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Chair's Column: Addressing our Loneliness Epidemic

By John H McEniry IV, Fagron North America, Fairhope, AL

I recently ran across a compelling article titled “America's Loneliness Epidemic: A Hidden Systemic Risk to Organizations.” The article was written by Michael Lee Stallard, who is the President and Cofounder of Connection Culture Group. In the article, Mr. Stallard discusses the risks to individuals and organizations associated with the growing lack of social connections developed between individuals, as well as the steps that some organizations are taking to address this issue. Candidly, this article hit close to home, both in my personal experiences and in the experiences of many friends and colleagues. Though our profession relies on personal interaction – be it with colleagues within an organization, our clients, or opposing counsel – the lack of personal connection is prevalent in our adversarial, fast-paced, and high-stress profession.

While each person will find a different avenue to address this important issue, I would suggest that members of the ABA Health Law Section consider the Section as a place where substantial personal connections may be developed. In my experience, members of the Section are the friendliest group of lawyers with whom I have had the pleasure of interacting. The collegiality of this group is what sets the Section apart from similar organizations and is truly the best-kept secret of the healthcare bar. My closest friends and confidants have come from my participation in the Section. So, if you are a member, but not active within the Section, please consider attending an upcoming conference or other gathering of members. You’ll not only gain valuable knowledge regarding cutting-edge issues from the top experts in various areas of health law, but you’ll also have the opportunity to develop equally valuable personal connections. Join us! Get active in the Section! Enjoy the Section’s “Culture of Connection!” You’ll be glad that you did.

The below is reprinted with permission from Michael Lee Stallard.

America's Loneliness Epidemic: A Hidden Systemic Risk to Organizations

Much has been written about America’s loneliness epidemic, including in the workplace. The word “loneliness” in the work context is a misnomer. It doesn’t capture the whole story.

What about all of the individuals who might not think of themselves as lonely and yet the demands of work and task-oriented activities such as time in front of screens have crowded out time for anything more than superficial relationships? Many people lack sufficient, positive human connection (or social connection) and may be unaware of the ramifications. Left unchecked, the deficiency of connection today presents widespread risks not just to individuals but to organizations.

From a biological standpoint, social connection is a primal human need. Its presence appears to improve the cardiovascular, endocrine and immune systems’ performance. In contrast, studies have shown that “disconnection” is unhealthy for individuals:

- Loneliness is associated with poorer cognitive performance, including poorer executive function and social cognition.
- Loneliness may impair executive control and self-regulation, including with respect to greater smoking and alcohol consumption.
• Social disconnectedness is related to lower levels of self-rated physical health.
• Loneliness is associated with substance abuse, depressive symptoms and suicidal ideation.

Given these findings, it follows that researchers found greater employee loneliness leads to poorer task, team role and relational performance. One might assume that the higher up the organization you go, the more connected you feel, but that isn’t necessarily the case. Research reported in Harvard Business Review found that half of CEOs report feeling lonely and 61% of those CEOs believed it hindered their performance.

Prevalence of social disconnection

A considerable amount of evidence suggests that social disconnection is prevalent today. Based on its research findings, Cigna reported data in 2018 that chronic loneliness in America has reached epidemic levels. This is consistent with an earlier analysis on the potential public health relevance of social isolation and loneliness.

Looking forward, it would appear that over the next decade the workforce may become even more disconnected. Since 2011, research on adolescents has found they spend more time interacting with electronic devices and less time interacting with each other, while also experiencing declining well-being. As artificial intelligence further increases the presence and role of machines in people’s day-to-day lives, an unintended consequence is that technology may diminish people’s ability to connect.

The role of chronic stress

Why is social disconnection problematic in the workplace? In answering this question one ought to address the topic of stress. While it is a term we often hear, it is difficult to fully comprehend the far-reaching psychological and physiological consequences associated with stress.

In measured amounts, stress serves to ready the nervous system for the task at hand. Here, odd as it sounds, stress can be a good thing. However, as Dr. Ted George of the National Institutes of Health describes in his book “Untangling the Mind,” stress can have negative effects. With increasing levels of stress, the nervous system processes the stress as a threat. In extreme circumstances, stress moves the individual from being guided by rational thought processes to the instinctual responses characterized as “fight,” “flight” and “shutdown.”

When people experience chronic stress, they don’t feel well and often resort to ingesting substances or engaging in behaviors that provide temporary relief. The danger is that this may lead to developing addiction. In a review of 83 studies on addiction with at least 500 subjects, Sussman et al. (2011) found that nearly half the adult US population suffers from one or more addictions that have “serious negative consequences.” The addictions studied included substance addictions (alcohol, eating disorders, mood-altering legal and illegal drugs, and tobacco) and process addictions (dependence upon busyness and work, exercise, gambling, online gaming or social media, shopping, love and sex).

One of the best-known means to cope with stress is to increase positive social connections. Being in an environment that fosters supportive relationships and human connection serves to stabilize the responses of the nervous system, preventing it from processing the stressor as a threat.
Cultures of connection

UCLA neuroscientist Matthew Lieberman describes social connection as a “superpower” that makes individuals smarter, happier and more productive. Leaders at all levels of an organization would be wise to assess workplace culture through the lens of connection. Are attitudes, uses of language and behaviors drawing people together and connecting them? Or are they creating a stressful and/or relationally-toxic environment that pushes people apart?

In our research, we found that cultures of connection are best for individual well-being and for helping organizations thrive too. Specifically, cultures of connection convey several performance advantages upon organizations including higher employee engagement, tighter strategic alignment, superior decision-making, greater innovation and more adaptability to cope with rapid change taking place in the world today. These advantages add up to a powerful competitive advantage.

World’s best hospital has connection in its DNA

The power of connection is on full display at Mayo Clinic, America’s top-ranked hospital and arguably the best hospital in the world. From the time of its founding in 1889, Mayo Clinic has been intentional about cultivating connection and community. Will Mayo, one of the earliest leaders, communicated an attitude that valued connection and warned about the dangers of isolation when he stated: “Our failures as a profession are the failures of individualism, the result of competitive medicine. It must be done by collective effort.”

One of the ways this is manifest is in Mayo Clinic’s practice of compensating physicians through paying a salary rather than by an activity-based system. Not only does this promote collaboration for the good of the patient but it also alleviates the financial and time pressure of trying to see too many patients in a day, which often serves to diminish the physician-patient connection.

Mayo Clinic’s stated mission and values point to being guided by the intent of its founders, the original Mayo physicians and Sisters of St. Francis. Mayo Clinic’s mission is “To inspire hope and contribute to health and well-being by providing the best care to every patient through integrated clinical practice, education and research” (italics mine). The language used to describe its values includes the following:

- “Compassion … [that treats] patients and family members with sensitivity and empathy,”
- “Healing [that nurtures] the well-being of the whole person, respecting physical, emotional and spiritual needs,”
- “Teamwork [that values] the contributions of all, blending the skills of individual staff members in unsurpassed collaboration,”
- “Innovation [to] infuse and energize the organization, enhancing the lives of those we serve, through the creative ideas and unique talents of each employee,” and
- “Excellence [that delivers] the best outcomes and highest quality service through the dedicated effort of every team member.”

Notice that words and phrases that reflect and enhance connection are woven throughout: sensitivity, empathy, treating the whole person (including emotional and spiritual needs), teamwork, blending skills of the team, unsurpassed collaboration, each employee and every team member.
Mayo Clinic’s belief in the importance of connection goes beyond attitudes and language to practical steps taken to see that connection is infused in the culture. Mayo Clinic’s onboarding process for physicians and scientists includes extensive training in professionalism and communications, and assessments to help them develop emotional intelligence which is instrumental to connecting with others.

Physician leaders are selected, developed and assessed based on their ability to connect, which includes listening, engaging, developing and leading other physicians. Informal opportunities for connection among colleagues is encouraged by providing dedicated meeting areas for physicians to gather in.

Mayo Clinic’s intentionality and commitment is evident in a program called COMPASS (COlleagues Meeting to Promote and Sustain Satisfaction). Under this initiative, self-formed groups of 6-10 physicians get together for about an hour every other week, usually over breakfast or lunch, with up to $20 provided to each participant to cover the meal cost.

During the meal, physicians spend at least 15 minutes focused on discussing assigned issues related to the physician experience, such as resiliency, medical mistakes, work-life balance and meaning at work. Mayo Clinic’s research has found that participants in COMPASS experience statistically significant improvements in multiple domains of wellbeing and satisfaction that will help reduce the risk of physician burnout and reduce medical errors.

Conclusion

For-profit organizations can develop cultures of connection, too. Consider the connection culture of Costco, which Forbes and Statista research has consistently recognized as among the best large company employers in America, or the connection culture Alan Mulally cultivated when he led the turnaround of Ford.

Our current epidemic of social disconnection has arisen from multiple avenues including loneliness, social isolation and the busyness and increased screen time of modern life crowding out time for face-to-face human connection. Social disconnection is making people more vulnerable to the negative effects of stress. After one considers the prevalence and effects of social disconnection throughout an organization, it can be argued that social disconnection presents a systemic risk.

Connection matters. Organizations should be intentional about developing and sustaining cultures of connection that provide the structures and needed psychosocial support to foster inclusion and teamwork, minimize stress and reduce error — all of which will promote superior organizational outcomes. The net benefit amounts to better employee and organizational health, resilience and performance.

The American Bar Association Commission on Lawyer Assistance Programs provides resources for those encountering or struggling with substance use disorders or mental health issues. To learn more, please visit https://www.americanbar.org/groups/lawyer_assistance/resources/.
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Analyzing the First Eliminating Kickbacks in Recovery Act (EKRA) Enforcement Action and Its Application to Federal and State False Claims Statutes

By Patrick Ouellette, Esq., Massachusetts Executive Office of Health and Human Services, Boston, MA and Rachel V. Rose, Esq. Attorney at Law, Houston, TX

Until now, discussions around the scope of Eliminating Kickbacks in Recovery Act of 2018 (EKRA) 18 U.S.C. § 220 enforcement have been strictly theoretical due to a lack of public enforcement actions. Theresa C. Merced’s guilty plea to one count of an EKRA violation on January 10, 2020 is believed to be the first of its kind and has finally shed some initial light on how regulators view the federal law. This article will focus on what this case means – and does not mean – to EKRA compliance and the broader landscape of healthcare fraud and abuse enforcement.

EKRA was enacted under Section 8122 of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (the SUPPORT Act), Pub. L. 115-271 (Oct. 24, 2018). It is unique in that it applies to all types of payors (both public and private) and is intended to prevent individuals from referring substance use disorder patients to recovery homes, clinical treatment facilities, and laboratories covered by any healthcare benefit program in return for illegal kickbacks. Individuals found to be in violation of EKRA are subject to fines of up to $200,000 or imprisonment of 10 years, or both. And, unless a safe harbor provision is met under the Anti-kickback Statute of 1972 (AKS) and EKRA, then liability may be imposed under the AKS, too.

The EKRA Enforcement Action

Merced, of Jackson, Kentucky, was the office manager of St. John Neumann's Extended Hours clinic in Breathitt County, Kentucky, a substance abuse treatment clinic; her husband worked as a physician at the clinic. Merced, according to the plea agreement filed in the United States District Court Eastern District of Kentucky Central Division – Lexington, “solicited kickbacks from R.C. [the Chief Executive Officer (CEO) of a clinical toxicology lab] in exchange for her referral of urine drug testing to his laboratory; the solicited kickbacks included cash payments, the hiring of employees to work in the clinic, and the payment of certain utilities.”

The plea agreement stated that Merced had direct knowledge that this arrangement was illegal because she stated that she and “R.C.” needed to use discretion and she did not want to "be in trouble with the law." Merced received $4,000 as part of a total proposed cash payment of $14,000 and the hiring of five employees as requested by Merced in exchange for referrals for urine drug tests between December 2018 and August 2019. She was also charged with one count of making false statements under 18 U.S.C. § 1001 and one count of attempted tampering with records under 18 U.S.C. § 1512. She is scheduled to be sentenced on May 1, 2020. The U.S. Department of Health and Human Services, Office of Inspector General, and the Kentucky Office of Attorney General, Medicaid Fraud Control Unit led the investigation.
This case, in which an employee of a clinic serving substance use disorder patients uses his/her ability to make referrals to testing labs for direct monetary kickbacks appears to be exactly what the EKRA drafters contemplated to combat the opioid crisis. In reviewing Merced’s actions against the text of EKRA, they squarely fall into the statute’s purview, prohibiting individuals from soliciting or receiving “any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind, in return for referring a patient or patronage to a recovery home, clinical treatment facility, or laboratory.”

Merced, according to the charges filed in the United States District Court Eastern District of Kentucky Central Division – Lexington, violated EKRA when she solicited and received this remuneration knowingly and willfully, in cash and in kind, in return for patient referrals to a laboratory for the furnishing of services covered by a healthcare benefit program, in or affecting interstate commerce.

EKRA contains seven safe harbors, none of which appeared to be relevant to the actions taken by Merced. For instance, in reviewing one safe harbor against the facts of the Merced case, any argument that there was a principal-agent personal services and management contract between Merced and the clinical laboratory CEO would be nullified by the volume-based transactions between Merced and “R.C.” EKRA allows personal services and management contracts as a safe harbor. However, these transactions must be set forth in a formal agreement and not be “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.”

