts will look to the Herfindahl-Hirschman Index (HHI). The HHI is calculated by squaring the market share of each firm competing in the market and then summing the resulting numbers. Markets in which the HHI falls between 1,500 and 2,500 points are considered to be moderately concentrated, while markets with an HHI greater than 2,500 are considered highly concentrated.[7] If a transaction leads to an increase in HHI of more than 200 points to more than 2,500, then the transaction will be "presumed to be likely to enhance market power."[8]

Third, courts will look at other evidence to confirm any presumptions. While market concentration statistics are "of great consequence," they are "not conclusive indicators of anticompetitive effects."[9] Other evidence might include documents from the parties about the motivations for the transaction and testimony from payers about any changes in bargaining leverage that might be attributable to the transaction.

Fourth, courts consider defenses the parties might offer. This might include evidence that the transaction will yield efficiencies that will "enhance the merged firm's ability and incentive to compete, which may result in lower prices, improved quality, enhanced service, or new products."[10] Of particular relevance to many financially imperiled physician practices, the defendants may also invoke the so-called "failing firm defense" by presenting evidence that the practice would collapse but-for the transaction, causing physicians to leave the market.

Three recent cases challenging physician-hospital mergers, all discussed below, illustrate how these questions are answered, depending on whether the transaction is analyzed as a horizontal merger (between competing physician groups) or as a vertical merger (between a physician group and a hospital or health plan).

Over the last decade, physicians have been moving in ever-greater numbers away from independent practice towards full hospital employment or affiliation with a hospital system.

FTC and State of North Dakota v. Sanford Health and Mid Dakota Clinic[11]

In this horizontal merger case, the Federal Trade Commission (FTC) and the state of North Dakota successfully blocked Sanford Health, an integrated health system, from acquiring all the assets and capital stock of Mid Dakota Clinic, a multi-specialty physician practice.[12] In the Bismarck-Mandan region, Sanford operated an acute care hospital and employed 37 adult primary care physicians, five pediatricians, eight OB/GYN physicians, and four general surgeons. Mid Dakota Clinic employed 23 adult primary care physicians, six pediatricians, eight OB/GYN physicians, and five general surgeons. The court considered those four specialties that both Sanford and Mid Dakota provided as the relevant product markets for the antitrust analysis.

The court found that Sanford would have the following shares post transaction: 99.8% of general surgeon services, 98.6% of pediatric services, 85.7% of adult primary care physician services, and 84.6% of OB/GYN physician services. Based on the increase in concentra-

tion for each physician service line, the court presumed the transaction was likely to enhance market power and reduce competition.

Sanford was unable to rebut that presumption. It argued that it would not be able to increase prices to Blue Cross, the dominant buyer of physician services in the state. But the court found that after the merger, Sanford would have the power to force Blue Cross to either accept a price increase or leave the Bismarck-Mandan market.[13] Sanford contended the other hospital system could restore competition by bringing new physicians. The court rejected this argument because recruiting physicians to the region would be difficult and take too long to counteract the anticompetitive effects of the transaction.[14] Sanford also asserted a "weakened competitor" defense, but the court found that Mid Dakota was financially healthy and its physicians were not concerned about its long-term viability.[15]

Saint Alphonsus Medical Center–Nampa Inc. v. St. Luke's Health Systems[16]

In 2012, St. Luke's Medical Group, which operated an emergency clinic in Nampa, ID, acquired all the assets of Saltzer Medical Group, the largest independent multi-specialty physician practice in the state. St. Luke's also entered into a five-year professional service agreement with the Saltzer physicians, which the court considered to be the equivalent of a "merger."[17] Subsequently, the FTC, the state of Idaho, and two local hospitals sued and successfully obtained an order of divesture.

In the Nampa market, Saltzer had 16 primary care physicians, St. Luke's had eight, and the only hospital in Nampa had nine. After the acquisition, St. Luke's concentration of primary care physicians was "well above the thresholds for a presumptively anticompetitive merger."[18] In addition to the market share data, the court also found that the acquisition "limited the ability of insurers to negotiate with the merged entity."[19] Indeed, in an email, Saltzer executives stated that after the acquisition, it could use "the clout of [St. Luke's] entire network" in negotiations with insurers.[20]

To rebut the presumption of anticompetitive effects, St. Luke's asserted an efficiencies defense, primarily that the merger would allow St. Luke's to develop integrated care and risk-based reimbursement. The court set a high bar for such arguments, noting that the Supreme Court has never accepted an efficiencies defense. The court specified that a defendant must prove that the claimed efficiencies are "merger-specific" and "verifiable, not merely speculative."[21] Rejecting the defense, the court found that the Saltzer physicians and St. Luke's could provide integrated care and engage in risk-based contracting on their own, without an acquisition.

UnitedHealth Group–DaVita Medical Group Merger

Although not a typical hospital-medical group acquisition, UnitedHealth Group's acquisition of DaVita Medical Group in 2017 presented antitrust issues about the concentration of physician services. Among their various business lines, both United and DaVita employed numerous physicians. During the lengthy investigation of the merger, the FTC and various state attorneys general raised concerns about the market for managed care provider organization services offered to Medicare Advantage insurance plans. The enforcers viewed the merger as both a horizontal problem (the merged entity would control 80% of the physicians in the market) and as a vertical problem (because United could use its pre-merger position in the health plans and its post-merger physician position to harm competitors in the Medicare Advantage market). The government's vertical theory of harm was consistent with the approach taken in the FTC and Department of Justice (DOJ) Vertical Merger Guidelines released in June, under which a vertical merger "may diminish competition by allowing the merged firm to profitably use its control of the related product to weaken or remove the competitive constraint from one or more of its actual or potential rivals in the relevant market."[22] To resolve those issues, United agreed to divest DaVita's physician practice in Las Vegas.[23]

Because PSAs are creatures of contract, they are highly flexible. But that flexibility creates challenges for lawyers and the courts.

Collectively, these three examples illustrate the need to be cognizant of the following issues:

- Market concentration in a physician specialty in a geographic area can lead to a presumption that the acquisition of the physician practice is anticompetitive. As a practical matter, that presumption may be difficult to rebut. Whether a court defines the geographic market broadly or narrowly can be outcome determinative.
- Evidence or testimony from payers can play a key role in determining whether enforcers will seek to investigate or block a particular transaction. Parties should assess the likely reaction of insurers in their market.
- Enforcers and courts are often skeptical of merger defenses. Any efficiency, failing firm, or market entry arguments should be strongly supported by quantifiable and merger-specific evidence.

Hospitals and physician practices may wish to collaborate to provide integrated care or pursue value-based contracting, but not want to enter into a PSA or combine in a merger.

Background on Professional Services Agreements: "Employment Light"

For physician practices that wish to affiliate with a hospital, yet retain some degree of independence, the professional services agreement (PSA) has become a popular model. In the typical PSA, a hospital will contract to purchase all the clinical services of a physician practice to treat patients of the hospital. The physician practice will then assign its right to bill for its services to the hospital, and the hospital will assume responsibility for price setting and negotiating payer contracts. The hospital often takes the financial risk for the success of the physician practice by agreeing to pay for the physicians' services whether or not it can resell those services at a profit. At the same time, the physicians may retain responsibility for day-to-day practice management, generally subject to financial and clinical oversight by the hospital.

PSAs can offer benefits to both the physician group and the hospital. Many physician practices prefer autonomy and discretion over routine practice management, to include determining how best to achieve performance and financial objectives. At the same time, affiliation under a PSA gives practices access to the financial and clinical resources of a large system. Hospitals often find that physicians working under a PSA are more productive and efficient than physicians employed directly by the hospital, since PSAs allow doctors to retain an ownership mindset and determine the best way to achieve benchmarks.

Antitrust Pitfalls for PSAs

Because PSAs are creatures of contract, they are highly flexible. But that flexibility creates challenges for lawyers and the courts.

A PSA may create such tight integration between the hospital and the physicians that they become a single entity for purposes of antitrust law.[24] Historically, PSA arrangements have been viewed as similar to direct employment of the physicians by the hospital, which means merger law will apply. That was the case in *FTC v. St. Luke's Health System*, in which the FTC and Idaho Attorney General treated a five-year PSA as the "functional equivalent of an employment agreement" and challenged the transaction under Section 7 of the Clayton Act, which applies to mergers.[25] Given the significant likelihood that a PSA will be viewed as a merger, parties contemplating a PSA relationship should consider the risks discussed above.

Things become more complicated if a PSA is *not* viewed as a merger but as an ongoing agreement between separate entities, which is subject to Section 1 of the Sherman Act. There are two rules of decision under Section 1 of the Sherman Act. The *first*, the Rule of Reason, is the default standard for Section 1 cases, applicable to joint ventures and vertical agreements that "hold the promise of increasing a firm's efficiency and enabling it to compete more effectively."[26] Under the Rule of Reason, courts balance the anticompetitive effects of an agreement against its benefits in a properly defined relevant market. As a practical matter, analysis of a PSA under the Rule of Reason is similar to merger analysis under Section 7, focusing on geographic market definition and market shares in particular physician specialties.

The *second* rule of decision, the *per se* rule, applies to a narrow category of agreements that are "so plainly anticompetitive that no elaborate study of the industry is needed to establish their illegality."[27] Put differently, a plaintiff must show that the defendants entered into a "naked" horizontal agreement on price with "no apparent potentially redeeming value."[28] Critically, once the *per se* rule is found to apply, a plaintiff need not define the relevant market, show that the defendant had high market shares in that properly defined market, or prove anticompetitive effects.

To date, no court has applied the *per se* rule to a PSA. In one recent case, a state attorney general alleged that a hospital-physician practice PSA was *per se* illegal. Before the case settled, the court declined to rule out the possibility that the *per se* rule might apply, reasoning that a trial was necessary to determine "the degree of economic integration and decision-making relationship" between the hospital and physician practice.[29] Nevertheless, there is strong rationale to think that the Rule of Reason is the right approach. PSAs generally do include meaningful financial and clinical integration through the hospital's purchase of all the physicians' services. PSA arrangements are primarily vertical—a category analyzed under the Rule of Reason. Finally, adopting the *per se* rule could result in hundreds of PSAs across the country being declared unlawful without any inquiry into their competitive effects.

Steps practitioners can take to minimize antitrust risk in PSA relationships include:

- Consider whether the PSA affiliation would present antitrust risk if it were structured as a merger

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Antitrust laws will continue to play a central role in determining how hospitals and physicians can work together into the future.

between the hospital and physician group, since it is likely that enforcers will view the affiliation as a merger.

- To minimize risk that an affiliation will be deemed *per se* illegal, ensure that the PSA itself contains a detailed description of financial risk sharing and clinical integration that will be part of the relationship, and any consolidation of services that will result from the PSA.
- The PSA should also detail any powers reserved by the hospital over the practice, including authority over setting budgets and any significant decisions made by the practice.

Hospital–Physician Collaborations—Need for Integration

Hospitals and physician practices may wish to collaborate to provide integrated care or pursue value-based contracting, but not want to enter into a PSA or combine in a merger. Working together in a clinically integrated network (CIN) or an accountable care organization (ACO) is an alternate means to achieve those goals. The antitrust risk for these less-than-full affiliations is the same as the risk in PSAs discussed above: the collaboration between the hospital and practice could be viewed as an agreement that unreasonably restrains trade in violation of Section 1 of the Sherman Act.

