



Healthcare

The healthcare industry around the world is intricate and evolving. Healthcare laws and regulations affect all companies at some level. The healthcare industry is among the most highly regulated in the world, and all employers must comply with the medical privacy protections and healthcare benefits afforded their employees. Multinational companies must navigate sometimes quite divergent payment and reimbursement regimes and the pharmaceutical and medical device approval rules of multiple national governments, as well as regional and international requirements. Healthcare providers are subject to the licensing and oversight rules of every jurisdiction in which they do business.

Our lawyers represent healthcare clients all around the world. We live and work where our clients live and work. And we work together across our offices throughout Asia Pacific, Europe, the Middle East and the United States, combining global strategy with local implementation.

We counsel the healthcare industry in these areas:

- Antitrust and competition
- Project finance
- Healthcare transactional
- Healthcare fraud and compliance
- Health insurance and managed care
- Healthcare regulatory
- Healthcare technology
- Employment
- Payment reimbursement disputes
- Pensions
- Personal injury and product liability litigation
- Privacy
- Professional liability and litigation
- Restructuring

INSIGHTS

Publications

False Claims Act – Year in Review: 2018

4 FEB 2019

In this handbook, we look back on 2018 as a year of shifting enforcement policies and continuing jurisprudential uncertainty in the wake of *Escobar*.

Congress begins new session with scrutiny of drug pricing near the top of the agenda

1 FEB 2019

The cost of prescription medications and therapies has quickly emerged as one of the top priorities of lawmakers on both sides of the Capitol.

Healthcare market proves strong with investors finding returns generally outweigh the risk

30 JAN 2019

Takeaways from the JPMorgan panel, "Healthcare M&A Exits: Who's Buying, What Are They Buying, and Why?"

2018: the year in privacy

3 JAN 2019

A landmark year in state consumer privacy legislation.

Supporting the health of your health system

3 JAN 2019

Guidance to help tend to healthcare system wellness throughout the business life cycle.

CCPA: risk of class actions makes early preparation imperative

21 DEC 2018

Failure to address risk mitigation now could lead to significant liability if a company is breached following the CCPA's January 1, 2020 effective date.

DOJ moves to dismiss 11 qui tam lawsuits filed by professional relator concerning patient-support programs

20 DEC 2018

The DOJ acts on its commitment to seek dismissal of *qui tam* suits it views as not serving the public interest.

eSignature and ePayment News and Trends

20 DEC 2018

[ESIGNATURE AND EPAYMENT NEWS AND TRENDS](#)

In this issue, digitally transforming your business – the year's big legal and regulatory developments and breaking news.

A watershed moment for hemp and hemp-based CBD

14 DEC 2018

The 2018 Farm Bill creates a clear regulatory structure for the commercial development of industrial hemp, as well as stronger legal protections for hemp and hemp-based derivatives, like CBD.

Federal circuit judges disagree on proper standard for evaluating patent validity under 35 U.S.C. § 103

13 DEC 2018

The *prima facie* framework has become so common that two lines of cases are developing in both district courts and the Federal Circuit: the traditional *Graham* approach and the *prima facie* – rebuttal approach.

DOJ tells SCOTUS it plans to seek to dismiss a major *qui tam* action because burdensome FCA discovery would not be in the public interest

6 DEC 2018

The DOJ's filing is a significant development for FCA defendants and may portend more dismissals to come.

eSignature and ePayment News and Trends

26 OCT 2018

[ESIGNATURE AND EPAYMENT NEWS AND TRENDS](#)

In this issue, obtaining remote epayment authorizations from customers – are you in compliance? Plus the latest legislative and regulatory news.

Obtaining remote epayment authorizations from customers: are you in compliance?

26 OCT 2018

The consequences of non-compliance can be significant.

Record-breaking \$16 million settlement for potential HIPAA violations

22 OCT 2018

The settlement should be viewed as a clear message that OCR will continue to enforce HIPAA vigorously in the Trump era.

Supreme Court Corner Q3 2018

27 SEP 2018

The court rules on recovery of lost foreign profits and ponders patentability issues in an invention's sale to a third party that is obligated to keep the invention confidential.

Remote notarization: authentication requirements, by US state

14 SEP 2018

A high-level summary of remote notarization laws by US state.

California amends Consumer Privacy Act to clarify exemptions and fix some technical deficiencies, but significant work remains

10 SEP 2018

SB 1121 clarifies only a handful of the dozens of drafting ambiguities and drafting errors in the CCPA.

CRISPR technology and evolving scientific data: how biotechnology and pharmaceutical companies can mitigate potential product safety risks

16 AUG 2018

How may product safety issues impact those who develop, license or evaluate the potential of innovative gene therapies like CRISPR?

eSignature and ePayment News and Trends

23 JUL 2018

[ESIGNATURE AND EPAYMENT NEWS AND TRENDS](#)

This regular publication from DLA Piper aims to help companies identify significant news and legal developments impacting digital transactions.

Ready or not? Product liability and regulatory implications for digital health products

2 JUL 2018

As laws and regulations catch up with digital health innovation, there remains an open question: how will traditional product liability case law apply?