Anti-Kickback Statute and EKRA: Safe Harbor Comparison

Industry stakeholders are now on notice following Merced’s plea as to what can constitute an EKRA violation in the eyes of the regulatory authorities. Given the interplay between the EKRA and AKS safe harbors, and other similarities such as the potential for criminal and civil penalties, it is possible that future cases could include violations of both the AKS and EKRA. Under the AKS, individuals are barred from offering, paying, soliciting or receiving anything of value in exchange for patient referrals or items or services that are considered to be reimbursable by public healthcare programs such as Medicare and Medicaid, while EKRA applies to all payors.

The comparisons between the AKS and EKRA are natural, given the criminal elements in both laws as well as the similarities and differences between the EKRA and AKS safe harbors. While there are direct impacts on clinical laboratories previously covered only by AKS, EKRA is broader in nature. The safe harbor inconsistencies – the bona fide employment safe harbors, in particular – between the two will likely have important consequences for entities that have traditionally been leaning on compliance with the AKS, but were not applicable to Merced.

The AKS "bona fide" employee safe harbor, unlike EKRA, which does place limits on referral and commission volume, does not include such barriers, exempting "any amount paid by an employer to an employee, who has a bona fide employment relationship with the employer, for employment in the furnishing of any item or service for which payment may be made in whole or in part under Medicare, Medicaid or other Federal health care programs.” It is up to the government’s discretion what laws to utilize as the basis of its case. Just because the AKS (or the False Claims Act (FCA)) applied does not necessitate the government utilizing all options
available to it. It simply appears in this case that the government chose to focus on one law – EKRA.

False Claims Act Application to EKRA

The FCA enables either the federal government on its own or a private person on behalf of the government (a “relator”) to bring a case under the FCA. The federal government always remains a party of interest in any FCA case, whether or not it intervenes in a case that a relator brings.\(^\text{12}\)

The FCA, which also has a scienter requirement but differs from both EKRA and the AKS, sets forth “liability for any person who knowingly submits a false claim to the government or causes another to submit a false claim to the government or knowingly makes a false record or statement to get a false claim paid by the government.”\(^\text{13}\) These acts include:

(A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;
(B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim;
(C) conspires to commit a violation of the FCA;
(D) has possession, custody, or control of property or money used, or to be used, by the Government and knowingly delivers, or causes to be delivered, less than all of that money or property;
(E) is authorized to make or deliver a document certifying receipt of property used, or to be used, by the Government and, intending to defraud the Government, makes or delivers the receipt without completely knowing that the information on the receipt is true;
(F) knowingly buys, or receives as a pledge of an obligation or debt, public property from an officer or employee of the Government, or a member of the Armed Forces, who lawfully may not sell or pledge property; or
(G) knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government.\(^\text{14}\)

Under the FCA, violators must make claims knowingly, which means they “(i) have actual knowledge of the information; (ii) act in deliberate ignorance of the truth or falsity of the information; or (iii) act in reckless disregard of the truth or falsity of the information.” FCA violations can be based on directly false claims, express false certification, or implied false certification, which can be brought directly by the federal government or by a private individual plaintiff.\(^\text{15}\) In \textit{Universal Health Services, Inc. v. United States ex rel. Escobar}, the Supreme Court held that “liability can attach when the defendant submits a claim for payment that makes specific representations about the goods or services provided, but knowingly fails to disclose the defendant’s noncompliance with a statutory, regulatory or contractual requirement. In these circumstances, liability may attach if the omission renders those representations misleading.”\(^\text{16}\) The Fifth Circuit, overturning the District Court, interpreted this to mean that “the Supreme
Court made clear that defendants could be liable under the FCA for violation statutory or regulatory requirements, whether or not those requirements were designated in the statute or regulation as conditions of payment.\textsuperscript{17}

The FCA allows relators to allege through “qui tam” actions that third parties defrauded the federal government. Relators may receive between 15 and 25 percent of the amount recovered by the government through the qui tam action if the government intervenes and between 25 and 30 percent of the amount recovered if the government declines to intervene. Currently, relators can use, among other types of violations, AKS violations to file qui tam actions.

A violation of the AKS can be the basis of an FCA qui tam lawsuit. How the FCA and EKRA interact from an enforcement perspective and how the federal government would perceive relators’ potential use of EKRA violations to file qui tam suits, for instance, remains in question. Here, since the EKRA violation was investigated at the outset by federal and state governments, unfortunately little clarity was gained with respect to potential qui tam actions under the FCA.

**State Law and Potential EKRA Liability**

Individuals who violate EKRA must also consider the potential triggering of state statutes that mirror the FCA and may introduce additional liability.\textsuperscript{18} The Massachusetts False Claims Act, for example, is enforced by the Massachusetts Attorney General’s Office and contains many of the same liability elements as the FCA discussed above as well as a provision that allows for its civil enforcement equivalent of FCA qui tam actions. The Texas Attorney General’s Office has prosecuted its own version of qui tam claims under the Texas Medicaid Fraud Prevention Act (TMFPA), which focuses on Medicaid fraud.\textsuperscript{19} Similar to Massachusetts, the TMFPA and other state-level False Claims Act-type statutes should serve as further levels of regulation that could be civilly enforced against EKRA violators on top of EKRA criminal punishment. These state law causes of action are often intertwined with the federal FCA.\textsuperscript{20}

**Conclusion**

Though Merced’s EKRA violation appears to be a relatively clear-cut case from a government investigation and case perspective, it is not particularly informative as to the interplay between EKRA and the AKS and FCA. It is important to remember the following: (1) a safe harbor under EKRA and the AKS must be met; (2) an EKRA violation constitutes a valid basis for a FCA case because although the government pursued Merced solely as a criminal matter, it could have brought a FCA case; and (3) EKRA, the AKS and FCA all have scienter requirements and the potential for criminal liability. Additionally, it cannot be overlooked or overstated that EKRA, although it applies to only three types of healthcare entities (i.e., recovery homes, laboratories and clinical treatment facilities), in a way is broader than the AKS since it also covers private payors. In sum, Merced should serve as a beacon of what could be coming down the road in terms of case law and compliance programs.

\textsuperscript{1} Congress Expands Ant-Kickback Statute to Include All Payors for Laboratories, Clinical Treatment Facilities and Recovery Homes (Dec. 7, 2018), \url{https://www.natlawreview.com/article/congress-expands-anti-kickback-statute-to-include-all-payors-laboratories-clinical}.


Id. at 1995.

United States ex rels. Lemon et al. v. Nurses to Go, Inc., Opinion, Case No. 18-2032 (5th Cir. May 7, 2019).

M.G.L. c. 12 §§ 5A - 5O.


The Massachusetts False Claims Act, Texas Medicaid Fraud Prevention Act, and the federal FCA all require knowledge by the individual or company accused of misleading or defrauding government entities through the use of false or fraudulent claims, records or statements. In the instance of Medicaid fraud, for example, an individual could face civil enforcement actions by the Texas Attorney General’s Office or potentially criminal enforcement by the Texas Medicaid Fraud Control Unit within its office; in addition to the actions taken at the state level, such Medicaid fraud, depending on the facts and circumstances, may also warrant federal review under the FCA.

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Both DOJ and OIG Announce Record-Breaking Year for Healthcare Fraud and Abuse Enforcement

Scott R. Grubman, Esq., Chilivis Grubman Dalbey & Warner, LLP, Atlanta, GA

When William Barr was nominated by President Trump to be the new Attorney General in late December 2018, many suggested that Barr’s previously-expressed contempt for the False Claims Act (FCA)’s whistleblower provisions might lead to a dramatic decrease in FCA enforcement activity under his administration. Combined with the fact that every new Department of Justice (DOJ) administration brings with it the possibility of shifts in enforcement priorities, many stakeholders in the world of healthcare fraud and abuse enforcement — including plaintiff and defense lawyers — feared that the multi-year trend of record-breaking enforcement in the healthcare industry would screech to a halt.

However, two recent reports — one from the DOJ, and the other from the Office of Inspector General for the United States Department of Health and Human Services (OIG) — both announcing that 2019 was yet another record-breaking year in terms of healthcare fraud and abuse enforcement activities, will certainly alleviate any such concerns that might still exist. These reports make it clear that the federal government has not slowed its healthcare fraud and abuse enforcement activity but that such activity has, instead, actually increased and expanded in many respects.

DOJ Announces Another Multi-Billion Dollar Year Under the FCA

On January 9, 2020, the DOJ announced that it had obtained more than $3 billion in settlements and judgments under the FCA in fiscal year 2019, and that of that total, $2.6 billion related to matters involving the healthcare industry. According to the DOJ’s press release, its 2019 enforcement activity affected virtually every type of healthcare business, including drug and medical device manufacturers, managed care providers, hospitals, pharmacies, hospice providers, laboratories, and physician groups.

Continued Focus on Opioids. As part of its press release, the DOJ noted that two of its largest 2019 FCA recoveries came from opioid manufacturers. According to the DOJ, this reflects “the department’s commitment to holding drug companies accountable for their role in the opioid crisis.” One of those matters was a $195 million settlement with Insys Therapeutics, resolving allegations that it paid kickbacks to induce physicians and other providers to prescribe Subsys (a sublingual fentanyl spray) for their patients. According to the government, the alleged kickbacks “took the form of sham speaker events, jobs for the prescribers’ relatives and friends, and lavish meals and entertainment.” Insys also allegedly encouraged its physicians to prescribe Subsys for patients who did not have cancer, and lied to government insurers about patient diagnoses.

Another opioid-related matter highlighted by the DOJ in its January 2020 press release was a $1.4 billion settlement with Reckitt Benckiser (RB) Group to resolve
potential civil and criminal liability related to its marketing of Suboxone, an opioid addiction treatment drug. Of the total settlement, $500 million represented a civil settlement with the federal government; the remainder represented civil settlements with state governments and forfeiture. One of the main allegations against RB Group was that it promoted Suboxone to physicians who were writing prescriptions for uses that were “unsafe, ineffective, and medically unnecessary.” The DOJ also alleged that RG Group promoted its drug using “false and misleading claims that it was less susceptible to diversion, abuse, and accidental pediatric exposure” and that it took steps to delay the entry of its generic competition into the market.

**Kickbacks and Beneficiary Inducement.** Many of the DOJ’s largest settlements involving the healthcare industry included allegations of unlawful kickbacks. In addition to the Insys matter discussed above, the DOJ highlighted in its January 2020 press release its settlement with Avanir Pharmaceuticals, which paid over $95 million to resolve allegations that it paid kickbacks in order to induce providers in long-term care facilities to prescribe Neudexta to dementia patients, although that was not an FDA-approved use of the drug. The alleged kickbacks from Avanir were in the form of money, honoraria, travel, and food, including payments to physicians to give talks as part of speaker programs. According to the DOJ, those talks were “primarily social, with no educational value.” Another kickback investigation resulted in pathology laboratory company Inform Diagnostics agreeing to pay $63.5 million to resolve allegations that it paid kickbacks to referring physicians in the form of subsidies for electronic health records (EHR) systems and free or discounted technology consulting services.

Relatedly, the DOJ continued to enforce the federal law prohibiting beneficiary inducement. For example, in its January 2020 press release, the DOJ highlighted settlements with seven drug manufacturers that paid a combined total of over $624 million to resolve claims that they unlawfully paid patient copayments through “independent foundations” that, according to the government, were “mere conduits.” Two of those companies, Astellas Pharma and Amgen Inc., agreed to pay a combined total of nearly $125 million in April 2019. According to the press release issued at the time of that settlement, “the companies’ payments to the foundations were not ‘donations,’ but rather were kickbacks that undermined the structure of the Medicare program and illegally subsidized the high cost of the companies’ drugs at the expense of the American taxpayers.”

**Individual Accountability.** When the DOJ issued the “Yates Memo,” which outlined the DOJ’s increased focus on individual accountability for corporate wrongdoing, FCA and healthcare lawyers across the country were abuzz with talk of increased criminal and civil enforcement actions against individuals. The DOJ’s January 2020 press release highlights the DOJ’s continued focus on individual accountability, stating that it “continued its commitment to use the [FCA] and other civil remedies to deter and redress fraud by individuals as well as corporations.” By way of example, the DOJ discussed settlements with the individual owners of multiple Osteo Relief Institutes for a total settlement of over $7 million. The allegations in that
investigation were that the defendants knowingly billed Medicare for medically unnecessary viscosupplementation injections and knee braces.

Continuing the Trend. Along with its press release, the DOJ also published its updated detailed FCA statistics. Those statistics show that 2019 was the 10th year in a row that healthcare-related FCA matters resulted in over $2 billion in judgments and settlements. Of the total 2019 recovery, a little over $1.9 billion (approximately 73 percent) came from qui tam (whistleblower) suits. In addition to the recoveries, the DOJ also reported that a total of 449 new qui tam suits were filed in 2019, and also reported that relator share awards for 2019 totaled over $244 million. Of that, approximately $176 million (72 percent) were from cases where the government intervened or otherwise pursued the matter.

OIG Also Had a Very Busy Year

The DOJ’s announcement followed the OIG’s Fall 2019 Semiannual Report to Congress. In that report, the OIG announced that its “expected investigative recoveries” for fiscal year 2019 totaled over $5 billion, and included over 800 criminal actions, nearly 700 civil actions, and over 2,600 exclusions. The OIG highlighted for Congress its legal and investigative activities related to Medicare and Medicaid, including matters against pharmaceutical companies, pharmacies, ambulance providers, laboratories, home health agencies, physicians and physician groups, durable medical equipment (DME) companies, hospitals, and nursing facilities.