In 1996, DOJ and the FTC jointly issued *Statements of Antitrust Enforcement Policy in Healthcare* (*Health Care Statements*) to provide guidance on what procompetitive cooperation among health care providers would not run afoul of the antitrust laws.[30] Statement Nine addresses "all types and combinations of health care providers" to include "physician-hospital organizations," joint ventures, CINs, and other collaborations involving joint negotiating or joint price setting.[31]

A CIN will not be *per se* illegal and will be analyzed under the Rule of Reason when the hospital-physician "integration through the network is likely to produce significant efficiencies that benefit customers, and any price agreements (or other agreements that would otherwise be per se illegal) by the network providers are reasonably necessary to realize those efficiencies."[32] A CIN's efficiencies can be achieved through either financial or clinical integration. Financial integration exists when hospitals and physicians agree to "share substantial financial risk for the services provided through the network."[33] Examples of financial integration include: providing services to a health plan at a capitated rate, providing services at a predetermined percentage of premium or revenue, and creating incentives for the network as a whole to contain costs.[34]

Clinical integration is "an active and ongoing program to evaluate and modify practice patterns by the network's [providers] and create a high degree of interdependence and cooperation among the [providers] to control costs and ensure quality."[35] Although the FTC does not require that providers use any particular method to achieve clinical integration, the networks that it has approved have included:

- clear goals for cost savings and quality improvement that can reasonably be achieved through integrating the network providers' clinical practices and modifying their practice patterns;

AHLA thanks the leaders of the Antitrust Practice Group for contributing this feature article: *Aimee DeFilippo, Jones Day (Chair); Ashley Fischer, McDermott Will & Emery LLP (Vice Chair—Educational Programming); Dionne Lomax, Affiliated Monitors Inc. (Vice Chair—Educational Programming); Robert Canterman, Federal Trade Commission Bureau of Competition (Vice Chair—Member Engagement); Lona Fowdur, Economists Incorporated (Vice Chair—Publishing); and Joe Miller, Mintz Levin Cohn Ferris Glovsky & Popeo PC (Vice Chair—Publishing).*

- selectively recruiting and retaining network providers who are likely to further the network's goals;
- significant investment of capital, both monetary and human, in the network infrastructure;
- shared electronic clinical records systems to facilitate care coordination, reduce duplication, and enhance efficiency;
- development of comprehensive evidence-based clinical guidelines designed to modify practice patterns and achieve practice goals;
- rigorous guideline implementation, performance measurement, and compliance mechanisms, to monitor and control how care is delivered; and
- in-network referrals to participating specialists, all of whom have committed to follow the network's clinical guidelines.[36]

More recently, FTC and DOJ issued guidance that eligibility criteria for ACOs are "broadly consistent" with the indicia of clinical integration that the agencies have described in the earlier *Health Care Statements* and advisory opinions.[37] As a result, the agencies will assess joint price setting by an ACO that participates in the Medicare Shared Savings Program under the Rule of Reason.[38]

Conclusion

Antitrust laws will continue to play a central role in determining how hospitals and physicians can work together into the future. Hospital acquisitions of physician groups will be scrutinized based on geographic market definition and market concentration. Contractual arrangements like PSAs can be subject to merger law, as well as antitrust laws governing agreements. And when otherwise independent physicians join a hospital's CIN or ACO, some level of financial and clinical integration must be achieved.

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34. *Id.* at 109.
35. *Id.* at 72.
36. *See, e.g.,* FTC Staff Advisory Opinion regarding Norman PHO (Feb. 13, 2013), http://www.ftc.gov/sites/default/files/documents/advisory-opinions/norman-physician-hospital-organization/130213normanphoadvltr_0.pdf; FTC Staff Advisory Opinion regarding TriState Health Partners, Inc. (Apr. 13, 2009), http://www.ftc.gov/sites/default/files/documents/advisory-opinions/tristate-health-partners-inc./090413tristateaoletter.pdf; FTC Staff Advisory Opinion regarding Greater Rochester Independent Practice Association, Inc. (Sept. 17, 2007), http://www.ftc.gov/sites/default/files/documents/advisory-opinions/greater-rochester-independent-practice-association-inc./gripa.pdf.
37. DOJ and FTC Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program (Oct. 2011), https://www.govinfo.gov/content/pkg/FR-2011-10-28/pdf/2011-27944.pdf.
38. *Id.*

Feature

Reining in the Anti-Kickback Statute? Commission-Based Payments and the Relevant Decisionmaker Test

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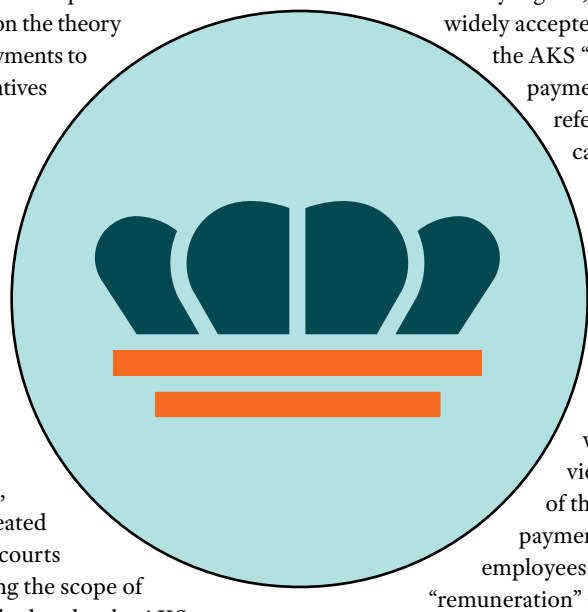
Over the last number of years, the federal Anti-Kickback Statute (AKS)[1] has solidified its place as one of the federal government's most useful tools in health care fraud and abuse prosecutions, both criminal and civil. This is especially true when it comes to investigations involving entities that rely on sales representatives to market their products and services, such as pharmacies, laboratories, and home health agencies. In recent years, the federal government has prosecuted dozens of entities and individuals on the theory that commission-based payments to these marketing representatives are unlawful kickbacks in violation of the AKS.



From this enforcement landscape have arisen a number of federal court opinions discussing the scope of the AKS and what type of arrangements the statute was designed to prohibit. This article discusses the "relevant decisionmaker" test, which the Fifth Circuit created in 2004 and various other courts have considered in deciding the scope of conduct that can be punished under the AKS.

The AKS: A Brief Primer

The AKS makes it a crime to "knowingly and willfully" solicit, receive, offer, or pay, any remuneration in return for the furnishing or arranging for the furnishing of, or the purchasing, leasing, or ordering of, any item, service, good, or facility for which payment may be made in whole or in part under a federal health care program.[2] Criminal violations of the AKS can result in prison sentences of up to ten years and fines of up to $100,000.[3] In addition to criminal penalties, violations of the AKS can result in civil damages and penalties under the federal False Claims Act (FCA)[4] and administrative liability such as civil monetary penalties and exclusion.[5]

According to the U.S. Department of Health and Human Services Office of Inspector General (OIG), one of the purposes of the AKS "is to protect patients from inappropriate medical referrals or recommendations by health care professionals who may be unduly influenced by financial incentives."[6] The government has consistently argued, and federal courts have widely accepted, that a payment violates the AKS "if even one purpose of the payment is to induce or reward referrals of Federal health care program business."[7]

The AKS contains various safe harbors, which serve as exceptions to the prohibitions contained in the statute.[8] If an arrangement fits squarely within a safe harbor, it will not be considered a violation of the AKS. One of those safe harbors covers payments made to bona fide employees. Specifically, the term "remuneration" as used in the AKS does not include "any amount paid by an employer to an employee, who has a bona fide employment relationship with the employer."[9] Another AKS safe harbor covers "personal services and management contracts." Under that safe harbor, prohibited "remuneration" does not include a payment made by a principal to an agent as compensation for the services of the agent, so long as certain standards are met including, among other requirements, that the agreement be set out in a writing and signed by the parties, is for not less than one year, and the aggregate compensation paid to the agent is consistent with fair market value and "is not determined in a manner that takes into account the volume or value of any referrals or business otherwise

generated between the parties for which payment may be made in whole or in part under Medicare, Medicaid or other Federal health care programs."[10]

AKS Prosecutions Involving Commission–Based Payments

Because payments made in exchange for federal health care program referrals implicate the AKS, and because various types of health care entities, such as home health agencies, hospices, pharmacies, and laboratories, often pay individuals on a commission basis for marketing/sales activities, it is not surprising that these types of arrangements are often the subject of enforcement actions. Entities can attempt to avoid liability under the AKS by ensuring that the arrangement falls within the employment safe harbor, which requires that the marketer be a bona fide *employee* of the entity under common law rules applicable to employer-employee relationships.[11]

Absent bona fide employment,[12] however, it is challenging for these entities to ensure that payments to independent contractors fall within a safe harbor. That's because, as discussed above, the safe harbor for personal services and management contracts does not apply where the compensation is determined in a manner that in any way takes into account the volume or value of referrals or business payable by a federal health care program. Put another way, if the entity pays the independent contractor in a way that takes into account the volume or value or federal health care program business (i.e., by paying the contractor a percentage of reimbursement received from the federal health care program or even a flat fee per referral), the government will likely argue that the arrangement does not qualify for safe harbor status and, if the requisite intent exists, both the payer and the payee will likely be viewed as having violated the AKS.

To illustrate this point, in an advisory opinion from 1998, OIG stated:

> Sales agents are in the business of recommending or arranging for the purchase of the items or services they offer for sale on behalf of their principals . . . any compensation arrangement between a Seller and an independent sales agent for the purpose of selling health care items or services that are directly or indirectly reimbursable by a Federal health care program potentially implicates the [AKS], irrespective of the methodology used to compensate the agent.[13]

Eight years later, OIG reiterated its concern with these types of arrangements: "Percentage compensation arrangements are inherently problematic under the [AKS], because they relate to the volume or value of business generated between parties."[14]

Because payments made in exchange for federal health care program referrals implicate the AKS, and because various types of health care entities, such as home health agencies, hospices, pharmacies, and laboratories, often pay individuals on a commission basis for marketing/sales activities, it is not surprising that these types of arrangements are often the subject of enforcement actions.

For these reasons, as one can see by reviewing the cases cited below, the government has initiated a number of investigations and prosecutions under the AKS where an entity pays an independent sales representative on a referral-based commission.

The Relevant Decisionmaker Test

These AKS prosecutions based upon commission-based payments to marketers have led to the development of case law on the issue of the proper scope of the AKS. Specifically, can a commission-based payment to a non-physician marketer violate the AKS? If so, under what circumstances? As with most questions in the area of health care fraud and abuse, the correct answer to both questions is, of course, "it depends."

Fifth and Seventh Circuits: *Miles* and *Polin*

The seminal case is *United States v. Miles*, which the Fifth Circuit decided in 2004.[15] The defendants in *Miles* were convicted on various counts, including violations of the AKS.[16] The entity at issue in *Miles*—APRO—was a home health company that paid the defendants' marketing firm—Premier—to distribute information regarding the entity's home health services to doctors.[17] Specifically, the marketing firm would deliver "literature and business cards to local medical offices" and, from time to time, "plates of cookies to doctors' offices."[18] According to the Fifth Circuit's opinion:

> When a physician determined that home health care services were needed for a patient, the physician's office might contact [the defendant], who would then furnish APRO with the patient's name and Medicare number for billing purposes. APRO paid Premier $300 for each Medicare patient who became an APRO client as a result of Premier's efforts.[19]

The government claimed that APRO's payments to Premier constituted unlawful kickbacks in violation of the AKS, and the defendants were convicted.[20] It

was not disputed that "APRO's payments to Premier were based on the number of Medicare patients that APRO secured from Premier's activities."[21] The Fifth Circuit stated that the "only issue in dispute is whether Premier's activities constituted referrals within the meaning of the statute."[22]

The defendants in *Miles* argued that they could not have violated the AKS because Premier "never actually referred anyone to APRO, but simply engaged in advertising activities on behalf of APRO."[23] They argued that the AKS was "designed to ensure that a doctor's independent judgment regarding patient care is not compromised by promises of payment from Medicare service providers" and that "Premier did not unduly influence the doctors' decisions."[24]

On appeal, the Fifth Circuit agreed with the defendants, holding that there was no evidence "that Premier had any authority to act on behalf of a physician in *selecting* the particular home health care provider."[25] The Fifth Circuit cited testimony that was presented at trial that "Premier had no role in selecting the particular home health care provider but that the decision was made by the doctor's office staff from among ten agencies, including APRO."[26] The Fifth Circuit held that Premier simply supplied promotional materials to doctors and it was only *after* the doctor decided to send a patient to APRO that the doctor's office contacted Premier, which then supplied the necessary billing information to APRO and collected payment.[27] According to the Fifth Circuit, "[t]he payments from APRO to Premier were not made to the relevant decisionmaker as an inducement or kickback for sending patients to APRO."[28]

While the holding in *Miles* certainly seemed to limit the types of arrangements that could properly be considered violations of the AKS, the Fifth Circuit did acknowledge that there were certain situations "where payments to non-doctors would fall within the scope of the statute."[29] As an example, the Fifth Circuit cited the Seventh Circuit's earlier decision in *United States v. Polin*.[30] *Polin* involved payments by a pacemaker monitoring service to a pacemaker sales representative based on the number of patients that the sales representative signed up with the service.[31] In *Polin*,

> [t]he salesman's responsibilities included selling pacemakers, attending implant procedures, and making sure that patients were monitored following implantation. In fulfilling this latter responsibility, the salesman testified that when a physician decided to use an outside service, the salesman would contact a service provider and set up the monitoring for the patient. That is, the salesman would make the decision as to *which* service provider to contact for the patient.[32]

According to the Fifth Circuit, because the salesman in *Polin* was the "relevant decisionmaker and his judgment was shown to have been improperly influenced by the payments he received from the monitoring service," the Seventh Circuit properly upheld the convictions in that case.[33] But *Polin* was "simply different" from *Miles*, the Fifth Circuit held.[34] The Fifth Circuit concluded that APRO's payments to Premier were not illegal kickbacks under the AKS and reversed the defendants' convictions on those counts.[35]