A Year of “Takedowns.” The OIG also highlighted its various Medicare Fraud Strike Force “takedowns,” including “Operation Brace Yourself,” which, according to the OIG, “dismantled a healthcare fraud scheme involving over $1.2 billion in losses.” Operation Brace Yourself involved charges against 24 individuals who were allegedly involved with fraudulent telemedicine companies and DME companies that paid kickbacks to ordering physicians. Two other takedowns that were highlighted by the OIG in its report were the Appalachian Regional Opioid Strike Force Takedown in April 2019, which resulted in charges against 60 individuals, including 31 doctors, seven pharmacists, and eight nurse practitioners, as well as “Operation Double Helix,” which resulted in criminal charges against 35 defendants associated with telemedicine companies and cancer genetic testing laboratories (CGx), and an alleged loss of over $2 billion.

Other takedowns listed in the OIG’s report included other opioid-related takedowns in Texas, Appalachia, and the Northeast resulting in criminal charges against a combined 160 defendants; a compounding pharmacy takedown in September 2019 which resulted in criminal charges against 33 defendants; and takedowns in Los Angeles, Georgia, Florida, and the Midwest, leading to charges against a total of 170 defendants. According to the OIG, in the semiannual reporting period alone (April through September 2019), Medicare Fraud Strike Force takedowns resulted in charges against a total of 482 defendants.
Conclusion

These two reports, along with the nearly daily press releases coming from various United States Attorneys Offices throughout the country announcing significant criminal and civil healthcare fraud and abuse enforcement actions, demonstrate the federal government’s continued focus on the healthcare industry in relation to its enforcement activities. Combined with the fact that, other than defense-related spending, healthcare remains the top federal government expenditure and most likely will for many years to come, healthcare attorneys must continue to keep abreast of developments in the area of healthcare fraud and abuse, while businesses and individuals in the healthcare industry must continue to remain vigilant and concerned.


6 Id.

7 Id.


9 Id.


11 The “Yates Memo” was issued in September 2015 by then Deputy Attorney General Sally Q. Yates, and was officially titled “Individual Accountability for Corporate
Wrongdoing.” According to the DOJ, the Yates Memo represented a shift towards holding individuals accountable for fraud in situations where, prior to the Yates Memo, a corporation would resolve a fraud investigation without any individuals being held accountable. After the Yates Memo was released, portions of the Memo were incorporated into official DOJ policy. A copy of the Yates Memo can be found at https://www.justice.gov/archives/dag/file/769036/download.


15 Id. at 8.


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Physician Law Evolving Trends and Hot Topics: Telehealth

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I. Introduction – What is Telehealth? Is it Different from Telemedicine?

This article introduces the range of legal issues that providing clinical services via telehealth may implicate. The purpose of this article is to set forth a framework for analysis of the practice of medicine through telehealth modalities in the United States.

This article is organized into five sections, including this introduction. Section II explores the state-specific regulatory and scope of practice issues that clinicians need to consider when providing services in various jurisdictions. Section III addresses coverage and reimbursement of clinical services delivered via telehealth, and the differences involved depending on who is paying for such services. Section IV discusses how federal and state fraud and abuse laws apply in the telehealth context. Finally, Section V includes a number of important, miscellaneous issues that arise in this context.

Please note that this article is meant to function as a guide to key issues, and does not attempt to comprehensively address all applicable telehealth laws for each state across the United States.

A. Telehealth vs. Telemedicine

As the utilization of “telemedicine” or “telehealth” has increased in recent years, what exactly these terms reference remains somewhat elusive, and more often than not they are used somewhat interchangeably. “Telemedicine” is traditionally used to reference the clinical services that are delivered via telehealth technology, while “telehealth” is a more expansive term which describes the range of healthcare services that can be delivered through this technology, including diagnosis and management, education, monitoring and other services. Because it is more expansive, this article uses “telehealth” instead of “telemedicine.”

B. Telehealth Terminology

Certain terms are used throughout this article. An “originating site” references the site where the patient is located during a telehealth encounter, while a “distant site” references the location of the clinician while he/she treats the patient. Under the “hub” and “spoke” model, an
arrangement which describes a healthcare facility’s clinicians rendering services to patients at other facilities, the physician is located at the “hub” facility, while the patient is located at the “spoke” facility.

C. Telehealth Modalities

Telehealth generally encompasses three different clinical modalities, or ways of delivering healthcare services to patients. “Synchronous audio-video” references a live, two-way, audio-video communication between a practitioner and a patient. In everyday terms, this looks like a “video chat” one might have through services like Skype, or the FaceTime feature on an iPhone. This most closely replicates the face-to-face interaction that is normally involved in establishing a practitioner-patient relationship.

In addition to synchronous, or live, communication, telehealth may also include “store and forward” communication, a type of “asynchronous” communication where a patient captures — and “stores” — clinical data, and then transmits — or “forwards” — such data to a practitioner to evaluate it remotely. Clinical services that commonly utilize “store and forward” technology include x-ray or CT image analysis, and pre-recorded photographs or videos highlighting a patient’s symptoms. From a clinical perspective, this type of communication is most widely utilized in disciplines like dermatology and ophthalmology, where an image may be sufficient to competently treat a patient.

A third type of telehealth technology is remote patient monitoring, or “RPM.” RPM involves using digital technology to collect medical and other forms of data from individuals in one location and electronically transmit that information securely to healthcare providers in a different location for assessment and recommendations. Typically, this involves monitoring data like a patient’s vital signs, blood pressure, weight, blood sugar, oxygen levels, or heart rate, and enables a clinician (or team of clinicians) to monitor a patient’s progress over an extended period of time.

D. Online Questionnaires, Faxes, Artificial Intelligence, etc.

What about smart questionnaires, live “instant messaging,” faxing, email, texting, and the like? What constitutes “telehealth” varies. However, the Centers for Medicare & Medicaid Services (CMS) defines telehealth to include two-way, real-time, interactive communication between a patient at an originating site and a physician at a distant site, and specifically excludes
communication through telephones, fax machines, and email.\textsuperscript{1} Many states’ definitions follow CMS’s lead in this definition of telehealth by explicitly including synchronous audio-video communication and excluding other, less interactive forms of communication.\textsuperscript{2} In particular, a number of states exclude online questionnaires from their definition of telehealth. As states continue to update their telehealth regulations, however, many are expanding the definition of “telehealth” to include store-and-forward and RPM.

II. State-Specific Regulatory Issues

As a profession, medicine is regulated on a state-by-state basis, by a combination of state medical board standards and state law. As such, while the practices of a particular clinician likely will not vary from state to state, the rules surrounding such practices almost certainly will change, and in some situations quite materially. This is perhaps the most ubiquitous challenge facing providers delivering services to patients across state lines via telehealth and their counsel. This section outlines the primary issues that must be considered when crossing state lines to provide professional services.

A. Licensure

When providing services via telehealth, a clinician generally needs to be licensed in the state in which the patient is located. There are exceptions to this statement, which is discussed below. However, as a general matter, for reasons related to states’ consumer protection interests, a state has an interest in maintaining oversight when a practitioner is providing services to residents of that state, via telehealth or otherwise.

Licensure requirements and the issues they address vary between states. Some states explicitly address telehealth in their state medical licensing laws and define the practice of medicine to include telehealth that reaches into their state. Some states indirectly address telehealth by deeming the act of diagnosing or recommending treatment through any “electronic” means to constitute practicing medicine in their state.\textsuperscript{3} Other states use broader language, such as “by any means or instrumentality,” to implicitly subject out-of-state physicians to their medical licensing laws.\textsuperscript{4} Still other states do not address telehealth, directly or indirectly, in their state physician licensing statutes or regulations. Most importantly, as a general rule, all state medical boards require a license granted by the board to practice medicine in their state. Therefore, in the absence of licensure exceptions for telehealth or special telehealth licensure requirements, all states’ medical boards require a physician to obtain a license to practice medicine in their state.
before allowing the physician to provide services via telehealth to a patient physically located in their state. Some of the exceptions to this general rule are addressed below.

B. Licensure Exceptions

There are at least nine state medical or osteopathic boards that issue special licenses or certificates permitting clinicians to provide services via telehealth: Alabama, Louisiana, Maine, Minnesota, New Mexico, Ohio, Oregon, Tennessee (osteopathic board only), and Texas. There is also legislation pending in a 10th state, Georgia, to do the same. Some states waive licensure requirements for practitioners in neighboring states, such as New York and Maryland. Other states create exceptions for specific circumstances. Ohio, for instance, allows clinicians who have treated patients outside of Ohio to provide follow-up treatment when the patient returns to Ohio, as long as such treatment is for the same condition for which the physician last treated the patient outside of Ohio. There are also states that have exceptions for professional consults between clinicians, colloquially known as “curbside consults.” Such states generally require each physician to be licensed in the state in which the physician is physically located, and that the services provided be along the lines of a second opinion. Still other states exempt physicians from licensure requirements only when the services they provide are infrequent, and prohibit out-of-state physicians providing services to residents of the state from performing certain actions within the state.

C. Interstate Medical Licensure Compacts

Interstate Medical Licensure Compacts (IMLCs) provide an expedited pathway to licensure for qualified physicians who wish to practice in multiple states. If they satisfy certain requirements for eligibility for IMLC licensure, physicians who are licensed in one of the 29 states to have joined the IMLC as well as Washington, DC and Guam may be able to obtain a license to practice in another IMLC state faster than a physician from a non-IMLC state. Importantly, physicians in IMLC states do not automatically have licensure in other IMLC states. To be eligible for expedited licensure through the IMLC, physicians must:

- Possess a full and unrestricted license to practice medicine in an IMLC state;
- Either hold primary residence in one’s State of Principal Licensure (SPL), conduct at least 25 percent of one’s practice of medicine in the SPL, be employed by an entity in the SPL, or use the SPL as one’s state of residence for U.S. federal income tax purposes;
• Have graduated from an accredited medical school, or a school listed in the International Medical Education Directory;
• Have successfully passed each component of the United States Medical Licensing Examination (USMLE), Comprehensive Osteopathic Medical Licensing Examination of the United States (COMLEX-USA), or equivalent in no more than three attempts;
• Hold a current specialty certification or time-unlimited certification by an American Board of Medical Specialties (ABMS) or American Osteopathic Association/Bureau of Osteopathic Specialists (AOABOS) board;
• Have no history of disciplinary actions toward one’s medical license;
• Have no criminal history;
• Have no history of controlled substance actions toward one’s license; and
• Not currently be under investigation.12

D. Establishing a Physician-Patient Relationship

After licensure, the next question that a physician should ask before providing clinical services in another state is what that state requires to establish a physician-patient relationship. Treating a patient without successfully establishing a physician-patient relationship as required by state law leaves physicians at risk of engaging in the unauthorized practice of medicine.

Historically, the question for physicians utilizing telehealth was whether a physician-patient relationship could be established via telehealth, or if such a relationship could only be established through an in-person consultation. This issue was litigated to great effect by the Texas Medical Board and telehealth services provider Teladoc, which ultimately resulted in the Texas Medical Board updating its telehealth regulations to enable providers to establish a physician-patient relationship via telehealth in late 2017.13 Today, a physician-patient relationship can be established via telehealth in all 50 states. However, it is often less clear whether a physician-patient relationship can be established, for instance, via store-and-forward communication, text message, or email. Many states specifically delineate the types of communication that are not sufficient to establish a physician-patient relationship. Arkansas, for instance, states that a professional relationship cannot be established through an internet questionnaire, email message, patient-generated medical history, audio-only communication (including interactive audio), text messaging, facsimile alone, or any combination thereof.14 Maryland, meanwhile, allows a physician-patient relationship to be established via interactive
audio or audio-video communication. Other states, such as Missouri, defer to the applicable standard of clinical care, providing that a physician-patient relationship can be established via telehealth if the standard of care does not require an in-person encounter (while also stating that an online questionnaire is not sufficient to establish such a relationship). Maine allows a physician-patient relationship to be established via telehealth, but specifically states that such a relationship cannot be established through use of an online questionnaire.

Finally, providers and counsel should note that establishing a physician-patient relationship involves more than the telecommunication modality utilized, and may implicate other regulatory requirements discussed herein. For instance, under New Jersey law, a physician-patient relationship can be established only if the provider verifies the patient’s identity, the provider informs the patient about the provider’s clinical qualifications, and the provider reviews the patient’s medical records before the interaction begins (with exceptions). These rules can also be discipline-specific. In Delaware, for example, while a physician-patient relationship typically requires interactive communication, the regulations specifically state that such standards do not apply to radiology or pathology.

E. Informed Consent

State laws involving informed consent require clinicians to educate their patients about the benefits, risks, costs, and limitations of a particular course of treatment. At least 38 states currently have telehealth informed-consent requirements, and both the Federation of State Medical Boards (FSMB) and the American Medical Association (AMA) have outlined guidelines for providers obtaining informed consent from patients before providing treatment via telehealth, focusing on a patient’s right to refuse services via telehealth without impacting the patient’s ability to receive other healthcare services and to validate and identify the provider’s credentials. The guidelines also address provider obligations, including identifying the patient’s location, disclosing financial interests they might have, informing the patient about how to obtain follow-up care, describing how the patient can obtain his or her medical records, disclosing privacy risks that may exist, highlighting the limitations that exist when providing treatment via telehealth, explaining fees and other payment matters, and obtaining the patient’s express informed consent.

The rights of patients and obligations of providers are ultimately informed by applicable state law, which varies state by state, but often incorporates many of the concepts outlined in the
FSMB and AMA guidelines. Many states specify whether informed consent must be in writing or can be obtained verbally, but the act of obtaining informed consent should always be documented, regardless of state.22 Other states, such as Mississippi, have specific requirements for informed consent when treatment is provided via telehealth, including that patients must be informed about the risks and benefits of telehealth and how they can obtain follow-up care, and must receive information about the treatment they will receive.23 Providers should note, however, that there is considerable variance among the states in how they approach this issue. Indiana, for instance, explicitly prohibits requiring healthcare providers to obtain a separate, written consent before providing services via telehealth.24

F. Patient and Provider Verification/Validation

Telehealth technology advances seemingly by the day, yet there are still limitations involved with this technology when compared with in-person treatment. During in-person consultations, patients can fairly easily verify their provider’s qualifications, providers can verify the patient’s identity, and there are no questions about where the patient and the provider are located. In this sense, telehealth complicates matters; where the provider and the patient are located matters for purposes of state law, and there is increased risk of unlicensed or under-credentialed individuals misrepresenting their qualifications. For these reasons, states such as South Carolina require providers to disclose their name, location, and credentials to patients when providing services via telehealth.25 Some states, including Louisiana, Mississippi, and South Carolina, also require clinicians to verify the patient’s identity and/or location before providing services via telehealth.26

G. Medical Records and Patient Privacy

Numerous states expressly provide that any electronic records or other documents created during or as a result of a telehealth encounter become part of the patient’s permanent medical record and are subject to all other general requirements of patient medical records.27 Similarly, numerous states have taken care to ensure that any electronic records or other documents created during or as a result of a telehealth encounter are subject to all other medical record privacy and confidentiality requirements.28 As a general matter, healthcare providers and their counsel should assume that all federal and state privacy and security obligations, as well as medical record
retention obligations, that apply to in-person encounters in the state in which the patient is located also apply to services provided via telehealth.

For example, when contracting with a telehealth vendor to provide the technology with which to connect with patients, physicians that are “covered entities” as defined under the Health Insurance Portability and Accountability Act (HIPAA) should require that the vendor sign a business associate agreement, and should perform due diligence as needed to confirm that the vendor employs reasonable and appropriate technical, administrative, and physical safeguards to protect the information.

H. Remote Prescribing

*Federal Law.* In addition to state statutes and regulations governing telehealth, providers and their counsel must consult state pharmacy and prescribing laws to ensure that their remote-prescribing practices are legal. Historically, the regulation of controlled-substance prescribing practices is within the jurisdiction of the federal Drug Enforcement Administration (DEA), leaving states to primarily focus on regulating the prescribing of non-controlled substances. In recent years, however, states have begun to enact their own restrictions regarding practices in prescribing controlled substances, adding requirements beyond those imposed by the DEA. This intersection between state and federal law is one of the most complicated features of the telehealth regulatory landscape and requires significant attention from providers and their counsel.

In 2008, Congress enacted the Ryan Haight Online Pharmacy Consumer Protection Act (the Ryan Haight Act) following the death of Ryan Haight, an 18-year-old who overdosed on Vicodin that he obtained through an online pharmacy from a clinician he never met. In response to a growing number of rogue online pharmacies engaging in dangerous practices, Congress passed this law to prohibit any person from dispensing a controlled substance through the internet without a “valid prescription.” A “valid prescription” requires the prescribing practitioner to conduct at least one in-person evaluation of the patient, unless the prescribing provider is a “covering practitioner” who conducts a medical evaluation remotely at the request of a provider who is temporarily unavailable and has previously examined the patient in person.

The Ryan Haight Act does not apply to the “practice of telemedicine.” However, the scope of the telemedicine exception is significantly limited, such that in most cases it will not
allow a provider to prescribe controlled substances without performing a prior in-person examination. The practice of telemedicine exceptions allow a provider to prescribe controlled substances to a patient without personally performing an in-person physical exam of the patient if the following three conditions are met:

- The patient is being treated by, and physically located in, a DEA-registered hospital or clinic during the telemedicine encounter;
- The remote telemedicine provider is registered with the DEA in the state in which the patient is physically located during the telemedicine encounter; and
- The telemedicine physician interacts with the patient using a two-way, real-time interactive audio and video communications system during the telemedicine encounter.\(^{33}\)

Further complicating matters, one of the main elements of the Ryan Haight Act telemedicine exception — a special registration process through which clinicians could obtain training and permission from the DEA to prescribe controlled substances via telehealth without performing an in-person evaluation — was never promulgated by the DEA, despite receiving explicit instruction from Congress more than 10 years ago.\(^{34}\)

In recent years, as the opioid epidemic has swept across the United States, lawmakers have become increasingly aware that many of the regions most impacted by this epidemic are rural, and that patients struggling with substance use disorder (SUD) have not been able to obtain necessary medication because of the Ryan Haight Act prohibition on prescribing controlled substances via telehealth without a prior in-person evaluation amidst nationwide physician shortages, particularly in behavioral health. In 2018, the SUPPORT for Patients and Communities Act was signed into law, introducing several reforms in this area.\(^{35}\) First, it added the home as an approved “originating site” for Medicare beneficiaries receiving treatment for SUD, thereby enabling physicians to provide SUD treatment to Medicare beneficiaries, including by prescribing controlled substances, when such patients are located in the home, as of July 1, 2019.\(^ {36}\) Second, it instructed state Medicaid programs to develop guidance setting forth how they would allow for controlled substances to be prescribed to patients for purposes of SUD treatment via telehealth.\(^ {37}\) Third, it reinforced the DEA’s obligation to develop the telemedicine registration process discussed above by October 2019.\(^ {38}\)
State Law. Many states have enacted their own restrictions on prescribing controlled substances, in addition to the limitations set forth under applicable federal law. For instance, in 2018 Connecticut passed a law allowing clinicians to engage in medication-assisted treatment via telehealth, but prohibiting them from prescribing opioids in the process. Thus, it is critical to consider both federal and state law when determining what practices are acceptable in a particular state concerning controlled substances and remote prescribing.

More broadly, state regulation of remote prescribing generally includes professional licensing rules for clinicians, as well as requirements imposed upon pharmacies and pharmacists regarding dispensing medication. In response to the “pill mills” that gave rise to the Ryan Haight Act at the federal level, many states enacted laws to curb the practices of rogue online pharmacies. As a result, many states, including without limitation Arkansas, Colorado, Delaware, Hawaii, Idaho, Iowa, Kansas, Kentucky, Mississippi, and Wisconsin, continue to explicitly prohibit prescribing medication pursuant to an online questionnaire. Some states go further, prohibiting prescribing if a provider has not treated the patient in person. Arkansas law governing the practices of pharmacies and pharmacists states that a “proper physician-patient relationship” must exist before a prescription is issued, and requires an in-person evaluation to establish a “proper physician-patient relationship.” Importantly, however, the fact that a state does not explicitly prohibit such conduct does not necessarily mean that it is permitted. For instance, while California law in this area does not explicitly state as much, the California Medical Board has disciplined medical professionals for prescribing medication pursuant to an online questionnaire.

With such laws in place, there is risk in prescribing medication pursuant to these types of communication, even when a clinician feels that he/she has gathered enough information to satisfy the applicable standard of care. As direct-to-consumer platforms grow, prescribing medication pursuant to online questionnaires, interacting with artificial intelligence tools, and text-message communication raise potential legal issues that an increasing number of clinicians and attorneys must navigate. The intersection between state telehealth and pharmacy law is a source of considerable confusion, particularly when such authorities conflict or impose additional requirements for telehealth.

III. Reimbursement
Coverage and reimbursement for telehealth services (or the lack thereof) is one of the most complex and frustrating areas of telehealth law to navigate for providers and their counsel. Controlling legal authority and coverage policies vary significantly depending on how the services at issue are being financed, i.e., whether a third-party payor is paying for the services and, if so, what that payor requires in order for claims to be paid. This section contains a high-level overview of the issues that providers should understand when submitting claims for telehealth services to Medicare, state Medicaid programs, and commercial insurers.

A. Medicare Reimbursement

Medicare coverage of telehealth services is historically restrictive, in part because CMS initially perceived telehealth as a way to help rural beneficiaries access care, but not necessarily as a clinical tool to be used more broadly. Congress amended the Social Security Act to cover telehealth services in 1997, and established the definition of “Medicare telehealth services” at that time. At a baseline level, in order for Medicare fee-for-service to cover services delivered via telehealth, those services must satisfy the following requirements (with certain exceptions):

- the originating site (i.e., where the patient is located) must be in a qualifying rural area,
- the beneficiary must be located at a qualifying originating site,
- the provider must be an eligible “distant site practitioner,”
- the interaction must be an interactive, real-time, audio-video communication, and
- the service must be included on the current year’s list of covered telehealth services.

*What is a Qualifying Rural Area?* Qualifying areas must be health professional shortage areas, or HPSAs, with certain exceptions, including being outside of a “Metropolitan Statistical Area” in a rural census tract, or in a county outside of a Metropolitan Statistical Area. Conceptually, designation as a HPSA indicates that there are healthcare provider shortages in primary care, mental health, or dental health. Geographic areas that qualify as HPSAs typically experience a shortage of a particular type of provider in the entire service area. In practice, this means that a patient located in an area sufficiently populated with behavioral health clinicians is unlikely to be eligible to receive behavioral health services via telehealth. It also makes it virtually impossible for facilities in urban areas to obtain reimbursement for telehealth services. Providers can determine whether or not they practice in a qualifying area by using the Medicare Telehealth Payment Eligibility Analyzer on the Health Resources and Services Administration (HRSA) website.
What is a Qualifying Originating Site? For the most part, qualifying originating sites are limited to the following:

- physician or practitioner’s office;
- critical access hospital;
- rural health clinic;
- federally qualified health center (FQHC);
- inpatient or outpatient hospital;
- a hospital-based or critical-access hospital-based renal dialysis center (including satellites);
- skilled nursing facility;
- renal dialysis facility (for the purposes of certain monthly clinical assessments related to treatment for end-stage renal disease);
- the patient’s home (for the purposes of certain monthly clinical assessments related to treatment for end-stage renal disease or treatment of substance use disorder or a co-occurring mental health disorder);
- mobile stroke unit (for purposes of diagnosis, evaluation, or treatment of symptoms of an acute stroke); or a
- community mental health center.\(^4^6\)

Notably, Congress recently added several approved originating sites to this list through the Balanced Budget Act of 2018, including mobile stroke units, renal dialysis facilities, and the patient’s home for purposes of monthly assessments in the context of home dialysis. There have also been a series of waivers under which Medicare’s traditional telehealth reimbursement requirements have been waived for patients participating in certain value-based demonstrations, such as the Next Generation accountable care organization (ACO) telehealth waiver, and Medicare Advantage plans have had flexibility to offer additional telehealth services as “supplemental” benefits, which is discussed in part B of this section.\(^4^7\) Except under these very narrow circumstances, Medicare does not cover telehealth services rendered to patients in their homes as fee-for-service benefits. In addition to the reimbursement of the physician at the distant site, qualifying originating sites may also bill Medicare for a facility fee related to the provision of the telemedicine service.
Who is a Qualifying Distant-Site Practitioner? In addition to requiring practitioners to be licensed to provide the services at issue, CMS only covers telehealth services delivered by the following types of practitioners: physicians; physician assistants; nurse practitioners; clinical nurse specialists; nurse-midwives; clinical psychologists; clinical social workers; registered dietitians or nutrition professionals; and certified nurse anesthetists.48

What Constitutes Qualifying Technology? Generally speaking, “Medicare telehealth services” must be provided using an “interactive telecommunications system.”49 “Interactive telecommunications system” means “multimedia communications equipment that includes, at a minimum, audio and video equipment permitting two-way, real-time, interactive communication between the patient and distant-site physician or practitioner. Telephones, facsimile machines, and electronic mail systems do not meet the definition of an interactive telecommunications system.”50 In other words, CMS requires these services to be provided via synchronous, audio-video communication between the practitioner and the patient, and explicitly excludes certain devices and methods of communication: telephones, facsimile machines, and e-mail communications.

What is a Qualifying Service? To be covered by CMS, a clinical service must be included on that year’s “telehealth list,” which is available on the CMS website and includes the codes required to submit claims for such services.51 CMS typically adds a few new services each year. For instance, there were 97 for calendar year 2019, including newly added coverage for prolonged preventive services through HCPCS codes G0513 and G0514.52

B. Telehealth Beyond “Medicare Telehealth Services”

Most services provided utilizing digital health technology must satisfy the reimbursement standards outlined above to be covered by CMS. However, there are certain services that, despite being colloquially known as telehealth, are not considered “Medicare telehealth services” by CMS. As a result, these services do not need to satisfy the statutory reimbursement requirements for “Medicare telehealth services.” This means that, among other things, Medicare covers these services when they are provided to patients in the home, and regardless of whether or not the patient is located in a rural area.

Remote Patient Monitoring. CMS has covered RPM since 2018.53 Officially called “Chronic Care Remote Physiological Monitoring,” CMS expanded RPM coverage in 2018 by implementing coverage of CPT Codes 99453, 99454, and 99457.54 CMS now provides broader
coverage for the “remote monitoring of physiologic parameters (e.g., weight, blood pressure, pulse oximetry, respiratory flow rate) including initial patient set up and education on using the equipment (CPT 99453), data transmissions reviewed on a monthly basis (CPT 99454), and 20 minutes or more of a clinician’s professional time requiring interactive communication with the patient or caregiver each month (CPT 99547).”