Limiting the *Miles* Holding

The Fifth Circuit has since cautioned lower courts that its ruling in *Miles* should not be construed broadly. Instead, the Fifth Circuit has made clear that *Miles* "stands for a narrow legal proposition: Where advertising facilitates an independent decision to purchase a healthcare good or service, and where there is no evidence that the advertiser 'unduly influence[s]' or 'act[s] on behalf' of the purchaser,' the fact that the healthcare provider compensates the advertiser, on its own, is insufficient to support a conviction under the [AKS]."[36]

In *United States v. Shoemaker*, the Fifth Circuit appears to have significantly limited the *Miles* holding in affirming an AKS conviction.[37] Defendant Shoemaker was the Chief Operating Officer of a community hospital, and defendant Garner owned and operated a nurse staffing business. The hospital entered into a contract with Garner's nurse staffing business and the evidence presented at trial demonstrated that Garner paid the Chairman of the hospital's board of trustees (Chandler) $5 for every nursing hour his company spent at the hospital in return for Chandler ensuring that the

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hospital would continue to use Garner's company for contract nurses.[38] The evidence showed that the parties to this arrangement created false invoices to make it appear that the payments were made for accounting services.[39]

The district court granted judgments of acquittal on the AKS counts of the indictment on the grounds that there was no evidence that the payee was a "relevant decisionmaker" pursuant to the holding in *Miles*.[40] The Fifth Circuit reversed the district court, concluding that the holding in *Miles* was inapplicable. Specifically, the court held that, unlike in *Miles*, *Shoemaker* did not deal with advertising services.[41] Instead, the evidence demonstrated that the payments were designed to induce Chandler to "recommend" Garner's nursing company.[42] According to the Fifth Circuit:

> That is, in paying Chandler, Garner was not asking for a brochure bearing his company's name to be distributed to [hospital] staff; rather, enough evidence showed that he wanted Chandler to exploit his personal access to [hospital] executives, including Shoemaker, and to ensure that [the hospital] favored Garner's company when it chose nursing services. This conduct is an archetypal example of the undue influence prohibited by the statute.[43]

The court in *Shoemaker* held that the real focus of *Miles* was not on labels, but on intent; i.e., "whether the evidence could establish intent to induce 'referrals.'"[44] The court held that this focus on intent "accords with Congress's concerns in enacting the statute—to broaden liability to reach operatives who leverage fluid, informal power and influence."[45] The court in *Shoemaker* concluded that there was sufficient evidence to support a conviction for conspiring to violate the AKS and that the district court erred in granting the defendants' motion for judgment of acquittal.[46]

Eleventh Circuit: *Vernon* and *Starks*

In 2013, the Eleventh Circuit also examined the holding in *Miles* in deciding whether certain AKS convictions were proper. In *United States v. Vernon*, the defendants were convicted of health care fraud and AKS violations.[47] The defendants were executives of Medfusion, a specialty pharmacy that filled prescriptions for hemophilia medications.[48] The government in *Vernon* alleged that, in order to gain more Medicaid business, the pharmacy "made sizable payments to individuals and businesses if they would refer their hemophiliac clients to Medfusion for prescription filling."[49]

Specifically, Medfusion would pay 45% to 50% of its profits to Lori Brill, who worked as a "patient advocate" for hemophiliac patients, attending medical appointments with her clients, helping them with routine life tasks, and assisting them in filling prescriptions.[50] Brill referred her hemophilia clients to Medfusion for the filling of their medications.[51] "To retain control over where her clients filled their [hemophilia] medication prescriptions, Lori Brill continued to provide various services to her clients, serving as their patient advocate."[52]

In contrast to the lack of decisionmaking authority by the defendants in *Miles*, the evidence elicited at trial in *Vernon* demonstrated Brill's overwhelming control over her patients' decisions. For example, several of Brill's former clients testified that Brill would take them to doctors' appointments, speak with doctors on their behalf, receive prescriptions from doctors and ensure they were filled, and call her clients to ensure that they had an adequate supply of the medication on hand.[53] One former client testified that when a doctor wrote a prescription, Brill would take the prescription from the patient and bring it to the pharmacy herself, where she would have them filled.[54]

While the Eleventh Circuit in Vernon rejected the defendants' attempt to shoehorn the facts of their case into the holding of Miles, it is important to note that the Eleventh Circuit did not reject Miles' "relevant decisionmaker" test.

On appeal, the defendants in *Vernon* argued that the conduct at issue did not violate the AKS because the payments at issue were made to Brill, a non-physician who could not "refer" patients to the pharmacy within the meaning of the AKS.[55] The Eleventh Circuit rejected this argument, holding that "the plain language of the statute is not limited to payments to physicians who prescribe medication."[56] The Eleventh Circuit cited the Seventh Circuit's decision in *Polin* and held that, like the defendant in *Polin*, Brill "was effectively responsible for deciding which specialty pharmacy to use for the filling of her [] patients' prescriptions."[57] Specifically, the Eleventh Circuit said that there was "overwhelming evidence" that Brill "had the capacity to, and did, refer their hemophiliac clients to Medfusion" for the filling of prescriptions.[58] In fact, the Eleventh Circuit noted that some of Brill's clients "did not even know which pharmacy filled their prescriptions because they gave control of that decision to Lori Brill."[59] The fact that Brill could not herself prescribe the medication was irrelevant, according to the Eleventh Circuit.[60]

Although the holding in Miles has not been expressly overruled by the Fifth Circuit, and has not been expressly rejected by any other circuit, it has certainly been limited.

In support of its decision, the Eleventh Circuit in *Vernon* also cited its earlier decision in *United States v. Starks*.[61] The court noted that, in *Starks*, it had affirmed AKS convictions based on payments made by a non-physician director of a drug addiction treatment center to two "community health aides" working for a nonprofit agency that advised pregnant woman about drug abuse treatment.[62] The community health aides, neither of whom were physicians, and neither of whom could prescribe treatment, were paid $250 for each patient that they referred to the treatment center.[63]

The Eleventh Circuit in *Vernon* rejected the defendants' reliance on *Miles*, holding that the facts in *Miles* were "materially different" from the facts in *Vernon*.[64] Unlike the defendants in *Miles*, the Eleventh Circuit held, Medfusion's payments *were*, in fact, made to the "relevant decisionmaker," Lori Brill, who had her own personal relationships with her clients "and decided where to fill her clients' prescriptions."[65]

While the Eleventh Circuit in *Vernon* rejected the defendants' attempt to shoehorn the facts of their case into the holding of *Miles*, it is important to note that the Eleventh Circuit did *not* reject *Miles*' "relevant decisionmaker" test. Instead, the Eleventh Circuit simply held that, even under that test, the conduct at issue fell within the purview of the AKS. The court in *Vernon* left open the possibility that it might adopt the relevant decisionmaker test to strike down a conviction in a case where the payments at issue were made to someone who did not exercise control over where referrals were sent.

District Court Decisions Distinguishing *Miles*

A number of federal district courts outside of the Fifth Circuit have cited, and distinguished, the *Miles* holding in opinions discussing the scope of conduct that falls within the purview of the AKS.

In *United States v. Krikheli*, for example, the defendant was charged with violating the AKS by personally, or through intermediaries, arranging for patients to be referred to a radiological testing facility in exchange for payments to the referring doctors and the defendant.[66] According to the government, the defendant arranged for doctors to send patients to the facility in exchange for monetary kickbacks.[67] At first, the defendant made these arrangements himself but at some point, he began to do so through two intermediaries, continuing to receive a commission for each referral arranged by the intermediaries.[68]

Krikheli moved to dismiss the charges against him, in part based on the relevant decisionmaker holding from *Miles*.[69] He argued that "only the doctors were decision-makers under the circumstances of their cases, and that 'any parts of the indictment alleging unlawful payments to non-doctors . . . must be dismissed."[70]

The district court in *Krikheli* rejected this argument. The court held that even if it were to apply the relevant decisionmaker test, it would not help the defendant because there was nothing to suggest that the defendant was "providing advertising or public relations services of the sort provided . . . in *Miles*."[71] Instead, the evidence showed that payments were made to doctors to induce them to refer patients to the facility and the fact that the defendant may have used intermediaries was not relevant since the AKS prohibits both direct and indirect payments.[72]

The district court in *United States v. George* also rejected a *Miles*-based argument.[73] The defendant in *George* owned a referral agency that entered into a written agreement with a home health company which, in part, called for the defendant's agency to "[v]isit doctors, hospital case managers, discharge planners or social workers and convince them to refer patients to the [home health company.]"[74] The defendant's agency received payment for these referrals.[75]

At a bench trial, the defendant argued that the arrangement in question was not covered by the AKS, citing *Miles, Polin,* and *Vernon*.[76] The district court in *George* distinguished the defendant's actions from the actions of the defendants in *Miles*. Specifically, the court held that George referred specific patients to the

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home health company, "effectively telling the patients to go there for home health services."[77] The district court in *George* also rejected the defendant's argument that the arrangement fell within the personal services and management contracts safe harbor.[78] Because the defendant was paid on a "per-patient basis," the compensation took into account the "volume of referrals" and, therefore, did not qualify for safe harbor status.[79]

Similarly, in *United States v. Iqbal*, the defendant, who managed a large number of medical practices, was charged with violating the AKS by attempting to enter into a "50/50 profit sharing" arrangement with a home health agency in exchange for referrals.[80] The government alleged that the primary purpose of the arrangement was "to induce the referral of patients insured by Medicare or Medicaid."[81] After a bench trial, the district court concluded that the government had met its burden of proving that Iqbal solicited remuneration "in the form of 50% of the profits generated by patients for whom he arranged referrals" and that "[t]he payments solicited were for the purpose of inducing" the referrals.[82]

Iqbal cited *Miles* and argued that he could not have violated the AKS because there were no payments to a "relevant decisionmaker."[83] The district court rejected this argument. First, the district court noted that *Miles* was subsequently "limited to its facts" by *Shoemaker*.[84] The district court also noted that Iqbal represented to the home health agency that he "could cause the doctors to make the referrals, and would do so if [the agency] agreed to pay him a share of the profits."[85] According to the court in *Iqbal*, "[t]his is a clear payment based on the value of the referrals, which is a violation of the law."[86]

The district court in *Iqbal* also noted that the Eighth Circuit had not followed *Miles*, but cited an Eighth Circuit opinion from 1996—*United States v. Jain*—affirming an AKS conviction "where the defendant had attempted to shield his receipts of kickbacks for referrals by using a contract purporting to pay him for non-existent marketing services."[87] The court concluded that the situation in *Jain* was very similar to the situation in *Iqbal* and that because Iqbal stated that he could influence referrals, the government had met its burden.[88]

The Current Viability of the Relevant Decisionmaker Test

Although the holding in *Miles* has not been expressly overruled by the Fifth Circuit, and has not been expressly rejected by any other circuit, it has certainly been limited.

In light of *Shoemaker* and other subsequent decisions, it is clear that the Fifth Circuit would be reluctant to apply the holding of *Miles* unless the facts are nearly identical to the facts at issue in that case. The same is true for other circuits, including the Seventh and Eleventh. Specifically, *Miles* appears to be viable only where payments were made to marketers who had no ability to influence where referrals were sent. By contrast, if the payee has the ability to exert such influence, such as through personal relationships with the referral source (as in *Shoemaker*) or through control over the patient (as in *Vernon*), courts will likely be reluctant to apply the holding in *Miles*.

Conclusion

The federal government continues to bring enforcement actions, both criminal and civil, against entities and individuals that enter into commission-based payment arrangements. Although courts around the country seem to have substantially limited the holding of *Miles* and have consistently distinguished factual patterns from the facts at issue in *Miles*, it is important for any defense lawyer representing a client in such an action to analyze the arrangement at issue, compare it with the arrangement at issue in *Miles*, and consider, where appropriate, moving to dismiss AKS charges where payments are made to individuals who cannot be considered "relevant decisionmakers."