**Communication Technology Based and Remote Evaluation Services.** Effective in 2019, CMS distinguished a number of services, which it calls “communication technology based and remote evaluation services,” from Medicare telehealth services. CMS explained that it has come to view Medicare telehealth services as specifically referencing the physician services listed on the “telehealth list” on the CMS website. Thus, CMS now covers “virtual check-ins,” “store-and-forward” communication, and interprofessional consults, regardless of where the patient is located geographically or whether the patient is at an approved originating site.

“Virtual check-ins” are “brief check-in services furnished using communication technology that are used to evaluate whether or not an office visit or other service is warranted.” Clinicians only receive separate payment for “virtual check-ins” if the patient does not have an office visit shortly after the virtual check-in, and the patient has not had an in-person visit for the same issue in the preceding week. If the patient does have an office visit shortly after (or before) the virtual check-in, the clinician’s payment is wrapped into payment for the in-office visit. Patient consent is required, and coverage is available only for existing patients.

CMS describes store-and-forward services as “the remote professional evaluation of patient-transmitted information conducted via pre-recorded ‘store and forward’ video or image technology.” The same requirements regarding consent, pre-existing relationships, and reimbursement also apply. “Interprofessional consults” provide a method of paying clinicians who consult with originating-site clinicians from a distant site, but do not assume responsibility for the patient’s care, instead providing technical expertise to the originating-site physician.

**Additional Telehealth Services and Medicare Advantage.** Beginning in 2020, Medicare Advantage plans will be authorized to cover “additional telehealth services” for their beneficiaries. “Additional telehealth services” are services that (1) do not meet the requirements for “Medicare telehealth services,” and (2) the Medicare Advantage plan has determined can be provided in a clinically competent manner via telehealth. Importantly, “additional telehealth benefits” will be covered as basic, not supplemental, benefits. While a
detailed discussion is beyond the scope of this article, the importance of this distinction is that basic benefits are factored into the capitated payments that CMS makes to Medicare Advantage plans, while supplemental benefits are not. As a result, looking to 2020 and beyond, providers should note that certain Medicare beneficiaries will be eligible to receive additional treatment via telehealth, though the exact details of what those services are will vary from one Medicare Advantage plan to another. Additionally, providers should note that all Medicare Advantage requirements, such as provider credentialing and the coverage appeals process, will apply. As a result, even providers with deep experience in obtaining reimbursement from Medicare for telehealth services may face new requirements in obtaining coverage for “additional telehealth services” provided to Medicare Advantage beneficiaries.

C. Medicaid Reimbursement

As of 2019, all 50 state Medicaid programs cover live, synchronous, audio-video interactions of some type; at least 11 states cover services provided via store-and-forward communication, and at least 20 state Medicaid programs cover RPM.64 MassHealth, the Massachusetts Medicaid program, was the last state to adopt reimbursement of telehealth encounters utilizing live audio-video technology when it expanded coverage of certain behavioral health services to include those delivered via telehealth in January 2019.65 As a federal-state partnership, there are certain requirements that the federal government imposes upon all state Medicaid programs regarding telehealth, including that states satisfy federal requirements of “efficiency, economy and quality of care.”66 States are free to select from a variety of HCPCS codes, CPT codes, and modifiers to identify, track and reimburse providers for services delivered via telehealth. Coverage policies and the coding required to obtain reimbursement vary considerably by state. Some state Medicaid programs limit the providers eligible to receive payment for services delivered via telehealth, and whether a state Medicaid program will pay a “facility fee” to the originating site varies state-by-state. The differences can be quite drastic, so it is critical to examine a state Medicaid program’s telehealth landscape before making any major decisions involving Medicaid patients. As a reminder, this means reviewing the law in every state where a patient will be located, not just where providers will be located.

D. Private Payors
Private-payor reimbursement for telehealth must be determined on a patient-by-patient, plan-by-plan basis. There are, however, state-level legal requirements concerning reimbursement for telehealth services that apply to private payors in a majority of states. Generally known as “parity” laws, these laws address two questions: whether payors need to cover services when they are delivered via telehealth if the service is covered when provided in-person (known as “coverage parity” laws), and whether payors need to pay the same amount for a service when it is delivered via telehealth and when it is delivered in person (known as “payment parity” laws). More than 35 states currently have coverage parity laws in place, while just 10 have payment parity laws.

Importantly, determining that a state has parity laws in place does not necessarily mean one is “out of the woods.” Indeed, some states have parity laws which defer to the terms of contracts between payors and providers. For example, California has a coverage parity law which states that no payor “shall require that in-person contact occur between a health care provider and a patient before payment is made for the covered services provided through telehealth, subject to the terms and conditions of the contract entered into between the enrollee or subscriber and the health care service plan, and between the health care service plan and its participating providers or provider groups.” Thus, in California, agreements between payors and providers carry the day, even if they provide that the payor will not cover any services rendered via telehealth. This underscores the importance of reviewing coverage documents with particular attention to provisions addressing telehealth.

When structuring a telehealth program, counsel should review the laws of every state in which program patients will be located, determine whether those states have payment and/or coverage parity laws in place, and consider whether there are any limitations on such laws (to the extent that they exist) in addition to reviewing the specific provisions of the payor contracts.

E. Cash Pay

The newest trend in telehealth’s constantly evolving landscape is providing direct-to-consumer (or DTC) services, which seek to bypass payors, reimbursement restrictions, and the administrative complexity of the American healthcare system. The concept is simple — provide care directly to patients, and they pay for the services out-of-pocket. This allows telehealth platforms, and the providers rendering services through them, to avoid the headaches associated with fraud and abuse issues. However, there is a common misconception that DTC operations
are not subject to any regulatory oversight. As discussed below, DTC operations, and the providers treating patients through them, remain subject to applicable state law, even if certain federal authorities that only apply to claims submitted for services billed to Medicare, Medicaid, and other public payors (with exceptions) — e.g., HIPAA, the physician self-referral prohibition (the Stark law) and the federal anti-kickback statute (the AKS) — do not.

IV. Fraud and Abuse Issues Unique to Telehealth

As with any delivery method for the practice of medicine in the United States, a physician undertaking a telehealth endeavor is subject to a multitude of complex federal and state health-care fraud and abuse statutes, regulations, and case law. In general, the fraud and abuse laws applicable to other forms of healthcare delivery equally apply in the case of telehealth. In addition, fraud and abuse issues that arise specific to telehealth relate to the infrastructure, equipment, and support necessary to implement any effective telehealth endeavor. This section provides an overview of the key issues and arrangements that could arise in the telehealth context that pose particular healthcare fraud and abuse risks, but a discussion of the full range of possible fraud and abuse risks presented by telehealth arrangements is beyond the scope of this article.

A. Federal Kickback and Beneficiary Inducement Restrictions

The AKS prohibits the knowing or willful offer, payment, solicitation, or receipt of remuneration (including any kickback, bribe, or rebate), directly or indirectly, overtly or covertly, in cash or in kind, as inducement for the referral of patients or arranging for the referral of patients to receive services for which payment may be made in whole or in part under a “Federal health care program” (defined to include Medicare, Medicaid and TRICARE, and state healthcare programs). However, the statute’s prohibition is not limited to payments for referrals; the statute also prohibits payments to induce the purchasing, leasing, or ordering of any good, facility, service, or item for which payment may be made under a federal healthcare program, or recommending or arranging for the purchasing, leasing, or ordering of any such item or service. Voluntary safe harbors apply, so if an arrangement meets the requirements of an applicable safe harbor, then the arrangement will not be prosecuted under the statute. Notably,
meeting all components of a safe harbor is not required, as ultimately whether or not the AKS is implicated turns on intent.

There are two safe harbors to the AKS that specifically relate to healthcare technology, including technology used in the telehealth context. These safe harbors apply to situations in which a physician receives items and services necessary to engage in electronic prescribing (including hardware, software, information technology and training), as well as situations in which a physician receives items and services necessary to create, transmit, and receive electronic health records (including software, information technology and training), all subject to a number of conditions. Such arrangements between clinicians on the one hand, and hospitals or other healthcare facilities or technology providers on the other hand, where the clinician receives such items or services for free or a discounted cost, could potentially implicate the AKS, depending on the intent of the parties in entering into the arrangements. Structuring such arrangements to comply with the applicable safe harbors provides some certainty regarding avoidance of a finding of a violation. In addition, other safe harbors frequently looked to in the context of relationships with physicians or other referral sources, including the personal services and management contracts safe harbor and employee safe harbor, could equally apply in the telehealth context depending on the arrangement in question (e.g., where a health system contracts with a physician to provide services via telehealth).

It is important to note that whether or not the services in question are reimbursed by a federal healthcare program do not necessarily impact risk of violation of the AKS. A telehealth arrangement could implicate the AKS by inducing other referrals for which governmental payor reimbursement is available. For example, the AKS could be implicated if a cardiologist provided free telehealth equipment to a general practitioner and offered free telehealth consultations to the general practitioner’s patients in return for the general practitioner’s referral of patients to the cardiologist for Medicare-covered cardiology services. In addition, various state anti-kickback laws may be implicated when private-payor reimbursement is available, or regardless of source of payment.

A provision under the Civil Monetary Penalties (CMP) statute addressing beneficiary inducement often goes hand-in-hand with analysis under the AKS when items or services of value are provided to Medicare and Medicaid beneficiaries. In particular, the applicable provision prohibits the offer or transfer of remuneration that a person knows or should know is
likely to influence a beneficiary’s selection of a particular provider for the provision of items or services payable under the Medicare or Medicaid program. The beneficiary inducement CMP could be implicated in the telehealth context when, for example, a Medicare patient is provided with a tablet or other device to facilitate consultations with a practitioner or to gather and transmit data for the purpose of RPM. A number of exceptions to the CMP apply, including an exception for items or services that improve a beneficiary’s ability to obtain items or services payable by Medicare or Medicaid (i.e., promoting access to care), and that pose a low risk of harm to both Medicare and Medicaid beneficiaries and the Medicare and Medicaid programs.74

In particular, the items or services offered pose a low risk of harm if: (1) they are unlikely to interfere with, or skew, clinical decision making; (2) they are unlikely to increase costs to federal healthcare programs or beneficiaries through overutilization or inappropriate utilization; and (3) they do not raise patient safety or quality-of-care concerns.75 Although broad in concept, commentary and guidance from the Office of Inspector General (OIG) of the U.S. Department of Health and Human Services should be reviewed and analyzed closely to determine the scope of this exception and applicability to any particular scenario. The OIG has also stated that there is no violation of the CMP statute where the items or services provided to beneficiaries have a retail value of no more than $15 per item or $75 in the aggregate, per person on an annual basis, if such items are not cash or cash equivalents.76

The OIG is responsible for publishing advisory opinions interpreting the AKS and the beneficiary inducement CMPs. The OIG has published multiple advisory opinions addressing telehealth-related issues.

Advisory Opinion 98-18 addressed a proposed arrangement between an ophthalmologist and an optometrist for the sublease of certain telehealth imaging equipment, whereby the ophthalmologist leased the equipment pursuant to a written lease with a fair market value rental amount to the optometrist, and provided free telehealth consultations for the optometrist’s patients as to whether the patient required ophthalmology services. The optometrist also could use the equipment to provide other services to the patients independent of the telehealth consultations. The OIG determined that the arrangement did not implicate the AKS for the following reasons: (1) the lease agreement for the equipment complied with the equipment lease safe harbor requirements; (2) patients referred for ophthalmology services after the free telehealth consultation were allowed to choose any ophthalmologist to provide the recommended
services; and (3) the ophthalmologist’s free telehealth consultations only resulted in minimal and incidental business benefits for the optometrist.

Advisory Opinion 99-14 involved a health system that operated a rural telehealth network under a federal grant, and wanted to fund and continue to administer the network after the grant expired, including compensation for practitioners and certain costs of equipment. The OIG found that although the health system’s ongoing financial support could implicate the AKS since it would confer benefits on both the practitioners and the “spoke” facilities, the OIG would not impose sanctions based on a number of factors, including the clear congressional intent favoring the study and development of rural telehealth networks and community benefit to rural citizens through increased access to care.

Advisory Opinion 04-07 analyzed an arrangement between a health system and school-based clinics in rural areas, where physicians at one of the health system’s “hub” facilities would consult with nurses at school-based clinics on appropriate follow-up care resulting from screening tests, including potential consultation via telehealth. Students who required a referral to another physician would be referred to their primary care provider. Those who did not have a primary care provider would be provided a list of primary care providers in their town. The health system paid for the telehealth equipment and the services of the physicians. The OIG concluded that although the health system conferred benefits on potential referral sources, and the AKS could be implicated, the OIG would not impose sanctions because the screening services were non-reimbursable services for purposes of federal healthcare programs, there were otherwise sufficient safeguards in place, and the OIG acknowledged the “obvious public benefit in facilitating better access to screening services for low-income children in rural areas.”

Advisory Opinion 11-12 addressed a nonprofit health system’s proposal to provide neuroemergency clinical protocols, technological devices, and services to community hospitals to facilitate immediate consultations with stroke neurologists, and where the parties could use one another’s trademarks and service marks for some marketing activities, and each community hospital agreed not to participate in other neuroemergency telehealth services without the health system’s approval for the duration of the agreement. Under the arrangement, participation was based on access to care considerations, not volume or value of any actual or anticipated referrals. On its face, the arrangement implicated the AKS and did not satisfy any safe harbor because it involved the free provision of valuable items and services among hospitals, all of which had
previously referred Medicare business to and from each other. However, the OIG concluded that the facts and circumstances adequately reduced the risk under the AKS. This opinion highlighted a common impediment to increased use of telehealth. Telehealth projects inherently require a large upfront investment to develop the technology infrastructure necessary to realize the much larger cost-reduction, efficiency, and quality of care benefits of telehealth for Medicare patients and private-pay patients alike. The OIG took a progressive step in this opinion by recognizing the AKS as a potential barrier to telehealth projects across the country. As such, the OIG permitted the proposed arrangement for the following reasons:

- The objective of the telehealth project was to *reduce* the number of transfers of stroke patients to the funding hospital in circumstances where those patients can be managed at the local hospital if telehealth resources are available.
- Neither the volume nor value of a hospital’s previous or anticipated referrals, nor the volume nor value of any other business generated between the parties, would be a condition of participation in the telehealth project.
- The primary beneficiaries of the telehealth project would be the stroke patients who, with the funding hospital’s support, could be treated at the local hospital emergency departments, when treatment is most effective. It would also benefit the patients who need the more advanced level of care that the funding hospital can provide, but who might not otherwise have been able to receive it due to capacity issues.
- The timely treatment of stroke patients would likely decrease the incidence of stroke-related disabilities, which, in turn, would likely decrease the costs associated with treating and supporting such patients.

Advisory Opinion 18-03 addressed a proposal by a FQHC look-alike to provide telehealth equipment at no cost to a rural health clinic to help provide HIV treatment services to patients. The FQHC look-alike proposed to use funds from a state grant dedicated to HIV treatment to fund the purchases involved in the proposed arrangement. The OIG concluded that the arrangement posed a low risk under the AKS for a few reasons. First, the OIG noted that there were anti-steering safeguards in place, since the rural health clinic advised its patients that they could use any provider for HIV treatment or consultation, and the FQHC look-alike permitted the rural health clinic to use the telehealth equipment to connect patients with other providers. Second, the risk of over-utilization was mitigated, since the rural health clinic would
have performed preliminary tests and referred patients for consultations otherwise. Third, the OIG emphasized the benefit of increased access to preventive HIV treatment, which could “reduce the prevalence of HIV and promote public health.” Fourth, the OIG emphasized that although the FQHC look-alike could benefit from the arrangement, the primary beneficiaries would be the clinic patients who could receive HIV prevention services more conveniently and efficiently.

Most recently, OIG Advisory Opinion 19-02 addressed a proposed arrangement whereby a pharmaceutical company sought to loan a smartphone to low-income patients which would be stripped of all functionality except for an app which tracks data regarding use of a drug and other related data, as well as the ability to make domestic calls for purposes of reaching customer support with questions. The offer of the phone would not be advertised, would not have independent value since essentially all other functionality was removed, and would be loaned for 8-12 weeks for the duration of the drug therapy to patients who met financial need criteria and did not otherwise own a smartphone. The OIG found that this arrangement could potentially implicate the AKS as well as the beneficiary inducement CMPs, because by taking the device the patients would believe they needed to continue to work with the pharmacy in question. However, the OIG found that the arrangement met the access-to-care exception under the beneficiary inducement CMPs, and the OIG would not impose sanctions under the AKS under the circumstances. The device promoted access to care because it was necessary in order to receive the full scope of benefits of the drug therapy, which is payable by Medicare. The provision of the device for free posed a low risk of harm because it did not affect prescribing decisions, only certain eligible patients would receive the device, the offer would not be advertised, the use of the device was time-limited, and the device did not have real independent value (the OIG stated that if the phone had access to an internet browser or other functionality, the conclusion likely would be different). This opinion is noteworthy in that it addresses the RPM modality, as opposed to real-time audiovisual consultations between a patient and practitioner. As RPM grows in popularity, it is helpful to have an advisory opinion supportive of providing free or discounted technology to foster increased adoption of the modality, where certain safeguards are in place.

In summary, telehealth arrangements in which free telehealth equipment or services are provided should be analyzed for possible anti-kickback and beneficiary inducement risks.
However, there has been steadily increased recognition of the value of telehealth in increasing access to medically necessary care, including in the RPM context, and if structured thoughtfully with appropriate safeguards in place, such arrangements may be permissible.

Another common anti-kickback potential issue that can arise relates to the scenario where a telehealth services vendor enters into arrangements with medical groups or individual physicians. Depending on certain factors, such as how the services are marketed, how the physicians are featured, and how the funds flow generally works, the AKS could potentially be implicated if federal healthcare program reimbursement is involved (for further discussion regarding such arrangements, see Section IV.E).

**B. Federal Self-Referral Prohibition**

The federal physician self-referral law (the Stark law) prohibits physicians from referring Medicare beneficiaries for certain “designated health services” (DHS) reimbursable by Medicare to an entity with which the physician (or an immediate family member) has a financial relationship. The Stark law definition of a financial relationship includes almost any arrangement in which a physician receives something of value from an entity to which he or she makes referrals, including direct and indirect compensation and ownership interests.

The Stark law is narrower in its scope than the AKS in certain respects, since it is limited to DHS (which includes, without limitation, lab, radiology and certain other imaging, and inpatient and outpatient hospital services), and since a physician (or his or her immediate family member) must have a financial relationship with the entity performing DHS. However, in other ways it is potentially broader, or is at least easier to run afoul of, because it is a strict liability offense (i.e., it does not require a threshold level of intent). It is also notoriously difficult to navigate and maintain all agreements in compliance with the requirements at all times. Similar to the safe harbors under the AKS, compliance with one of the exceptions to the Stark law protects a physician from liability under the self-referral prohibition. However, a critical difference is that while the AKS safe harbors are voluntary, meeting all requirements to a Stark law exception is mandatory to avoid violation, if the Stark law otherwise applies.

Applicability of the Stark law to various arrangements is nuanced and complex, and an in-depth summary is outside the scope of this article. However, as with the AKS, telehealth arrangements that involve free telehealth equipment or services, volume discounts, “per-click” payments, or advertisements on physician websites should be analyzed for possible self-referral
risks and self-referral exceptions (in addition to analysis under the Stark law as applicable for all physician relationships, whether involving telehealth or not).

Similar to the AKS safe harbors discussed above, two exceptions under the Stark self-referral prohibition are relevant in the context of healthcare technology, including telehealth services. These exceptions apply specifically to financial arrangements in which a physician receives free electronic prescribing technology or training or free electronic health records software, information technology, or training. In addition, other exceptions frequently looked to, including the personal services and fair market value exceptions, could equally apply in the telehealth context, depending on the circumstances.

C. False Claims Act and Civil Monetary Penalties

Specific healthcare fraud and abuse violations, such as violations of the AKS and the Stark law, are often coupled with more general federal sanctions under the Federal False Claims Act (FCA) and the CMP authority of the OIG. The FCA prohibits, among other things, knowingly submitting or causing to be submitted false or fraudulent claims for payment or false statements or certifications to the federal government. CMPs are applicable if a person knowingly presents, or causes to be presented, to a state or federal government employee or agent any false or improper claims. Consequences under the FCA and CMP can be steep. For example, violations of the FCA are subject to treble damages and penalties.

As adoption of telehealth continues to grow, there has been a corresponding uptick in attention by regulators. Some of this activity has focused on regulatory compliance and sound billing practices. In April 2018, the OIG published a report on a post-payment audit of telehealth claims that CMS processed in 2014 and 2015. Using a 100-claim sample, the OIG determined that 31 of the claims that CMS paid did not satisfy the “Medicare telehealth services” requirements. Most frequently, the claims failed to satisfy the “originating site” requirement. In the report, the OIG recommended that CMS continue to engage in post-payment audits of telehealth claims, a recommendation that the OIG had already made in its 2017 Work Plan, which called for further review of payments for telehealth services. This underscores the importance of ensuring that a telehealth program is in compliance with applicable regulatory and fraud and abuse authorities.

There has also been a corresponding increase in enforcement activity. Beginning in late 2018 and continuing into 2019, the Department of Justice (DOJ) issued several indictments
targeting allegedly fraudulent telehealth endeavors. In October 2018, for instance, the DOJ took action in \textit{United States v. Roix}, where the alleged scheme involved improperly solicited prescriptions for pain creams resulting in almost $1 billion in false claims. Then, in April 2019, the DOJ cracked down on an allegedly fraudulent arrangement involving dozens of durable medical equipment (DME) companies and practitioners delivering services via telehealth resulting in more than $1.2 billion in false claims, which the DOJ called “one of the largest health care fraud schemes investigated by the FBI and HHS-OIG and prosecuted by the DOJ.”

Scrutiny is also increasing in the direct-to-consumer space, with several major newspapers publishing articles in 2019 questioning the prescribing and clinical practices of a number of internet-based telehealth platforms. As telehealth utilization continues to grow across all markets, increased scrutiny is to be expected.

\textbf{D. State Fraud and Abuse Laws}

The federal Stark law and AKS are only the starting point for a telehealth program fraud and abuse analysis. Indeed, given the limited reimbursement available under Medicare, Medicaid, or other federal healthcare programs (although, as referenced earlier in this chapter, the reimbursement landscape is changing), many providers that provide services via telehealth do so on a cash-pay basis only, or by possibly contracting with private third-party payors as well. Such services may be subject to any self-referral and anti-kickback laws of the states into which the telehealth program may reach, depending on the specific state law.

State statutes and regulations can vary significantly in how they address fraud and abuse concerns. Certain states have chosen to integrate the federal fraud and abuse statutes into their state Medicaid statutes. Some apply where reimbursement for the item or service is payable by a healthcare insurer, and others apply regardless of reimbursement source. In addition, a state may create telehealth-specific fraud and abuse laws. For example, Texas specifically requires physicians practicing telehealth to establish certain protocols to reduce the additional fraud and abuse risks presented by telehealth activities.

Thus, physicians should be aware that a federally compliant telehealth arrangement may still be subject to state fraud and abuse sanctions if the applicable state telehealth laws and fraud and abuse laws are not independently identified and addressed.

\textbf{E. Corporate Practice of Medicine and Fee-Splitting}
Successful telehealth ventures are often composed of the three following players — technology experts, venture capitalists, and physicians or other practitioners. Whenever business ventures include the close alignment of licensed healthcare professionals and non-licensed individuals or entities, the arrangement should be reviewed carefully to identify any potential violation of a state’s fee-splitting rules or corporate practice restrictions, in addition to potential kickback and self-referral issues. A common scenario where this arises is where a technology vendor, backed by venture capital, develops a telehealth platform and otherwise provides related administrative services so that providers can utilize the technology platform to provide services.

Many states expressly prohibit the “corporate practice of medicine,” meaning an unlicensed individual or entity is prohibited from engaging in the practice of medicine.95 This means that, in some states, only licensed physicians or other healthcare providers may contract with other licensed physicians to provide healthcare services, unless an exception applies. Similarly, in many states, only licensed healthcare providers are allowed to own or control a company that is “practicing medicine.”96 The criminal act of aiding and abetting the unlicensed practice of medicine is potentially a concern that should be considered for all involved in a telehealth venture, depending on the state(s) of operation.97 Whether there is a violation may be a nuanced analysis, as the distinction between what is and is not the practice of medicine by a person (or corporation) varies from state to state, and often is not clearly defined. Prior to engaging in a telehealth venture, to the extent unlicensed individuals or entities are involved, a close review of the applicable state laws where patients will receive the services should be undertaken to determine if there is a corporate practice of medicine prohibition, and if so the scope of such prohibition, including any medical board guidance or prior enforcement actions.98

In addition to the corporate practice of medicine, many states prohibit physicians from “splitting” their fees with non-physicians.99 Therefore, although a “lay entity” technology company or venture capitalist may wish to receive a portion of the profits of the venture, either as an owner in the venture or by receiving a percentage of profits from the professional entity, in many states such arrangements could raise potential issues under applicable fee-splitting statutes (as well as potentially under corporate practice of medicine and/or anti-kickback statutes).

The variety in state laws and enforcement on these issues requires legal counsel to thoughtfully consider how best to structure the arrangement on a state-by-state basis. For example, if a patient pays for an online consultation by a physician, who is permitted to share in
a portion of that payment and under what terms? Are there payments between the various parties to an arrangement that could be viewed as illegal kickbacks for generating healthcare business? Analyzing the applicable legal landscape and compliant structures by which the relevant parties can affiliate and receive compensation for their involvement should occur early in the planning process for any new telehealth venture.

V. Miscellaneous

A. Proxy Credentialing

CMS requires Medicare-participating hospitals to have an organized medical staff which operates under bylaws that are approved by the hospital’s governing body, and which is responsible for the quality of clinical care provided to hospital patients. The medical staff needs to examine the credentials of candidates for medical staff membership, and make recommendations regarding their candidacy in compliance with applicable state law. This presents operational challenges for originating site, or “spoke,” hospitals, whose patients are receiving treatment from clinicians located at other facilities. The credentialing process can be very labor-intensive, particularly if a clinician is simply providing coverage and not intending to be a long-term contributor to the originating site facility. Recognizing these difficulties, CMS and the Joint Commission have developed options for facilities to credential their providers. Specifically, the Joint Commission provides three options for credentialing providers treating patients via telehealth:

- Originating site fully privileges and credentials the practitioner;
- Originating site uses credentialing information from the distant site (if the distant site is Joint Commission-accredited); and
- Originating site uses the credentialing and privileging decision from the distant site to make a final privileging decision pursuant to specific conditions being satisfied (i.e., “credentialing by proxy”).