Endnotes

1. 42 U.S.C. § 1320a–7b(b).
2. *Id.*
3. *Id.* Until February 2018, the maximum sentence for a violation of the AKS was five years in prison and $25,000. The Bipartisan Budget Act of 2018, signed into law on February 9, 2018, increased these criminal penalties to their current levels.
4. 31 U.S.C. § 3729 *et seq*. The AKS expressly states that, in addition to the penalties provided for by the AKS itself, a claim to a federal health care program that includes items or services "resulting from" a violation of the AKS constitutes a "false or fraudulent claim" for purposes of the FCA.
5. 42 U.S.C. § 1320a–7a.
6. OIG Special Fraud Alert: Laboratory Payments to Referring Physicians, June 26, 2014, https://oig.hhs.gov/fraud/docs/alertsandbulletins/2014/OIG_SFA_Laboratory_Payments_06252014.pdf.
7. *Id. See also United States v. Borrasi*, 639 F.3d 774, 776 (7th Cir. 2011) (adopting "one purpose rule"); *accord United States v. Kats*, 871 F.2d 105, 108 (9th Cir. 1989); *United States v. McLatchey*, 217 F.3d 823, 835 (10th Cir. 2000).
8. 42 C.F.R. § 1001.952.
9. *Id.* § 1001.952 (i).
10. *Id.* § 1001.952 (d).
11. *Id.* § 1001.952 (i) and 26 U.S.C. § 3121(d)(2).
12. Importantly, while not the subject of this article, clinical laboratories will also have to contend with the Eliminating Kickbacks in Recovery Act, 18 U.S.C. § 220 (EKRA). EKRA prohibits essentially the same conduct as the AKS, but is broader in two very important respects. First, EKRA applies to payments that vary based on the volume or value of referrals, whether those payments are made to an employee or an independent contractor. *Id.* § 220(b)(2). Second, EKRA applies to both federal health care programs and commercial health plans. *Id.* § 220(a)(1). EKRA is narrower than the AKS in one respect—it applies only to referrals to clinical laboratories, clinical treatment facilities, and recovery homes. *Id.*
13. OIG Advisory Opinion No. 98-10, https://oig.hhs.gov/fraud/docs/advisoryopinions/1998/ao98_10.htm.
14. OIG Advisory Opinion No. 06-02, https://oig.hhs.gov/fraud/docs/advisoryopinions/2006/ao0602.pdf.
15. 360 F.3d 472 (5th Cir. 2004).
16. *Id.* at 474.
17. *Id.* at 479.
18. *Id.*
19. *Id.*
20. *Id.*
21. *Id.* at 480.
22. *Id.*
23. *Id.*
24. *Id.*
25. *Id.* (emphasis in original).
26. *Id.*
27. *Id.*
28. *Id.*
29. *Id.*
30. 194 F.3d 863 (7th Cir. 1999).
31. *Miles*, 360 F.3d at 480 (citing *Polin*, 194 F.4d at 864–65).
32. *Id.* (emphasis in original).
33. *Id.* at 481.
34. *Id.*
35. *Id.*
36. *United States v. Crane*, 781 Fed. App'x 331, 334–35 (5th Cir. 2019).
37. 746 F.3d 614 (5th Cir. 2014).
38. *Id.* at 617.
39. *Id..*
40. *Id.* at 626.
41. *Id.* at 628–29.
42. *Id.* at 629.
43. *Id.*
44. *Id.*
45. *Id.* at 629–30.
46. *Id.* at 630–31.
47. 723 F.3d 1234, 1240–41 (11th Cir. 2013).
48. *Id.* at 1241.
49. *Id.*
50. *Id.* at 1245.
51. *Id.*
52. *Id.*
53. *Id.* at 1245–46.
54. *Id..* at 1246.
55. *Id.* at 1254.
56. *Id.*
57. *Id.*
58. *Id.*
59. *Id.*
60. *Id.*
61. 157 F.3d 833 (11th Cir. 1998).
62. *Vernon*, 723 F.3d at 1255 (citing *Starks*, 157 F.3d at 835–37).
63. *Id.*
64. *Id.* at 1255.
65. *Id.*
66. 2009 WL 4110306, No. 08-CR-528, at *1 (E.D.N.Y. Nov. 24, 2009).
67. *Id.*
68. *Id.*
69. *Id.* at *4.
70. *Id.*
71. *Id*. at *6.
72. *Id.*
73. 171 F. Supp. 3d 810 (N.D. Ill. 2016).
74. *Id.* at 812.
75. *Id.*
76. *Id.* at 814.
77. *Id.*
78. *Id.* at 815.
79. *Id.* (citing 42 C.F.R. § 1001.952(d)(5)).
80. 2016 WL 520982, at * 1 (E.D. Mo. Feb. 10, 2016).
81. *Id.*
82. *Id.*
83. *Id.* at *3.
84. *Id.*
85. *Id.*
86. *Id.*
87. *Id..* (citing *United States v. Jain*, 93 F.3d 436 (8th Cir. 1996)).
88. *Id.*

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A Delicate Balance: New Privacy Challenges for Public Health Disclosures During the COVID-19 Pandemic

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Vladimir Edmondson, Senior Compliance Director and Chief Privacy Officer, OhioHealth

When enacting the Health Insurance Portability and Accountability Act of 1996 (HIPAA),[1] Congress ushered in a new generation of privacy protections for patients' health information and established a national framework for patient privacy. Since that time, the health industry has established robust privacy programs aimed at protecting patient data to comply with this sweeping legislation, as well as with corresponding state privacy laws that have cropped up throughout the country to protect a patient's right to privacy. One of the many important lessons learned during the COVID-19 pandemic may be the critical role of public health officials and their need to use patient information for responding to such a crisis. Considering the numerous parties involved in public health activities related to COVID-19, as well as the volume of relevant information, the balance between public health needs and an individual's right to privacy must be carefully considered.

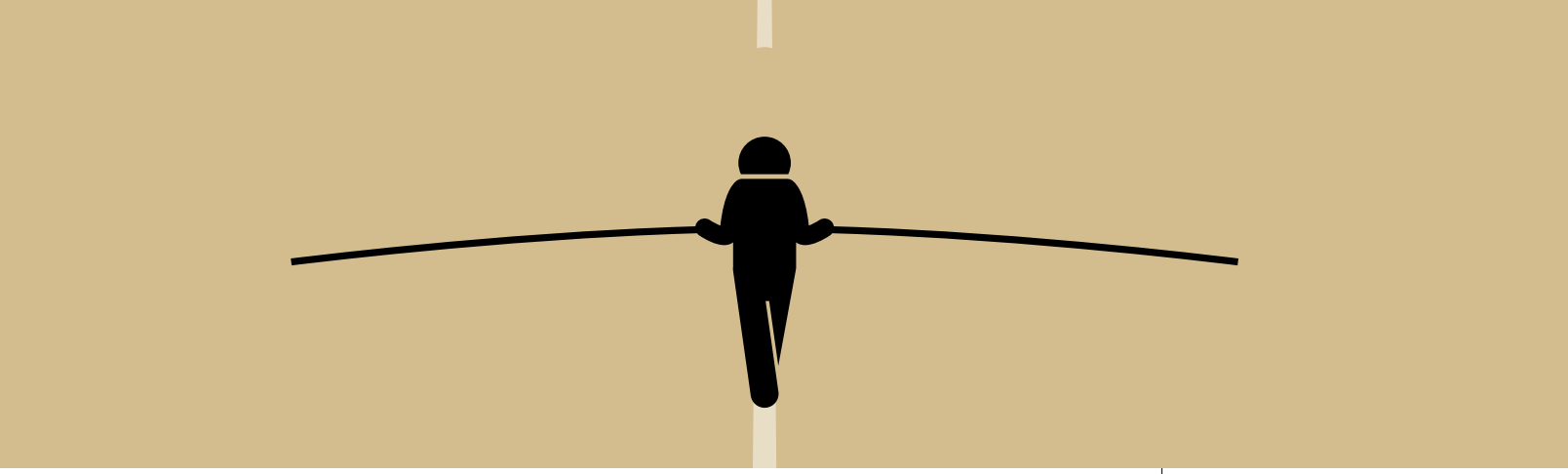
In general, federal privacy laws attempt to strike a delicate balance of protecting a patient's right to privacy "while allowing the flow of health information needed to provide and promote high quality health care and to protect the public's health."[2] This balance is accomplished through two primary mechanisms: (a) a broad preemption provision that saves most state public health laws from preemption under HIPAA; and (b) a number of exceptions to HIPAA for a wide range of public health activities. From the perspective of compliance and privacy officers, previous requests related to public health activities have been relatively straightforward, that is until this public health emergency. The need for access to patient information for public health activities designed to successfully respond to a public health emergency, such as the COVID-19 pandemic, may prove to be a different story considering the magnitude of the response required to win this battle.

HIPAA and Public Health

When drafting the HIPAA privacy provisions more than 20 years ago, Congress deferred most of the details to the U.S. Department of Health and Human Services (HHS) Secretary, who was charged with promulgating privacy regulations to address individual rights for health information, including when authorization would be required, the procedures to exercise such individual rights,[3] and when uses and disclosures should be required.[4] Congress was, however, very deliberate to ensure that the sweeping federal law did not impede public health activities by including the following statutory language: "Nothing in this part shall be construed to invalidate or limit the authority, power, or procedures established under any law providing for the reporting of disease or injury, child abuse, birth, or death, public health surveillance, or public health investigation or intervention."[5]

The Privacy Rule and Public Health

Pursuant to the authority granted under HIPAA, the Secretary issued extensive regulations to implement the privacy provisions of the statute referred to as The Standards for Privacy of Individually Identifiable Health Information (Privacy Rule).[6] The Privacy Rule regulates how a covered health plan, health care clearinghouse, and health care provider (Covered Entities)[7] may use and disclose protected health information (PHI) and establishes a number of privacy rights for individuals, including, most notably, a requirement that Covered Entities obtain an individual's authorization for a wide range of disclosures of the individual's PHI.[8] Within the vast public health network mobilized to combat the COVID-19 pandemic,[9] the use of PHI could span a large range of public health practice and research, including such traditional public health activities as program operations, public health surveillance, outbreak investigations, direct health services, and public health research.[10] Recognizing that "public health reports made by Covered Entities are an important



means of identifying threats to the health and safety of the public at large,"[11] the Privacy Rule incorporates a savings clause for conflicting state laws based on the statutory provision,[12] as well as several provisions exempting public health activities from these stringent requirements.[13]

Preemption of State Public Health Laws

An additional reason for the Administrative Simplification Regulations, which include the Privacy Rule, expressed in the 2000 Preamble, is "to improve the efficiency and effectiveness of health care delivery by creating a national framework for health privacy protection that builds on efforts by states, health systems, and individual organizations and individuals."[14] Consistent with the goal of Congress to establish a national framework for patient privacy that sets a "floor" or basic set of privacy protections for individuals,[15] the Privacy Rule makes clear that any state law that is "contrary"[16] to a specific federal law is preempted, unless the state law is more stringent.[17] For a law to be considered more stringent, it would need to provide greater privacy protections for the individual.[18] Considering that public health laws typically provide for uses and disclosures of PHI for public health reasons, they are unlikely to be more stringent. In support of Congress' goal of protecting this important function from preemption, the Secretary included several provisions allowing for disclosures of PHI for public health activities stating that "[t]he HIPAA Privacy Rule recognizes the legitimate need for public health authorities and others responsible for ensuring public health and safety to have access to protected health information to carry out their public health mission."[19]

First and foremost, a broad exception under the Privacy Rule protects state public health laws (and procedures established under such laws) from preemption if they provide for the "reporting of disease or injury, child abuse, birth, or death, or for the conduct of public health surveillance, investigation, or intervention."[20] All other state laws also may be protected from preemption if the Secretary determines that the law is necessary for "purposes of serving a compelling need related to public health, safety, or welfare" and "that the intrusion into privacy is warranted when balanced against the need to be served."[21] Although these provisions would likely protect many state public health activities, there are two notable limitations. First, the savings clause only applies to state-related laws and activities in contrast to the statutory provision that applies to *any* laws.[22] Second, it is conceivable that novel public health activities in response to the COVID-19 pandemic may not be easily tied to an underlying state law. From a practical standpoint, the impact of these limitations is substantially mitigated by the broad exceptions under the Privacy Rule for public health activities.

The Public Health Exceptions

In addition to the aforementioned savings clause, the Privacy Rule includes a number of exceptions that permit Covered Entities to disclose PHI for a broad list of public health activities without obtaining patient authorization or providing the patient an opportunity to agree or object.[23] These exceptions allow for uses and disclosures of PHI that would not have met the limited language of the savings clause. For example, these exceptions are not predicated on a state law that mandates disclosure of PHI for public health activities, nor do they all require state involvement. Rather, they allow Covered Entities *to decide* whether to disclose PHI for public health reasons. The exceptions most relevant to the COVID-19 pandemic are discussed below.

Public Health Authorities. The first exception is for disclosures to public health authorities.[24] In addition to the standard reporting of disease, such as positive COVID-19 tests, or vital events such as COVID-19 related deaths, this exception allows Covered Entities to make disclosures for public health surveillance, investigations, and interventions if certain conditions are met.