Credentialing by proxy is permitted only if the originating site hospital’s governing body establishes an agreement with the distant site hospital, or distant site telemedicine entity, ensuring that the distant site hospital is a Medicare-participating hospital; that the clinician providing services is privileged at the distant site hospital, and included on a list of the distant site clinician’s privileges to the originating site hospital; the distant site clinician is licensed to practice in the state in which the originating site hospital is located; and the originating site...
documents its internal review of the distant site clinician’s performance of clinical privileges and sends such information to the originating site to use in reviewing the performance of the distant site clinician, which must at least include reviewing all adverse events that result from the telehealth services provided by the distant site clinician to the originating site hospital’s patients, and complaints the originating site has received about the distant site clinician.104 Importantly, hospitals utilizing proxy credentialing must ensure that their hospital bylaws allow for this practice to avoid a scenario where non-credentialed clinicians are providing services via telehealth.

B. Malpractice Insurance

When providing services via telehealth, providers must ensure that their medical malpractice coverage is effective. In particular, it is important to verify that the malpractice policy at issue applies to services provided via telehealth, and that it applies to services rendered in every state where a patient of the practitioner may be located.

VI. Conclusion

Telehealth regulation is among the fastest-evolving areas of healthcare law. This article is a helpful framework and starting point for legal analysis, but all stakeholders engaging in this exciting but unpredictable space should utilize experienced legal counsel.

This article is adapted from the ABA Health Law Section’s new book, 2019 Physician Law Evolving Trends and Hot Topics. The book represents the cutting edge of physician law, and is an excellent reference for clinicians and their counsel who want to stay abreast of current legal and regulatory issues impacting physician practice. For more information, go to:


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1 42 U.S.C. § 1395(m)(1); 42 C.F.R. § 410.78(a)(3).
2 See, e.g., CAL. BUS. & PROF. CODE § 2290.5(a).
3 See, e.g., GA. COMP. R. & REGS. § 360-3-07.
4 See, e.g., WIS. STAT. § 448.01(9)(a).
5 ALA. CODE § 34-24-502-507; LA. REV. STAT. 37:1276.1; ME. REG. § 02-373 Ch. 1; MINN. STAT. § 147.38; N.M. STAT. ANN. § 61-6-11.1; OHIO REV. CODE § 4731.296; OR. ADMIN. RULES § 847-025-0000 et seq.; 22 TAC § 172.12.
7 See, e.g., MD. CODE HEALTH OCC. § 14-302.
8 OHIO REV. CODE § 4731.41.
9 See, e.g., MASS. GEN. LAWS ch. 112, § 7 (providing that state licensure and registration requirements “shall not apply … to a physician or surgeon resident in another state who is a legal practitioner therein, when in actual consultation with a legal practitioner of the commonwealth”).
10 See, e.g., CONN. GEN. STAT. § 20-9(d).
11 See, e.g., CAL. BUS. & PROF. CODE § 2060 (stating that practitioners eligible for limited licensure exceptions “shall not open an office, appoint a place to meet patients, receive calls from patients within the limits of this state, give orders, or have ultimate authority over the care or primary diagnosis of a patient who is located within this state.”).
13 22 TAC § 174.2; see Teladoc, Inc. v. Texas Medical Board, 112 F. Supp. 3d 529, 533 (W.D. Tex., 2015).
15 CODE OF MD. ADMIN. REGS. § 10.32.05.05.
16 MO. REV. STAT. Ch. 191 § 191.1146.
17 02-373-006 ME. CODE R. § 3 (2016).
19 Del Code tit. 24, § 1769D.
22 See, e.g., CAL. BUS. & PROF. CODE § 2290.5(b).
See S.C. Code 40-47-37(C); ARIZ. REV. STAT. § 36-3602(B), (D); KY. REV. STAT. § 311.5975(1)(B); (5); TEX. OCC. CODE § 111.003.

See, e.g., ARIZ. REV. STAT. § 36-3602(B), (D); KY. REV. STAT. § 311.5975(1)(B); (5); TEX. OCC. CODE § 111.003.

See, e.g., ARIZ. REV. STAT. § 36-3602(B), (D); KY. REV. STAT. § 311.5975(1)(B); (5); TEX. OCC. CODE § 111.003.

See, e.g., ARIZ. REV. STAT. § 36-3602(C); CAL. HEALTH & SAFETY CODE § 123149.5(a); COLO. REV. STAT. §§ 25-1-801, 25-1-802; 22 TEX. ADMIN. CODE § 174.1 et seq.


SUPPORT for Patients and Communities Act (H.R. 6), § 2001; 42 U.S.C. °§ 1395m(7). The concept of an “originating site” is discussed in the Medicare reimbursement portion of this chapter.

SUPPORT for Patients and Communities Act (H.R. 6), § 1009; 42 U.S.C. °§ 1396a.

SUPPORT for Patients and Communities Act (H.R. 6), § 3232; 21 U.S.C. °§ 831(h)(2). The DEA did not meet this deadline.


See 42 U.S.C. °§ 3195m(m); 42 C.F.R. °§ 410.78.

42 C.F.R. °§ 410.78(b)(4).


Available at https://data.hrsa.gov/tools/medicare/telehealth. HRSA, part of the Department of Health and Human Services, is the primary federal agency for improving healthcare to people who are geographically isolated or economically or medically vulnerable.

42 C.F.R. °§ 410.78(b)(3).

See, e.g., 42 C.F.R. °§ 510.605 (waiving certain telehealth requirements for patients participating in the Combined Joint Replacement (CJR) model).

42 C.F.R. °§ 410.78(b)(2).

42 C.F.R. °§ 410.78(b).

Id.

Id.

42 C.F.R. °§ 410.78(b); https://www.cms.gov/medicare/medicare-general-information/telehealth/telehealth-codes.html.


Id.


“We have come to believe that section 1834(m) of the Act does not apply to all kinds of physicians' services whereby a medical professional interacts with a patient via remote communication technology. Instead, we believe that section 1834(m) of the Act applies to a discrete set of physicians' services . . . . For CY 2019, we are aiming to increase access for Medicare beneficiaries to physicians' services that are routinely furnished via communication technology by clearly recognizing a discrete set of services that are defined by and inherently involve the use of communication technology.” 83 Fed. Reg. 59483 (Nov. 23, 2018).

Id.

Id.


42 C.F.R. °§ 422.135.

Id.


67 CAL. HEALTH & SAFETY CODE § 1374.13(c) (emphasis added).

68 42 U.S.C. § 1320a-7b(b).

69 42 U.S.C. § 1320a-7b(b).

70 42 C.F.R. § 1001.952.

71 42 C.F.R. § 1001.952(x), (y).

72 42 C.F.R. § 1001.952(d)(i).

73 42 U.S.C. § 1320a-7(a)(5).

74 42 U.S.C. § 1320a-7a(i)(6)(F).

75 42 C.F.R. § 1003.110.


78 42 C.F.R. § 411.354.

79 Id.; 42 C.F.R. §§ 411.351 et seq. (setting forth relevant definitions, exceptions, and other applicable regulations).

80 Id. at § 411.357(v), (w).

81 42 C.F.R. § 411.357.


83 42 U.S.C. § 1320a-7a(a).

84 31 U.S.C. § 3729(a); 28 C.F.R. § 85.5.


86 Id.


90 On October 9, 2019, CMS and OIG respectively issued highly anticipated proposed rules which would revise the current AKS safe harbors, Stark law regulations, and one of the beneficiary inducement civil monetary penalties exceptions, and include the addition of some new safe harbors and exceptions. While this article reflects the current regulations only, it is worth noting that these proposed rules signal a recognition of the importance of telehealth, and technology innovation more generally, as a critical part of the promotion of coordinated care. If finalized as written, the rules will provide additional flexibility related to utilization of telehealth by both patients and providers. For example, participants in value-based enterprises would have a safe harbor which would expressly permit the provision of patient engagement tools and supports, which could include items to assist with access to services via telehealth.

91 See, e.g., ALA. CODE. § 22-1-11(c); ALA. ADMIN. CODE r. § 560-x-4.04.

92 See, e.g., MASS. GEN. LAWS Ch. 175H § 3.

93 See, e.g., CAL. BUS. & PROF. CODE § 650.

94 22 TEX. ADMIN. CODE § 174.3.

95 See, e.g., CAL. BUS. & PROF. CODE §§ 2052, 2400.

96 See, e.g., CAL. CORP. CODE § 13400 et seq.

97 By analogy, in the context of dentistry, a large dental management company entered into a significant settlement upon a finding by the New York Attorney General that it was engaged in the unauthorized practice of dentistry and illegal fee-splitting. See https://www.pbs.org/wgbh/frontline/article/dental-chain-violated-new-york-law-settlement-says/.


99 See, e.g., N.Y. EDUC. LAW § 6509-a; 8 NYCRR § 29.1(b)(4).

100 42 C.F.R. § 482.22.
An originating site can rely upon the credentialing of another Medicare-accredited hospital or a “distant site telemedicine entity,” per 42 C.F.R. § 482.12(a)(9).

References:
101 42 C.F.R. § 482.22(a)(2).
102 Joint Commission, MS 13.01.01.
103 An originating site can rely upon the credentialing of another Medicare-accredited hospital or a “distant site telemedicine entity,” per 42 C.F.R. § 482.12(a)(9).
104 42 C.F.R. § 482.22(a)(3).
ANNUAL REGIONAL LAW FIRM RECOGNITION

• SHAPING THE FUTURE OF HEALTH LAW
• NAVIGATING CLIENTS THROUGH COMPLEX CHALLENGES
• ANSWERING ABA’S CALL TO PROFESSIONALISM

Recognition is solely honorary in nature and not because of any qualification, skill or ability. This list was determined by reference solely to Health Law Section membership as reported to the ABA. No endorsement by ABA is granted, directly or indirectly, nor should be construed. Any lawyer or law firm who distributes this material agrees to comply at all times with all applicable state bar marketing regulations.
The ABA Health Law Section is proud to announce the seventh annual regional recognition program for the Northeast, Southeast & D.C., South, Midwest, and West Regions.

The Health Law Section has been the voice of the health law bar for over 20 years. As the profession’s standard-bearer, our central mission is to lead and shape the national discussion on pressing health law issues of the day. This national leadership is accomplished through our unparalleled resources, unrivaled depth and breadth of expertise, and the backing of ABA’s over 400,000 members. We are dedicated to fulfilling the ABA’s mission of promoting expertise and professionalism for the health law bar. We strive to promote an inclusive, diverse and well-rounded membership consisting of private practice, in-house, solo and government attorneys; academics and law students; and physicians, nurses and healthcare consultants that reflects our truly national character.

We place particular importance on regional member participation because the nation’s healthcare is regional in its organization and delivery. As a unique member-driven group, we depend on the support and commitment of this nation’s most influential health law attorneys. Our members are among the most experienced and dedicated health law practitioners in the country, serving in a wide variety of roles and commonly united in the pursuit of professional excellence. We tackle the toughest and most demanding health law issues by drawing upon our members’ diverse professional experiences and richly varied viewpoints. Our leading educational programs, policy activities and definitive publications rely upon our members’ commitment and engagement. We therefore recognize their dedication through this annual regional listing of the firms with the largest number of members in 2018 as reported to the ABA.

2018-2019 YEAR IN REVIEW

Members .............................................10,404  
Lawyers ..........................................................7,235  
Associates ..........................................................324  
Law Students ....................................................2,845

Age Breakdown* (%)  
30 & under: 5  
31-40: 16  
41-50: 20  
51-60: 26  
62-70: 24  
71 & over: 9

Gender* .................................................................(%)  
Male ..................................................49  
Female ..................................................46  
Non-Binary/3rd Gender .................................................5

Practice Areas* .................................................(%)  
Business & Transactions ..................................................14  
Litigation & Risk Management ........................................12  
Fraud & Compliance ..................................................11  
Physician Issues ..................................................10  
eHealth, Privacy & Security ........................................10  
Facility Operations ..................................................9  
Managed Care & Insurance ........................................9  
Payment & Reimbursement ........................................9  
Life Sciences ......................................................7  
Public Health & Policy ................................................6  
ADR & Conflict Management ......................................5  
Allied Professionals ..................................................3  
Post-Acute Care .....................................................2

Practice Settings* ...................................................(%)  
Private Practice .....................................................70  
In-House ..........................................................22  
Government/Judicial/Military ........................................4  
Academic/Legal Publishing ..........................................3  
Other ..............................................................1

Health Lawyer Circulation ..........16,800+  
(Published bi-monthly: 6 times annually)

Health eSource Circulation ..........9,000  
(Published monthly: 12 times annually)

HLbytes Circulation .................9,000  
(Published weekly: 46 times annually)

National Conferences .................5  
Washington Health Law Summit  
Emerging Issues in Healthcare Law  
Healthcare Fraud  
False Claims Act and Qui Tam Trial Institute  
Physicians Legal Issues

Distance Learning Events ...............52  
Total CLE Hours ............................................78  
Total CLE Credits Earned .............15,000  
Average Registrants Per Event: .......110

*Based on known lawyer members.
TOP RECOGNITION

The practice of health law is professionally challenging and demands dedication. We recognize the following firms and attorneys for answering this call to professionalism, for engaging the challenging health law issues of the day, and for their efforts to address healthcare clients’ complex problems through their membership in the ABA Health Law Section.