Under this exception, a Covered Entity must meet a two-prong test before using or disclosing PHI without

patient authorization, including that the entity seeking the information is:

- A *public health authority*; and
- *Authorized by law* to collect or receive such information for the purpose of preventing or controlling disease, injury, or disability.[25]

Under the Privacy Rule, a *public health authority* is defined as an agency or authority of the United States, a state, a territory, a political subdivision of a state or territory, or an Indian tribe responsible for public health matters as part of its official mandate.[26] This definition extends to a person or entity acting under a grant of authority from or contract with such public agency.[27] Interestingly, the Covered Entity may also disclose PHI to a foreign official acting in collaboration with a public health authority if directed to by a public health authority,[28] which actually broadened the scope of allowable public health authority disclosures from the original Notice of Proposed Rule Making issued in November 1999.[29] This last-minute change to the final Privacy Rule in 2000, allows Covered Entities to disclose PHI to a foreign government agency that is, for example, collaborating with the Centers for Disease Control and Prevention to limit the spread of infectious disease—yet again underscoring the value that the Privacy Rule placed on the importance of public health exceptions.[30]

In addition to being a public health authority, the entity seeking the information must be "authorized by law" to collect or receive the information.[31] Recognizing that public health authorities operate under broad mandates to protect the health of their constituent populations, the Secretary has interpreted the phrase "authorized by law" to mean that a legal basis exists for the activity, not that there is a specific law that authorizes the collection of the information requested.[32] Further, the Secretary referred to the phrase as "a term of art" that includes both actions that are permitted and actions that are required by law.[33]

This broad exception, coupled with the savings clause for public health laws, provides Covered Entities with significant regulatory relief from HIPAA necessary to respond to most governmental requests for PHI in public health emergencies such as the current one. In addition, the Office for Civil Rights (OCR), the federal agency responsible for enforcing HIPAA, expanded application of this exception to business associates during the COVID-19 pandemic in its *Notification of Enforcement Discretion*.[34] In this notification, OCR announced that it would not impose penalties for violations of certain provisions of the Privacy Rule for public health and health oversight activities during the COVID–19 pandemic, including the restrictions placed on business associates that their use and disclosure of PHI is limited to what is permitted under the contract (or required by law).[35]

In light of the number of agencies engaged in the pandemic response, however, it is possible that a Covered Entity may receive a request from a third party that is not authorized by law to receive such disclosures. In such an event, the Covered Entity must ascertain whether another exception applies.

FDA Regulated Products or Activities. Covered Entities may disclose PHI to individuals responsible for certain activities related to the quality, safety, or effectiveness of Food and Drug Administration (FDA) regulated products or activities.[36] Such purposes include:

- To collect or report adverse events, product defects or problems, or biological product deviations;
- To track FDA-regulated products;
- To enable product recalls, repairs, or replacement, or lookback; or
- To conduct post-marketing surveillance.[37]

This exception is particularly important considering the volume of Emergency Use Authorizations (EUAs) issued by the FDA for various diagnostic, therapeutic, and protective medical devices in response to the COVID-19 pandemic that require increased rigor around monitoring and reporting to ensure patient safety.

Contact Tracing. A lessor known exception under the Privacy Rule relates to contact tracing.[38] Depending on the respective state or local law, Covered Entities may disclose PHI *to a person* who may have been exposed to COVID-19 or may otherwise be at risk of contracting or spreading COVID-19 if the Covered Entity or public health authority is authorized by law to notify such person as necessary in the conduct of a public health intervention or investigation.[39] Although contact tracing is traditionally managed through departments of health, Covered Entities may be asked to assume a greater role during the COVID-19 pandemic in light of the magnitude of the exposure. Considering the potential for increased privacy concerns with contact tracing in which members of the public are notified about another's health status, the Covered Entity should make sure that any such activity is specifically authorized by state or local law or delegated by an agency authorized by law to engage in such activity.

Workplace Health. Another exception that may be put to the test during the COVID-19 pandemic is the workplace health exception that allows Covered Entities to disclose PHI to a patient's employer provided certain strict requirements are met.[40] Similar to the exception for contract tracing, there are significant risks associated with this type of disclosure and Covered Entities should carefully consider the following requirements:

- The *Patient* must be a member of the workforce of the employer and be provided advanced written notice by the Covered Entity that the PHI will be disclosed to the employer;[41]
- The *PHI* is limited to only *findings* concerning a work-related illness or injury or a workplace-related medical surveillance;
- The *Covered Entity* must be a covered health care provider who provides health care to the individual at the request of the employer, such as through an onsite employee clinic; and
- The *Employer's* need for obtaining the PHI is to conduct an evaluation relating to medical surveillance of the workplace or to record such work-related illness or injury in order to comply with certain Occupational Safety and Health Administration and other similar reporting obligations, including state reporting obligations.[42]

Although these exceptions provide relief from the Privacy Rule requirements related to obtaining patient authorization and providing opportunity to object, the remaining requirements still apply. For example, to the extent a Covered Entity makes a disclosure under any of these exceptions, it still must comply with the "minimum necessary" rule and limit the amount disclosed to that which is reasonably necessary to accomplish the purpose for which the request is made.[43] A Covered Entity may, however, reasonably rely on representations by the public official or other Covered Entity that the information requested is the minimum necessary for the stated purpose(s).[44]

Additional Exceptions

In addition to the traditional public health exceptions under the Privacy Rule, other exceptions under the Privacy Rule may apply to disclosures during this pandemic. For example, OCR recently issued guidance regarding *Disclosures to Law Enforcement, Paramedics, Other First Responders and Public Health Authorities* (*First Responder Guidance*), which maintained that "[a] covered entity may disclose PHI to a first responder who may have been exposed to COVID-19, or may otherwise be at risk of contracting or spreading COVID-19, *if the covered entity is authorized by law, such as state law, to notify persons as necessary in the conduct of a public health intervention or investigation.*"[45] The same guidance reminded Covered Entities that under certain circumstances, however, more than one provision of the Privacy Rule may apply to a use or disclosure. To that end, OCR clarified application of the broadly constructed and interpreted provision of the Privacy Rule that allows for uses or disclosures *to avert a serious threat to health or safety to a person or the public*.[46] The *First Responder Guidance* explained that Covered Entities may, consistent with applicable law and standards of ethical conduct:

> disclose PHI to prevent or lessen a serious and imminent threat to a person or the public, when such disclosure is made to someone they believe can prevent or lessen the threat, which may include the target of the threat. For example, HIPAA permits a covered entity, consistent with applicable law and standards of ethical conduct, to disclose PHI about individuals who have tested positive for COVID-19 to fire department personnel, child welfare workers, mental health crisis services personnel, or others charged with protecting the health or safety of the public if the covered entity believes in good faith that the disclosure of the information is necessary to prevent or minimize the threat of imminent exposure to such personnel in the discharge of their duties.[47]

The presumption of good faith for uses or disclosures to avert a serious threat to health or safety is met under the Privacy Rule if the Covered Entity's belief that led to such use or disclosure is based on its actual knowledge or in reliance on a credible representation by a person with apparent knowledge or authority.[48] In a pandemic, the Privacy Rule's permissive disclosure to prevent or lessen a serious or imminent threat to the health or safety of the person or the public may be the most often employed tool for good faith uses and/or disclosures that may or may not neatly fit within the Privacy Rule's public health exceptions.

The Road Ahead

When establishing the federal framework for the privacy of health information over two decades ago, Congress and the Secretary clearly considered both a patient's right to privacy and public health needs and attempted to balance the two through statutory and regulatory provisions. Albeit complex, these provisions cover a wide range of public health-related activities and have arguably had a relatively limited impact on patient privacy rights. As these provisions are put to the test during the COVID-19 pandemic, it will be important for compliance and privacy officers to remain

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Vladimir Edmondson, MPAff., CHC, serves as OhioHealth's Senior Compliance Director & Chief Privacy Officer. In this role, Mr. Edmondson is responsible for all aspects of OhioHealth's Privacy Compliance Program as well as the infrastructure of the Corporate Ethics & Compliance Program. He joined OhioHealth in January 2015 after spending more than a decade in the Institutional Compliance Office at The University of Texas MD Anderson Cancer Center, where Mr. Edmondson served as the Director of Compliance Programs.

vigilant to protect this delicate balance. To that end, compliance and privacy officers should be mindful that any state orders declaring mandatory public health disclosures contemplate that such disclosures are actually for "the reporting of disease or injury, child abuse, birth, or death, or for the conduct of public health surveillance, investigation, or intervention,"[49] which should be evident upon a close reading of the order. Privacy officers must also recognize the benefit and best practice of tracking any activities related to state-ordered mandatory public health disclosures, aside from their obligation to specifically account for any such disclosure at the patient's medical record level.

The views expressed in this article do not necessarily express the views of OhioHealth.

Endnotes

1. Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104–191, H.R. 3103, 104th Cong.
2. Office for Civil Rights (OCR) Privacy Brief, *Summary of the HIPAA Privacy Rule,* Last Revised May 2003, https://www.hhs.gov/hipaa/for-professionals/privacy/laws-regulations/index.html.
3. Health Insurance Portability and Accountability Act of 1996, Sec. 264, Pub. L. No. 104–191, H.R. 3103, 104th Cong.
4. Standards for Privacy of Individually Identifiable Health Information, 65 Fed. Reg. 82462, 82470 (Dec. 28, 2000) (codified at 45 C.F.R. pt. 164) (preamble).
5. 42 U.S.C. § 1320d–7(b).
6. 45 C.F.R. pts. 160, 162, 164.
7. *Id.* § 160.103.
8. *Id.* §§ 160.502 – .530.
9. The public health system includes public health agencies at state and local levels, health care providers, public safety agencies, human service and charity organizations, environmental agencies and organization, and a variety of related organizations. *See* Centers for Disease Control and Prevention, *The Public Health System & the 10 Essential Public Health Services* (Last Revised May 21, 2020), https://www.cdc.gov/publichealthgateway/publichealthservices/essentialhealthservices.html.
10. Centers for Disease Control and Prevention and the U.S. Department of Health and Human Services, *HIPAA Privacy Rule and Public Health* (Page Converted Apr. 11, 2003), https://www.cdc.gov/mmwr/preview/mmwrhtml/m2e411a1.htm
11. OCR, *Guidance: Disclosures For Public Health Activities* (Dec. 3, 2002, Revised Apr. 3, 2003), https://www.hhs.gov/sites/default/files/ocr/privacy/hipaa/understanding/special/publichealth/publichealth.pdf.
12. 45 C.F.R. §§ 160.201 – .205.
13. *Id.* § 164.512.
14. Standards for Privacy of Individually Identifiable Health Information, 65 Fed. Reg. 82462, 82463 (Dec. 28, 2000) (codified at 45 C.F.R. pt. 164) (preamble).
15. *Id* at 82462.
16. "Contrary" state laws are those that meet a two-prong test: (1) it would be impossible to comply with both the state and federal requirements; and (2) the provision of state law stands as "an obstacle to the accomplishment and execution" of the respective Privacy Rule. 45 C.F.R. § 160.202.
17. *Id.* § 160.203.
18. *Id.*
19. OCR, *Guidance: Disclosures For Public Health Activities* (Dec. 3, 2002, Revised Apr. 3, 2003), https://www.hhs.gov/sites/default/files/ocr/privacy/hipaa/understanding/special/publichealth/publichealth.pdf.
20. 45 C.F.R. § 160.203(c).
21. *Id.* § 160.204.
22. 42 U.S.C. § 1320d–7(b).
23. 45 C.F.R. § 164.512.
24. *Id.* § 164.512(b)(1).
25. *Id*
26. *Id*. at § 164.501 Definitions.
27. *Id.*
28. *Id.*
29. Standards for Privacy of Individually Identifiable Health Information, 64 Fed. Reg. 59918, 60056 (Nov. 3, 1999) (proposed).
30. Standards for Privacy of Individually Identifiable Health Information, 65 Fed. Reg. 82462, 82525 (Dec. 28, 2000) (codified at 45 C.F.R. pt. 164) (preamble).
31. *Id*. at § 164.512(b)(1).
32. Standards for Privacy of Individually Identifiable Health Information, 64 Fed. Reg. at 59929.
33. *Id.*
34. *Notification of Enforcement Discretion Under HIPAA To Allow Uses and Disclosures of Protected Health Information by Business Associates for Public Health and Health Oversight Activities in Response to COVID–19*, Apr. 2, 2020, https://www.hhs.gov/hipaa/newsroom/index.html, (published 85 Fed. Reg. 19392 (Apr. 7, 2020)).
35. *Id.*; *see also* 45 C.F.R. § 164.502(a)(3).
36. 45 C.F.R. § 164.512(b)(3).
37. *Id.*
38. *Id.* § 164.512(b)(4).
39. *Id.* § 164.512(b)(1)(v).
40. *Id.* § 164.512(b)(v).
41. *Note* this would not include family members of employees who receive care at workplace clinics. *Id.* § 164.512(b)(1)(v).
42. *Id.* § 164.512(b)(1)(v)(C).
43. *Id.* § 164.514.
44. *Id.* § 164.514(3)(ii)(a).
45. OCR, *Guidance: COVID–19 and HIPAA: Disclosures to Law Enforcement, Paramedics, Other First Responders and Public Health Authorities* (Mar. 24, 2020), https://www.hhs.gov/sites/default/files/covid-19-hipaa-and-first-responders-508.pdf.
46. 45 C.F.R. § 164.512(j).
47. OCR, *Guidance: COVID–19 and HIPAA: Disclosures to Law Enforcement, Paramedics, Other First Responders and Public Health Authorities* (Mar. 24, 2020), https://www.hhs.gov/sites/default/files/covid-19-hipaa-and-first-responders-508.pdf. *See also* 45 C.F.R. § 164.512(j).
48. 45 C.F.R. § 164.512(j)(4).
49. 45 C.F.R. § 160.203(c).