NORTHEAST

1. Verrill LLP
   One Portland Square
   Portland, ME 04101
   Phone: 855.307.0700
   verrill-law.com
   Practice Heads: Kathleen Gleason Healy and Andrew P. Rusczek

2. Mintz Levin Cohn Ferris Glovsky and Popeo PC
   Chrysler Center
   666 Third Avenue
   New York, NY 10017
   Phone: 212.935.3000
   mintz.com
   Practice Head: Karen S. Lovitch

3. Nixon Peabody LLP
   55 W 46th Street
   New York, NY 10036-4120
   Phone: 212.940.3000
   nixonpeabody.com
   Practice Head: Peter Armstrong Egan

   100 Light Street
   Baltimore, MD 21202
   Phone: 410.685.1120
   bakeroberhealthlaw.com
   Practice Heads: Ashby Q. Burks and Julie E. Kass

5. Garfunkel Wild PC
   111 Great Neck Road
   Suite 600
   Great Neck, NY 11021
   Phone: 516.393.2200
   garfunkelwild.com
   Practice Head: Fredrick I. Miller

6. Pepper Hamilton LLP
   3000 Two Logan Square
   18th and Arch Streets
   Philadelphia, PA 19103-2799
   Phone: 215.981.4000
   pepperlaw.com
   Practice Head: Rachael M. Bushey

7. Holland & Knight LLP
   10 St. James Avenue
   11th Floor
   Boston, MA 02116
   Phone: 617.523.2700
   hklaw.com
   Practice Heads: Maria T Currier and Jeffrey W Mittleman

8. Venable LLP
   750 E Pratt Street
   Suite 900
   Baltimore, MD 21202
   Phone: 410.244.7400
   venable.com
   Practice Head: Thora A. Johnson

8. Riker Danzig Scherer Hyland & Perretti LLP
   500 Fifth Avenue
   New York, New York 10110
   Phone: 212.302.6574
   riker.com
   Managing Partner: Glenn A. Clark

10. Stevens & Lee PC
    1818 Market Street
    29th Floor
    Philadelphia, PA 19103
    Phone: 215.575.0100
    stevenslee.com
    Practice Heads: Charles M. Honart and Joanne M. Judge

10. Foley Hoag LLP
    Seaport West
    155 Seaport Boulevard
    Boston, MA 02210-2600
    Phone: 617.832.1000
    foleyhoag.com
    Practice Heads: Thomas Baker and Colin Zick

The Northeast region includes Connecticut, Delaware, Maine, Maryland, Massachusetts, New Hampshire, New Jersey, New York, Pennsylvania, Rhode Island and Vermont.

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TOP RECOGNITION

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SOUTHEAST & DC

1. Nelson Mullins Riley & Scarborough LLP
   100 SE 3rd Avenue
   Suite 2700
   Fort Lauderdale, FL 33394
   Phone: 954.764.7060
   nelsonmullins.com
   Practice Head: Gabriel L. Imperato

2. Crowell & Moring
   1001 Pennsylvania Avenue NW
   Washington, DC 20004-2595
   Phone: 202.624.2500
   crowell.com
   Practice Heads: Christopher Flynn and Paul Mourning

3. Polsinelli LLP
   1401 I Street NW
   Washington, DC 20005
   Phone: 202.783.3300
   polsinelli.com
   Practice Head: Matthew J. Murer

4. King & Spalding PC
   1180 Peachtree Street NW
   Atlanta, GA 30309
   Phone: 404.572.4600
   kslaw.com
   Practice Head: James W. Boswell, III

5. Sidley Austin LLP
   1501 K Street NW
   Suite 600
   Washington, DC 20005
   Phone: 202.736.8000
   sidley.com
   Practice Heads: Meenakshi Datta, Paul E. Kalb, MD, and Richard D Raskin

6. Mintz Levin Cohn Ferris Glovsky and Popeo PC
   701 Pennsylvania Avenue NW
   Suite 900
   Washington, DC 20004
   Phone: 202.434.7300
   mintz.com
   Practice Head: Karen S. Lovitch

7. Williams Mullen
   Williams Mullen Center
   200 South 10th Street
   Suite 1600
   Richmond, VA 23219
   Phone: 804.420.6000
   williamsmullen.com
   Practice Head: Jamie Baskerville Martin

8. Hogan Lovells US LLP
   555 13th Street, NW
   Washington, DC 20004
   Phone: 202.637.5600
   hoganlovells.com
   Practice Head: Sheree R. Kanner

   901 K Street, NW
   Suite 900
   Washington, DC 20001
   Phone: 202.508.3400
   bakeroberhealthlaw.com
   Practice Heads: Ashby Q. Burks and Julie E. Kass

10. Holland & Knight LLP
    701 Brickell Avenue
    Suite 3300
    Miami, FL 33131
    Phone: 305.374.8500
    hklaw.com
    Practice Heads: Maria T Currier and Jeffrey W Mittleman

Southeast & DC region includes Florida, Georgia, North Carolina, South Carolina, Virginia, West Virginia and DC.

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The practice of health law is professionally challenging and demands dedication. We recognize the following firms and attorneys for answering this call to professionalism, for engaging the challenging health law issues of the day, and for their efforts to address healthcare clients’ complex problems through their membership in the ABA Health Law Section.

**SOUTH**

1. Waller Lansden Dortch & Davis LLP
   - Nashville City Center
   - 511 Union Street
   - Suite 2700
   - Nashville, TN 37219
   - Phone: 615.244.6380
   - wallerlaw.com
   - Practice Head: Ken Marlow

2. Baker Donelson Bearman Caldwell & Berkowitz – Baker Ober Health Law
   - 211 Commerce Street
   - Baker Donelson Center
   - Suite 800
   - Nashville, TN 37201
   - Phone: 615.726.5600
   - bakeroberhealthlaw.com
   - Practice Heads: Ashby Q. Burks and Julie E. Kass

3. Bradley Arant Boult Cummings LLP
   - 1600 Division Street
   - Suite 700
   - Nashville, TN 37203
   - Phone: 615.244.2582
   - bradley.com
   - Practice Head: Travis G. Lloyd

4. Husch Blackwell LLP
   - 111 Congress Avenue
   - Suite 1400
   - Austin, TX 78701
   - Phone: 512.472.5456
   - huschblackwell.com
   - Practice Head: Curt J. Chase

5. Butler Snow LLP
   - Renaissance at Colony Park
   - 1020 Highland Colony Parkway
   - Suite 1400
   - Ridgeland, MS 39157
   - Phone: 601.948.4711
   - butlersnow.com
   - Practice Heads: Mark W. Garriga, Health Law Practice Group Leader, and Ann E. Lundy, Assistant Practice Group Leader

6. Bass Berry & Sims PLC
   - 150 Third Avenue South
   - Suite 2800
   - Nashville, TN 37201
   - Phone: 615.742.6200
   - bassberry.com
   - Practice Head: Angela Humphreys

7. Stites & Harbison PLLC
   - 400 West Market Street
   - Suite 1800
   - Louisville, KY 40202-3352
   - Phone: 502.587.3400
   - stites.com
   - Practice Head: Janet A. Craig

8. Breazeale, Sachse & Wilson LLP
   - One American Place
   - 301 Main Street
   - 23rd Floor
   - Baton Rouge, LA 70821
   - Phone: 225.387.4000
   - bswllp.com
   - Practice Heads: Clay Countryman, Greg Frost, and Emily Black Grey

9. Haynes and Boone LLP
   - 2323 Victory Avenue
   - Suite 700
   - Dallas, TX 75219
   - Phone: 214.651.5000
   - haynesboone.com
   - Practice Head: Bill Morrison

9. Polsinelli LLP
   - 2950 N Harwood Street
   - Suite 2100
   - Dallas, TX 75201
   - Phone: 214.397.0030
   - polsinelli.com
   - Practice Head: Matthew J. Murer

The South region includes Alabama, Arkansas, Kentucky, Louisiana, Mississippi, Oklahoma, Tennessee and Texas.

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MIDWEST

1. Polsinelli LLP
150 N Riverside Plaza
Suite 3000
Chicago, IL 60606
Phone: 312.819.1900
polsinelli.com
Practice Head: Matthew J. Murer

2. Husch Blackwell LLP
4801 Main Street
Suite 1000
Kansas City, MO 64112
Phone: 816.983.8000
huschblackwell.com
Practice Head: Curt J. Chase

3. Foley & Lardner LLP
321 N Clark Street
Suite 2800
Chicago, IL 60654
Phone: 312.832.4500
foley.com
Practice Heads: Christopher Donovan and Judith Waltz

4. Quarles & Brady LLP
411 E Wisconsin Avenue
Suite 2400
Milwaukee, WI 53202
Phone: 414.277.5000
quarles.com
Practice Head: Amy Cotton Peterson

5. Hall Render Killian Heath & Lyman PC
500 N Meridian Street
Suite 400
Indianapolis, IN 46204-1293
Phone: 317.633.4884
hallrender.com
Practice Head: Gregg M. Wallander

5. Thompson Coburn LLP
505 N 7th Street
One US Bank Plaza
Suite 3500
St. Louis, MO 63101
Phone: 314.552.6000
thompsoncoburn.com
Practice Head: Evan Raskas Goldfarb

7. Dinsmore & Shohl LLP
255 E Fifth Street
Suite 1900
Cincinnati, OH 45202
Phone: 513.977.8200
dinsmore.com
Practice Head: Jennifer Orr Mitchell

8. Warner Norcross + Judd LLP
1500 Warner Building
150 Ottawa Avenue NW
Grand Rapids, MI 49503
Phone: 616.752.2000
wnj.com
Practice Head: Jeffrey S. Battershall

9. Godfrey & Kahn SC
One E Main Street
Suite 500
Madison, WI 53703
Phone: 414.273.3500
GKLaw.com
Practice Head: Thomas N. Shorter

9. The Health Law Partners PC
32000 Northwestern Highway
Suite 240
Farmington Hills, MI 48334
Phone: 248.996.8510
thehlp.com
Practice Head: Adrienne Dresevic

The Midwest region includes Illinois, Indiana, Iowa, Kansas, Michigan, Minnesota, Missouri, Nebraska, Ohio and Wisconsin.

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WEST

1. Hooper Lundy & Bookman PC
   101 W Broadway
   1875 Century Park East
   Suite 1600
   Los Angeles, CA 90067
   Phone: 310.551.8111
   health-law.com
   Practice Heads: Devin Senelick and Scott Kiepen
   Co-Chairs, Litigation Department
   Lloyd Bookman and Katrina Pagonis
   Co-Chairs, Regulatory Department
   Charles Oppenheim
   Chair, Business Department

2. Davis Wright & Tremaine LLP
   865 S Figueroa Street
   Suite 2400
   Los Angeles, CA 90017-2566
   Phone: 213.633.6800
   dwt.com
   Practice Heads: Ingrid Brydolf and Jason A. Farber
   and
   920 Fifth Avenue
   Suite 3300
   Seattle, WA 98104-1610
   Phone: 206.622.3150
   dwt.com
   Practice Heads: Ingrid Brydolf and Jason A. Farber

3. Polsinelli LLP
   1401 Lawrence Street
   Suite 2300
   Denver, CO 80202
   Phone: 303.572.9300
   polsinelli.com
   Practice Head: Matthew J. Murer

4. Sheppard, Mullin, Richter & Hampton LLP
   1901 Avenue of the Stars
   Suite 1600
   Los Angeles, CA 90067
   Phone: 213.620.1780
   sheppardmullin.com
   Practice Head: Eric A. Klein

5. Sutin Thayer & Browne PC
   100 Sun Avenue NE
   Suite 400
   Albuquerque, NM 87109
   Phone: 505.883.2500
   sutinfirm.com
   Practice Head: David H. Johnson

6. Crowley Fleck PLLP
   490 N 31st Street
   Billings, MT 59101
   Phone: 406.252.3441
   crowleyfleck.com
   Practice Heads: Kiely Keane and Stewart R. Kirkpatrick

7. Stoel Rives LLP
   760 SW Ninth Avenue
   Suite 3000
   Portland, OR 97205
   Phone: 503.224.3380
   stoel.com
   Practice Heads: Kelly Knivila and Anthony R. Miles

8. Keating Jones Hughes PC
   200 SW Market Street
   Suite 900
   Portland, OR 97201
   Phone: 503.222.9955
   keatingjones.com
   Practice Head: Molly K. Marcum

8. Parsons Behle & Latimer
   800 West Main Street
   Suite 1300
   Boise, Idaho 83702
   Phone: 208.562.4900
   parsonsbehle.com
   Practice Head: J. Kevin West

10. Foley & Lardner LLP
    555 S Flower Street
    Suite 3300
    Los Angeles, CA 90071-2411
    Phone: 213.972.4500
    foley.com
    Practice Heads: Christopher Donovan and Judith Waltz

10. Latham & Watkins LLP
    355 S Grand Avenue
    Suite 100
    Los Angeles, CA 90071-1560
    Phone: 213.485.1234
    lw.com
    Practice Heads: Daniel Meron and Daniel K. Settelmayer


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UPCOMING EVENTS

17th Annual Washington Health Law Summit
December 9-10, 2019
The Ritz-Carlton
Washington, DC

21st Annual Conference on Emerging Issues in Healthcare Law
March 11-14, 2020
Manchester Grand Hyatt Hotel
San Diego, CA

Physicians Legal Issues Conference
September 2020
Chicago, IL

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