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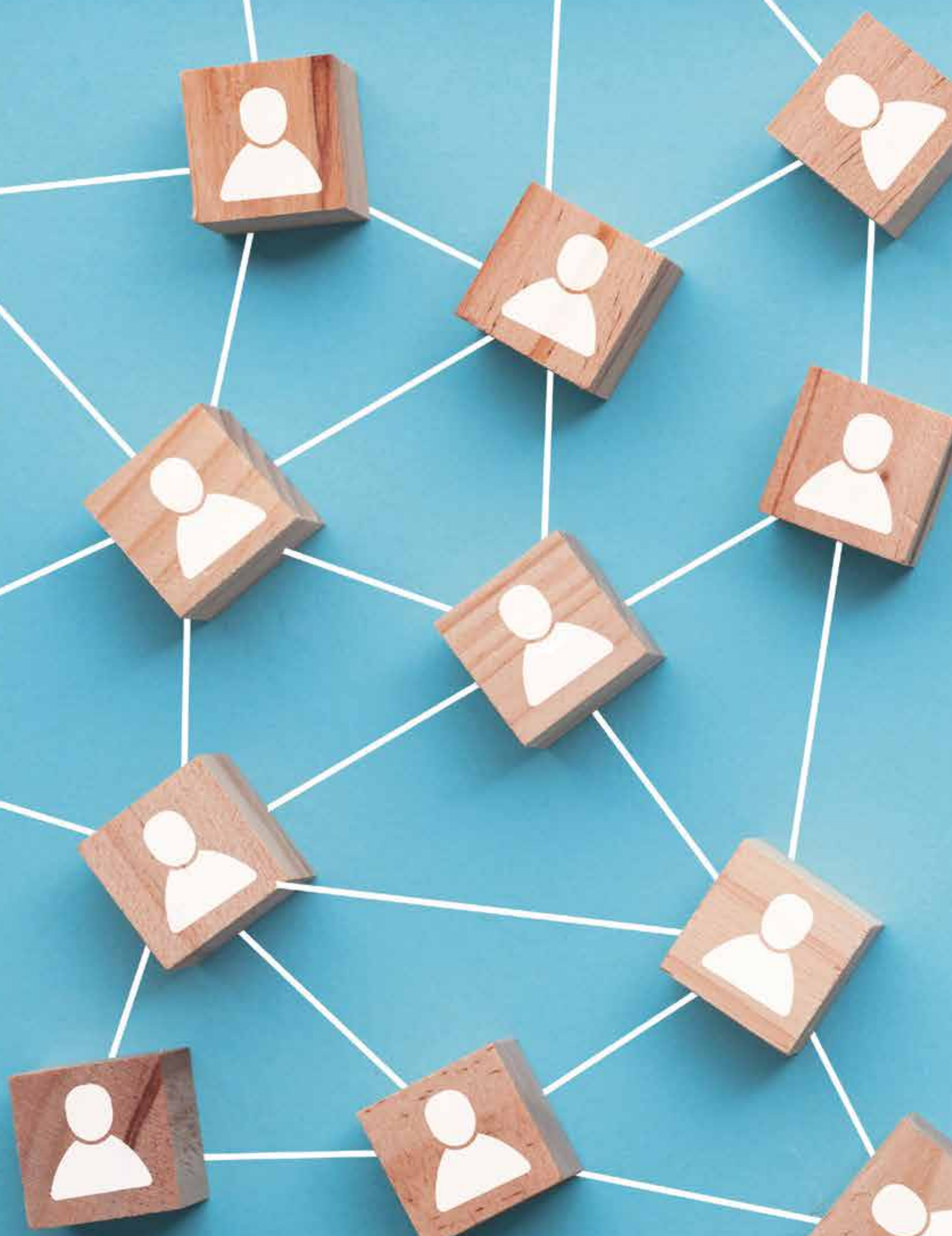

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Shannon B. Hartsfield is a health lawyer and the executive partner of Holland & Knight LLP's Tallahassee office. She focuses her practice on corporate compliance, particularly in the regulatory and data privacy areas. She is Board Certified in Health Law by The Florida Bar Board of Legal Specialization and Education. She advises clients on state and federal matters, including health care compliance programs, internal investigations, HIPAA and data privacy, cybersecurity, data breaches, cyber liability and reducing risk, consumer protection relating to privacy, patient engagement, informed consent, genetic testing, long-term care, telemedicine, health technology, fraud and abuse, licensure, EMTALA, electronic medical records, and prescription drug wholesaling.

If you have a burning question about some nuance of HIPAA, EMTALA, or other aspect of the alphabet soup that is stirred into health law and you have exhausted all resources in your office or firm, where can you turn? When your colleagues do not have the answer—or you are afraid to ask—the AHLA Communities gives you access to health law experts all over the country who are willing to help.

I have been an avid reader of the AHLA Communities, formerly the AHLA listservs, for more than 16 years. For a time, I helped moderate the Hospitals and Health Systems Forum, which involved encouraging participation and posting anonymous questions on behalf of others. On the AHLA Communities, you can post questions to and interact with hundreds of health lawyers and health law professionals from all over the country. AHLA includes many knowledgeable professionals who are generous with their time and expertise and who want to help their colleagues.

There are 16 Topical Communities, each of which addresses a niche area of health law such as fraud and abuse, health care delivery models, insurance, and, my personal favorite, health information. Chances are that one or more of the Communities are directly relevant to your practice or to your specific health law question. You may post queries to or read responses on relevant Communities through the AHLA website, or you can adjust your settings to receive emails directly in your inbox in real time or in a daily or weekly digest.

Some posts generate a lot of replies or initiate back-and-forth dialogue. Others seem to get little or no response. In those situations, it is highly likely that AHLA members have responded privately. Sometimes those who respond do not want to go on the record in such a public way, but they are willing to provide one-on-one assistance when they can.

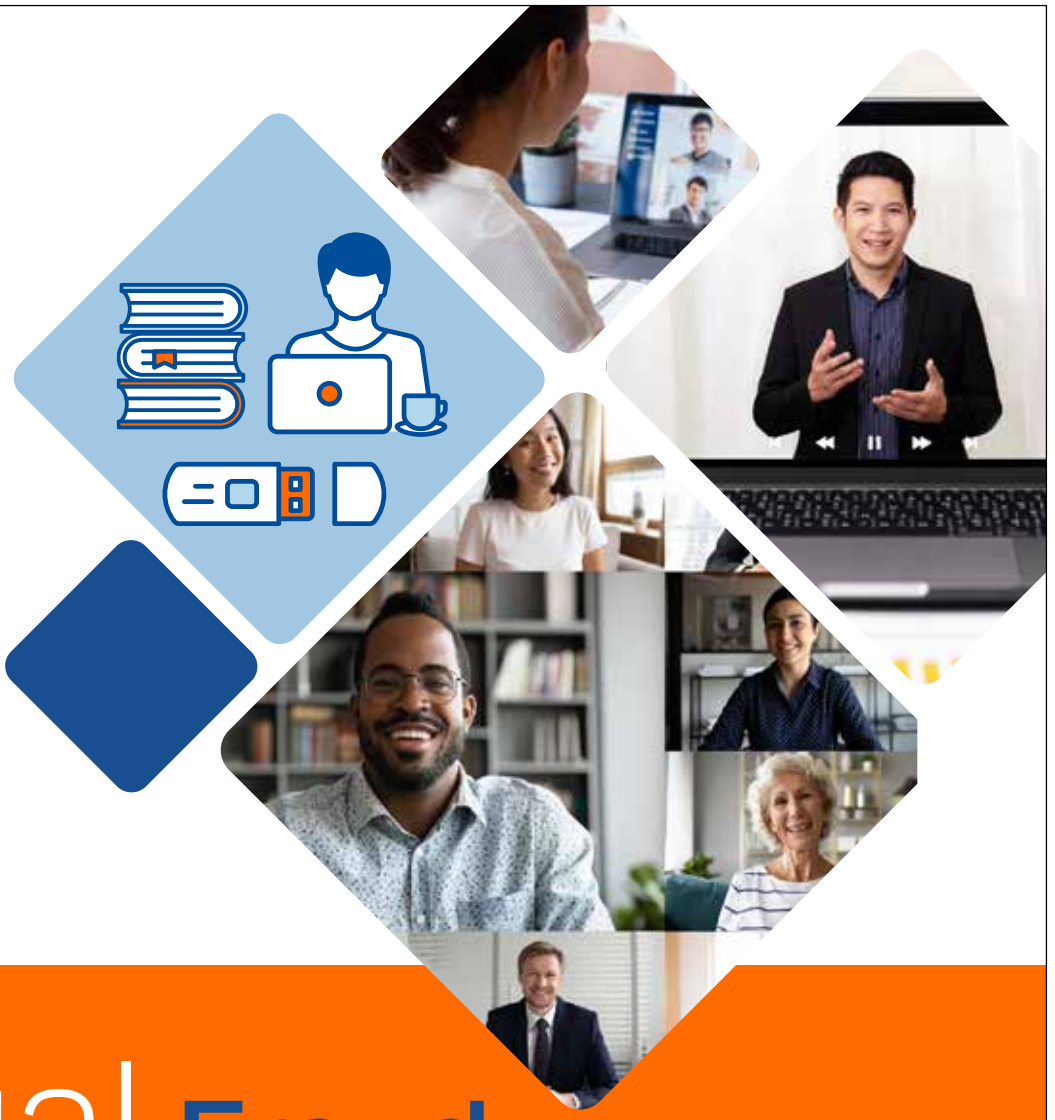
There have been many times when I have posed questions to a Community and received several extremely helpful responses through the public forum as well as through individual messages to my own email account. For example, I do a lot of work relating to HIPAA, and, thanks to the Communities, I have been able to engage in very useful offline discussions with fellow AHLA members on such esoteric issues as the meaning of "on behalf of" in the HIPAA business associate definition, and the meaning of the so-called "conduit exception."

There are several rules of the road for posting. You do not want to spam people with marketing pitches. Of course, you also want to make sure you do not inadvertently post something that could violate attorney/client privilege. The Communities are an ideal forum to post hypothetical questions that may inform real-life legal work you are handling, but you want to be sure that you are not seeking or providing actual legal advice.

Over the years, many of the posts on the various Communities have been archived and are easily searchable on the Communities website. When quick internet searches or even intensive searches of standard online legal resources have failed to shed light on some esoteric health law issue, the AHLA Communities archive has often come to the rescue. For example, there is not a lot of general guidance relating to the 2018 law relating to illegal remuneration for referrals to recovery homes, clinical treatment facilities, and laboratories, also known as the Eliminating Kickbacks in Recovery Act—or "EKRA." Searching the Communities for posts on EKRA reveals some helpful discussions on how laboratories may be dealing with the law, as well as references to in-depth articles on the topic. There is also some helpful dialogue regarding how providers might be able to handle negative online reviews without ending up using or disclosing protected health information in a way that violates HIPAA.

Sometimes online discussions from years ago will shed light on a current legal problem. So many AHLA members are willing to help each other and interact through the AHLA Communities. Personally, this is the most valuable aspect of my AHLA membership.

LEARN.
NETWORK.
ENGAGE.



Virtual Fraud and Compliance Forum

September 30–October 2, 2020

Join us for the annual Fraud and Compliance Forum. This important program brings together legal counsel, compliance officers, and government representatives for an invaluable learning and networking opportunity. We cover Stark, False Claims Act, Anti-Kickback Statute, and the enforcement efforts in these areas. The planning committee is working hard to put together a program that will address emerging regulatory trends, recent case law and legislative developments, and how they will affect legal and compliance practices in health care.

For More Information, visit:
www.americanhealthlaw.org/fraudcomplianceforum2020

From Drive Time to Thrive Time

Aaron Newcomer, PYA

Aaron Newcomer is a consultant within the valuation service line at PYA, a professional services firm serving clients in all 50 states. He specializes in compensation valuation and related consulting advisory services. Aaron also has experience with physician compensation arrangements, including their structure and design, and performing fair market value and commercial reasonableness analyses. In addition, he has a master's degree in health care management.

"Breakfast is the most important meal of the day." How many times have we heard that phrase throughout our lives? The focus of this article is not about nutrition—a public health degree does not qualify me to address that topic. The takeaway is that it matters how you start your day.

During the COVID-19 pandemic, many of us have been adjusting to new routines. Time I normally spend commuting in Atlanta morning traffic has been redirected toward additional workday preparation. Nevertheless, over the past couple months (as remote work has become the new norm for some), there have certainly been workdays when things did not go as planned. But there have also been days when mornings were filled with efficiency and early accomplishments. Carving out time in the morning to eat breakfast or work out allows me a few moments to think through a to-do list of tasks to accomplish before emails and office chats even begin. Taking these extra few minutes every morning keeps me focused on goals that otherwise may be deprioritized by incoming notifications.

As we are apt to do in any work environment, we may find ourselves losing focus and drive as the day progresses. For those working remotely, we may have found new freedom and flexibility in the way we approach the day's tasks and how we reenergize. Coffee breaks may turn into letting a dog outside, and microwaved leftovers in the break room may now be fresh lunches at home. I, for one, enjoy this flexibility, but to ensure breaks do not run longer than intended, it's important to establish a routine. Keeping a set lunch time or scheduled breaks throughout the day can help with accountability and offer a well-deserved reward after finishing a task. Structured workdays while working remotely, including time for breaks out of the chair and away from the computer, can offer a mental rest as well as a physiological boost.

Clearly, I would be remiss if I did not mention that structuring actual work is as important as structuring the environment around work. In professional services, impactful organizations rely on our expertise and creativity. However, the missions of these organizations require flexibility—there is no control over the needs that may arise, or, more importantly, *when* these needs require attention. Prioritizing by deadline is imperative but prioritizing by personal disposition to meet the deadline is a strategy that often is not considered. For example, if someone is a morning person, working on more complex tasks early and leaving more routine tasks for the afternoon may afford a sense of accomplishment early in the workday and minimize the time spent reprioritizing to-do lists. Another helpful strategy is to organize emails thoughtfully (e.g., move items out of the general inbox once completed, leaving a to-do list of emails front and center, where they cannot be overlooked).

In professional services, it can be difficult to find the end to a workday. Prior to the pandemic, non-remote employees may have shut down computers, driven home, and commenced their "after work" activities (i.e., spending time with family or friends, exercising, eating dinner, etc.). Even if one returns to work later in the evening, the physical and mental break this provides is tangible and beneficial. This distinction between during and after work activities may be even more blurred now, creating some confusion as to when the workday begins and ends. Setting a clear end to a workday is equally as important as setting a clear beginning. This may not always be possible, as some like to check email and handle tasks as they come in, but it can be beneficial to set boundaries to protect "after work" activities. My work computer stays in my home office. If an issue requires attention "after hours," then I go back to work in my home office.

Overall, staying organized is one way to maintain a healthy routine, during and after the pandemic. Depending on your own personal disposition, "organization" can have different meanings. Understanding when and how you work best is key to developing a successful routine. Working in professional services can be challenging, but a productive and structured ten-hour day feels better than an unproductive and disorganized eight-hour day.

Member News

Member Spotlight

Dionne C. Lomax
Managing Director, Antitrust and Trade Regulation
Affiliated Monitors Inc.
Boston, MA
dlomax@affiliatedmonitors.com

Which actor or actress would play you in a movie about your life?

Viola Davis would be a perfect fit. She has twice been named one of the 100 most influential people in the world by *Time* magazine, and having won an Academy Award, an Emmy Award, and two Tony Awards, is the first Black actress to achieve the Triple Crown of Acting. Like me, Davis approaches her craft with passion and excellence. I enjoy the depth of her characters and the authenticity and transparency she brings to each role. Not only that, I love her wardrobe in the hit TV series, "How to Get Away with Murder," where she portrays Annalise Keating, a law professor at a prestigious Philadelphia university. Like Annalise, I teach "Introduction to Law" at the Boston University Questrom School of Business, and I felt honored when two of my students told me that they loved my wardrobe, noting that I remind them of Annalise Keating. As a fashionista, their comparison of our wardrobes made me feel like I had finally arrived!

What was your most interesting job?

My most interesting job is one that I am currently enjoying as Managing Director of Antitrust and Trade Regulation at Affiliated Monitors, Inc. (AMI). AMI offers me a unique opportunity to combine my experience as a Trial Attorney at the U.S. Department of Justice Antitrust Division with my experience as a partner at several national law firms, to help companies facing challenges that may put them at risk for antitrust fines, treble damages, or reputational harm. I have always enjoyed serving clients and helping them find solutions to business challenges. Now, I partner with companies in a different way to help them improve compliance, which allows them to continue in business as stronger competitors, while also helping government agencies to be better stewards of public funds and fair competition.

What was your best vacation?

My best vacation was my trip to Australia. On that particular trip I tried so many new things and engaged in activities that previously terrified me. I climbed the Sydney Harbor Bridge, snorkeled for the first time in the Great Barrier Reef, and held a baby crocodile. Best of all, I had always had a childhood fascination of Koalas and waited a lifetime to finally hold one in my arms. It was cuddly and smelled just like the eucalyptus leaves they enjoy eating.

What movie have you watched multiple times?

I love the entire "Rocky" movie series, but my favorite is "Rocky III." I have seen it so many times I have memorized quite a bit of the dialogue. The movie resonates with me because it is a story of redemption and learning to regain the "eye of the tiger" when faced with a difficult challenge. I think we all need to adopt this approach at various times in life when faced with difficult circumstances. I have used it successfully myself on many occasions—thank you Rocky Balboa!!

What is the worst thing you've ever eaten?

My friends and family often joke that I eat like a five-year-old, which basically means that there are strict limits on the range of foods I am willing to consume. While in Australia I threw caution to the wind and tried kangaroo. Let's just say that I think kangaroos should only be enjoyed from afar.

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

After being in the private practice of law in six separate decades, **Paul R. DeMuro, PhD**, has accepted a position as the Chief Legal Officer, Health and Wellness, for the Royal Palm Companies in Miami, FL, where he is responsible for the legal work of the planned $60 million revolutionary medical center and the 100,000 square feet Center for Health + Performance. The project, part of a mixed-use downtown development, including the Legacy Hotel and Residences, is designed to be able to operate during future pandemics.

The Washington, DC office of global law firm K&L Gates LLP has added **Andrew D. Ruskin** as a partner in the health care practice. He joins the firm from Morgan Lewis & Bockius LLP. Mr. Ruskin concentrates his practice on advising hospitals, health systems, and pharmaceutical and medical device companies on a variety of Medicare and Medicaid regulatory, litigation, and transactional matters.

The National Society of Certified Healthcare Business Consultants (NSCHBC) has elected **David J. Zetter**, Senior Healthcare Consultant, to serve as President of the Society's 2020-2021 Board of Directors. Mr. Zetter is the President, founder, and lead consultant of Zetter HealthCare, LLC in Mechanicsburg, PA and has over 30 years of operational and health care experience. Mr. Zetter is nationally recognized for his presentations and expertise. He is well versed in health care regulatory requirements, revenue cycle management, credentialing and contracting, compliance, coding, and documentation.

Volunteer Recognition May 2020

AHLA has a wonderful tradition of members sharing their expertise and insight with each other. Members generously donate their time and energy through speaking, writing, and other service to the organization. Volunteers are the heart of the Association—thank you for all you do!

Programs and Distance Learning

Educational Call

Health Information and Technology Practice Group Educational Call
Jon Moore

Webinars

Medicaid Payment Reform – Uncertain Future of Supplemental Payments
Jennifer L. Evans, Polsinelli PC
Adam J. Hepworth, Foley & Lardner LLP

Hearing Rights for Advanced Practice Professionals
Katherine Markowski Dru, Hooper Lundy & Bookman PC
Nancy Roper Wilson

Crisis or Opportunity?: Hospitals Serving Special Populations and the Legal Challenges of Integrated, Accountable and Coordinated Care Part I: Convergence and Collaboration
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Michael N. Fine, Wyatt Tarrant & Combs LLP
Arthur J. Fried, Epstein Becker & Green PC
Christine L. White, Northwell Health

Lessons Learned from a CIA: From Implementation through Exit
Tamar Abell, TBA Consultants
William T. Mathias, Baker Donelson Bearman Caldwell & Berkowitz PC

State AG Enforcement Actions Against Health Providers
Kathleen Foote, Attorney General's Office, California Department of Justice
Alexis J. Gilman, Crowell & Moring LLP
Douglas Litvack, McDermott Will & Emery LLP
Kip Sturgis
Benjamin J. Ulrich, VMG Health

Cutting Edge Issues and Trends in Health Care Fair Market Value, Part II: Designing Compliant and Contemporary Physician Compensation Models That Support Value-Based Care
Andrea M. Ferrari, HealthCare Appraisers Inc
Kimberly A. Mobley, Sullivan Cotter and Associates Inc
Benjamin J. Ulrich, VMG Health
Joseph N. Wolfe, Hall Render Killian Heath & Lyman PC

AI and Health Law, Part IV: Privacy and Security
Adam H. Greene, Davis Wright Tremaine LLP
Alaap B. Shah, Epstein Becker & Green PC

Health Care Systems: Navigating the Tax Consequences for Nonprofit and For-Profit Structures
Amy Rhea Ciminello, Plante & Moran, PLLC
Travis F. Jackson, King & Spalding LLP

What Every Health Lawyer MUST Know About Working with Protection and Advocacy Organizations
David Carlson
Curt Decker
David Hutt
Eric J. Neiman, Lewis Brisbois Bisgaard & Smith LLP
Matthew W. Wolfe, Parker Poe Adams & Bernstein LLP

COVID-19 and Health Information Privacy: Waivers, Enforcement Discretion, and Outstanding Questions
Adam H. Greene, Davis Wright Tremaine LLP
Peter Kim, Providence Health & Services
Sean T. Sullivan, Alston & Bird LLP

Significant False Claims Act Case Law Developments and Preparing for FCA Enforcement in the Post-COVID-19 World
Robert S. Salcido, Akin Gump Strauss Hauer & Feld LLP

Publications, Resources, and Periodicals

Health Law Connections

Are Practice Losses Always Bad? Absolutely Not! (and CMS Agrees)
Albert D. Hutzler, HORNE LLP

30 Years After the ADA: Disability Discrimination in Health Care Under Section 1557 of ACA
Andrew C. Stevens, Arnall Golden Gregory LLP

Health Law Weekly

COVID-19 Telehealth Program Accepting Applications
Ashley L Thomas, Morris Manning & Martin LLP

Supreme Court Finds Federal Government Obligated to Pay Insurers ACA Risk Corridor Payments
Tamara Killion, Groom Law Group Chartered

Antitrust for Collaborations and Transactions in the Time of COVID-19
Alexis DeBernardis, Crowell & Moring LLP
Alexis J. Gilman, Crowell & Moring LLP

Department of Justice Launches National Nursing Home Initiative
Joanna Boyd, Venable LLP
Warren Hamel, Venable LLP
Thora A. Johnson, Venable LLP
Nick Mongelluzzo, Venable LLP
Gerry Sachs, Venable LLP
Evan Shea, Venable LLP
Courtney Sullivan, Venable LLP
Celia E. Van Lenten, Venable LLP

Devil Is in the Details: Staying Compliant While Accepting New HHS Distributions
Alexandra Busto, Nixon Peabody LLP
Laurie Tangora Cohen, Nixon Peabody LLP
Harsh P. Parikh, Nixon Peabody LLP
Sarah E. Swank, Nixon Peabody

Volunteer Pool and Complete Your Volunteer Profile

AHLA has revised the volunteer process. To opt-in to the Volunteer Pool and complete your Volunteer Profile, visit www.americanhealthlaw.org/volunteer. This will help us know what kind of volunteer opportunities you are interested in. Going forward, you will receive email alerts when we think you'll be a good fit for a new volunteer opportunity.

CMS Provides Risk Adjustment Flexibility Related to COVID–19
Jeff Joseph Wurzburg, Norton Rose Fulbright

Enforcement in the COVID–19 Era: The Government's Likely Playbook
Jason P. Mehta, Bradley Arant Boult Cummings LLP

NIH COVID–19 Support/Research at Academic Medical Centers and Other Facilities
Drew Allen Canning, Husch Blackwell LLC
Cori Casey Turner, Husch Blackwell LLP

F–A–Phew!: SBA FAQ Finally Clarifies Public Hospital Eligibility for the Paycheck Protection Program
Zachary J. Buxton, Baird Holm LLP

The FDA's Emergency Guidance for Mental Health and How Digital Health Manufacturers Are Responding
Bethany J. Hills, Morrison & Foerster LLP
Jean Nguyen, Morrison & Foerster LLP

Health Care Governance Challenges Towards (and Beyond) Re–Opening
Michael W. Peregrine, McDermott Will & Emery LLP

Health Care Risk Mitigation in the, Ever–Changing COVID Landscape
Elizabeth Dale Burrus, Spencer Fane LLP
Lauren Margaret Nelson, Spencer Fane LLP

Legal Publications

Health Law Watch
Scott Bennett, Coppersmith Brockelman PLC
Kathryn S. Burnett, Conner & Winters LLP
Gina W. Calabro, Ogletree Deakins
Lisa M. Campbell, Groom Law Group
Alisa Lieberman Chestler, Baker Donelson Bearman Caldwell & Berkowitz PC
Andrew J. Droke, Baker Donelson Bearman Caldwell & Berkowitz PC
Ben A. Durie, Hooper Lundy & Bookman PC
Alyssa Greenwald, Yale University
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Kristin Jenkins, Foley & Lardner LLP
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Alexandria N. Murphy, Baker Donelson Bearman Caldwell & Berkowitz PC
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Anil Shankar, Foley & Lardner LLP
Judith A. Waltz, Foley & Lardner LLP
Jeff Joseph Wurzburg, Norton Rose Fulbright

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COVID–19 GC Roundtable – Part 4
Mark A. Bonanno, Oregon Medical Association
Eric M. Fish, Federation of State Medical Boards
Sarah E. Swank, Nixon Peabody

Financial Stabilization and Recovery Options for Struggling Hospitals and Other Health Care Providers in the Age of COVID–19
Todd C. Baumgartner
Andrea M. Ferrari, HealthCare Appraisers Inc
Ross Norstrom

Fraud and Abuse: Government Enforcement in Lab Testing
Giovanni P. Giarratana, Bradley Arant Boult Cummings LLP
Somadina I. Nwokolo, Bradley Arant Boult Cummings LLP
Matthew E. Wetzel, GRAIL

The Lighter Side of Health Law
Norman G. Tabler Jr, Faegre Baker Daniels LLP (Ret.)

Transactions: Evolving Landscape of Vertical and Horizontal Integration
Carol Carden, PYA
Margaret J. Davino, Fox Rothschild LLP
Latoya Dawkins, Amgen

Practice Group Briefings

Highlights from the Final Notice of Benefit and Payment Parameters for the 2021 Benefit Year
Lee H. Rosebush, BakerHostetler
Don Walker, Texas Children's Hospital

Practice Group Bulletins

COVID–19 Alters the Landscape on Nursing Home Enforcement Activities
Mark A. Yost Jr, Lewis Brisbois

Fifth Circuit Affirms Inclusion of Medicare and Private Insurance Payments in Medicaid DSH Calculation; Children's Hospitals Petition Similar D.C. Circuit Holding to U.S.
Janus Pan, Bradley Arant Boult Cummings LLP

Interview with Bruce Sokler, Member and Co–Chair of the Antitrust Practice at Mintz
Lona Fowdur, Economists Inc
Bruce D. Sokler, Mintz Levin Cohn Ferris Glovsky & Popeo PC

Recently Issued Blanket Waivers Relax Stark Law and Anti–Kickback Statute Requirements for Real Estate Lease Arrangements with Referral Sources
Goran Musinovic, Realty Trust Group LLC
Grant T. Williamson, Realty Trust Group

Practice Group Toolkits

2020 Updated False Claims Act Toolkit
Jacqueline C. Baratian, Ascension
Brienne Marco, Spilman Thomas & Battle PLLC
Ayesha Mehdi, Spencer Fane LLP
Joseph Michael Miller, Shuttleworth & Ingersoll PLC

Update to HIT Enforcement Summary Tables
Adam H. Greene, Davis Wright Tremaine LLP
Jessica M. Lewis, UNC Health Care

Matched Mentors and Mentees

Mentors
Margia Corner
Jen McDowell
Pamela Jones

Mentees
Ashlee Germany
Amanda Ray
Danica Sun

Educating and Connecting: AHLA's New Learning Management Software Coming Soon

AHLA wants to keep pace with your educational needs, including offering additional educational opportunities online, providing learning that fits into your busy schedule, and creating learning paths that meet your unique goals. To accomplish this, AHLA is migrating from its current webinar platform to a full-featured learning management software (LMS) in early August.

This new, robust, and flexible Education Center will offer many benefits over our current webinar platform.

More Interactive Learning Experiences

We are incorporating the best authoring tools in the industry, which will allow our presenters to add interactions within the presentation to create a more interactive educational experience.

Integrated & Adaptive Learning Experiences

This platform will eventually host more than just webinars, allowing AHLA to develop learning experiences from across all our educational offerings, easily accessible in one location—part of AHLA's continued progression towards *a unified educational/learning platform*. Plus, we will be able to create a personalized learning experience by recommending courses based on your history in the LMS, past purchases, interests, and more.

An Intuitive Interface

This LMS was designed with you in mind, and the responsive design ensures the best and most engaging learning experience, regardless of the device used (desktop, tablet, or phone) or its features (screen size, platform, and orientation).

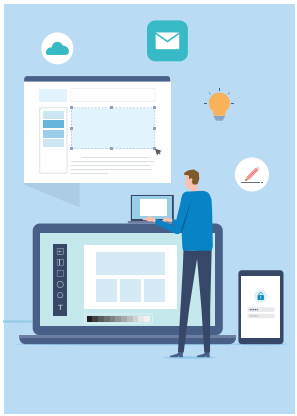
Room to Grow

Most importantly, this new LMS will be a flexible system, able to support AHLA's current educational programs and your future educational needs, including *additional flexibility with our on-demand offerings*.

During this migration, we understand how important access is to your previous education and reporting for your continuing education, so we have taken the following steps:

- The webinar platform at https://distancelearning.americanhealthlaw.org will be shut down on July 31, 2020 at 5:00 pm Eastern, with the new LMS platform at https://educate.americanhealthlaw.org tentatively launching on August 6, 2020.
- All on-demand products and webinar recordings from January 1–July 31, 2020 will be available on the new platform, while 2019 products will be available via the Health Law Archive for those who have active subscriptions. If you do not have an active subscription to the Health Law Archive and need access to an old webinar recording or on-demand product, please contact us at educate@americanhealthlaw.org.
- Your current AHLA login credentials will be the same credentials used to login to the new platform.
- Certificates for past webinars will be available by contacting ceu@americanhealthlaw.org and any certificates received in the new LMS platform will be available there.

We are excited about this new LMS and the enhanced educational offerings we plan to develop over the coming months and years. If you have any questions about the migration, please contact us at educate@americanhealthlaw.org.



Virtual Events

September 30-October 2

Fraud and Compliance Forum

October 22-23

Tax Issues for Health Care Organizations

November 5-6

Health Plan Law and Compliance Institute

11-13

Fundamentals of Health Law

For more information on all AHLA events and to register, go to www.americanhealthlaw.org/education-events or call (202) 833-1100, prompt #2.

AHLA's Online Career Center will allow you to:

Manage Your Career:

- Search and apply to more health law jobs than in any other job bank.
- Upload your anonymous resume and allow employers to contact you through the AHLA Career Center's messaging system.
- Set up Job Alerts specifying your skills, interests, and preferred location(s) to receive email notifications when a job is posted that matches your criteria.
- Access career resources and job searching tips and tools.
- Have your resume critiqued by a resume-writing expert.

Recruit for Open Positions:

- Post your job in front of the most qualified group of health law professionals in the industry.
- Promote your jobs directly to candidates via the exclusive Job Flash email.
- Search the anonymous resume database to find qualified candidates.
- Manage your posted jobs and applicant activity easily on this user-friendly site.

For more information and to start the journey to enhance your career or organization, please visit the AHLA Career Center at https://careercenter.americanhealthlaw.org.

Online Career Center Snapshot

2990+
Employers

940+
Job Seekers

30+
Open Positions

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MISSION

The Mission of the American Health Law Association is to provide a collegial forum for interaction and information exchange to enable its members to serve their clients more effectively; to produce the highest quality non-partisan educational programs, products, and services concerning health law issues; and to serve as a public resource on selected health care legal issues.

AHLA Diversity+Inclusion Statement

In principle and in practice, the American Health Law Association values and seeks to advance and promote diverse and inclusive participation within the Association regardless of gender, race, ethnicity, religion, age, sexual orientation, gender identity and expression, national origin, or disability. Guided by these values, the Association strongly encourages and embraces participation of diverse individuals as it leads health law to excellence through education, information, and dialogue.

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POSTMASTER: Send address changes and circulation inquiries to: AHLA, 1620 Eye Street NW, 6th Floor, Washington, DC 20006-4010.

ADVERTISING INDEX

Administrative Advocacy: A Tool to Aid Social Justice Reforms

DAVID S. CADE
Executive Vice President/CEO
dcade@americanhealthlaw.org

"Not everything that is faced can be changed, but nothing can be changed until it is faced."

James Baldwin, 1962

History teaches us that significant social changes generally follow periods of civil unrest, protest, and disruption. The Civil War preceded the 13th Amendment to abolish slavery in the United States. The Women's Suffrage movement ran for almost 100 years before the 19th Amendment was ratified to give women the right to vote. The Civil Rights movement prompted Congress to support a constitutional amendment to grant citizens living in the District of Columbia the right to vote in presidential elections. These movements were the product of persistent pressure by oppressed people and those who joined and supported their fight for liberation, equality, and dignity.

The shocking image of George Floyd's murder so unsettled, angered, and frustrated the people of the United States and communities around the world that civil unrest and protests erupted. This cultural inflection point refocused us on the systemic racism and indifference rooted in American culture, which has yet to address the history of slavery and is still racially divided.

We are experiencing another people's movement to change the systemic social and racial problems that have festered in this country for centuries. Mr. Floyd's murder focused immediate attention on police reform. It brought to light how racism is perpetuated by stereotypes, and the cries for change united with economic pressure are prompting reforms many thought would never happen.

Mr. Floyd's murder and the impact of COVID-19 have also underscored the nation's health care disparities. The CDC reports that African Americans contract the coronavirus at a rate approximately five times that of Whites. Health disparities among racial groups and the impact of social determinant factors on health outcomes and educational and economic successes and opportunities are not new. In 1966, Martin Luther King, Jr. stated that "[o]f all the forms of inequality, injustice in health care is the most shocking and inhumane."

As you consider the role you and your organizations can play in social justice reforms, it is important to have an Administrative Advocacy strategy as part of that effort. Organizations often have a Legislative Strategy that focuses on Congress or a state legislature. Administrative Advocacy, however, is a focused engagement with Executive Branch agencies, the equivalent state health department, or the local county or political district. Focused engagement means submitting comments to proposed rules and proactively informing agency officials about the challenges encountered as you administer and support programs within the regulatory environment.

Engagement also includes attending public hearings and submitting position papers. The goal is to humanize your cause and advocacy position. During my years in practice, including several years as a senior federal government policy official, Deputy General Counsel, and Acting General Counsel, I would often say that people need to see the problem. All too often individuals are regulating behaviors and industry practices without having spent time with the individuals or in the industry or community settings. I have often urged officials to visit nursing homes, clinics, and homeless shelters to better understand these operations and the individuals served before developing policies that impact them. Never assume that the regulators understand all the issues or have substantial familiarity with the individuals and industries being regulated. Your goal is to put a face on the issue. Let them see what life is like as a homeless vet. Let them see a child with high blood-lead levels. Let them hear from the family that has been victimized by discrimination and racial hatred. The voices of the oppressed are strong and impactful. Humanizing the problem is an effective way to tear down the barriers that exist between the regulators and the regulated and makes the problem harder to ignore. Let the officials see what they do not see or what they have chosen to ignore.

Change sometimes comes slowly and requires persistence. I have seen senior policy officials moved to tears and change positions when hearing the stories of young mothers moving through recovery and education programs trying hard to overcome economic, health, and education barriers that cultural racism erected. People are impacted by what they see and experience.

What is demonstrated by persuasive pressure is that change happens when people give voice to what needs to change. An effective Administrative Advocacy strategy can help amplify that voice for change.

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