Supreme Court agrees to hear *Fosamax*

29 JUN 2018

The grant of certiorari comes on the heels of Justice Anthony Kennedy's retirement announcement.

eSignature and ePayment News and Trends

29 JUN 2018

ESIGNATURE AND EPAYMENT NEWS AND TRENDS

In this issue, is your website ADA compliant? Plus news on federal and state law, federal and state regulatory activities, fresh judicial precedent and more.

Is your website ADA compliant? A brief look at the current legal status

29 JUN 2018

Websites too face regulatory issues around compliance with the Americans with Disabilities Act and other rules involving accessibility and accommodation.

***In re Fosamax*: Solicitor General recommends US Supreme Court review impossibility-preemption defense**

5 JUN 2018

The Solicitor General's recommendation substantially increases the chances that the Court will grant certiorari.

CPSC enforcement of Poison Prevention Packaging standards: a recent action – the first of many?

26 APR 2018

In addition to potential civil penalties, PPPA violations could also lead to costly recalls.

Avoid misclassification quagmires by understanding differences between contractors and employees

23 APR 2018

Classification missteps can translate to significant legal and economic risk for businesses, and workers who are not properly classified also face negative consequences.

ONC guide for accessing and using medical records breaks no new ground, instead doubles down on old processes

16 APR 2018

The ONC Guide to Getting and Using your Health Records educates patients on their rights of access and provides detailed instructions on how patients should request their records.

Massachusetts Supreme Court recognizes brand-name pharmaceutical makers owe duty to consumers of generic medications

19 MAR 2018

In an opinion with significant implications, the Massachusetts Supreme Court has recognized a narrow window of innovator liability against manufacturers of brand-name pharmaceuticals.

Regulation of medical devices - what is changing?

13 MAR 2018

After four years of deliberations, the new Medical Devices Regulation finally came into effect on 25 May 2017. This marks the commencement of a three-year transitional period for manufacturers of medical devices to update their policies and processes in order to distribute products in the EU market.

False Claims Act year in review: 2017

28 FEB 2018

Our new handbook looks at 2017, a year of significant recoveries, government enforcement reform and shifting jurisprudence post-*Escobar*, then considers the trends we anticipate in the months ahead.

The triple aim of healthcare

13 FEB 2018

Josh Kaye discusses the triple aim of innovative healthcare at this year's StartUp Health Festival.

Powering the cancer moonshot with visionary thinking

13 FEB 2018

Lisa Haile discusses the importance of visionary thinking at this year's StartUp Health Festival.

How to stay focused while fundraising

13 FEB 2018

Itai Nevo discusses the importance of staying focused while fundraising at this year's StartUp Health Festival.

Healthcare investment charges ahead in spite of lingering regulatory uncertainty

30 JAN 2018

Takeaways from our JP Morgan panel, "Healthcare M&A Exits, Who's Buying, What Are They Buying, and Why?"

Middle District of Florida reverses \$350 million verdict and joins other courts in enforcing Escobar's strict materiality standard

17 JAN 2018

The Middle District of Florida joins an increasing number of courts that have applied the heightened materiality standard identified in *Escobar*.

The Affordable Care Act: major actions in 2017 and what to expect in 2018

16 JAN 2018

We expect the ongoing policy and regulatory changes being contemplated through 2018 will continue to impact the evolution of the ACA and, therefore, its impact on the healthcare market, in ways that are both expected and unexpected.

Supporting the health of your health system - our most popular guidance

2 JAN 2018

[HEALTH SYSTEMS ALERT SERIES](#)

Treat the health of your entire healthcare system. DLA Piper's lawyers provide guidance to help you tend to your system's wellness throughout the business life cycle.

California Supreme Court endorses innovator liability against manufacturers of brand-name pharmaceuticals

22 DEC 2017

California Supreme Court: brand-name manufacturers owe a duty of reasonable care to ensure that product labeling includes adequate warnings.

Product liability implications in the digital health industry

4 DEC 2017

As digital health products become commercialized and their use becomes more mainstream, companies face a higher likelihood of product liability litigation and regulatory scrutiny.

Healthcare restructurings: four key issues to consider before a chapter 11 filing

9 NOV 2017

A healthcare restructuring can present a number of unique challenges.

The intersection of Federal Civil Enforcement: claims and healthcare restructurings

18 OCT 2017

It is well known that the healthcare industry as a whole has undergone significant changes, challenges and uncertainties in recent years... Taken together, these challenges have caused a number of healthcare companies to financially struggle and have resulted in a number of restructurings.

FDA announces major regulatory overhaul initiative

8 SEP 2017

This initiative will be a massive undertaking given the breadth of FDA's regulatory authority over a vast array of products and industries.

Coming soon from FDA? Streamlined safety information in prescription drug television ads

7 SEP 2017

If FDA proceeds, TV may feature even more drug ads, and the advice to "talk to your doctor" will become even more important.

Changes coming soon for pharmaceutical patent litigation in Canada: key points

25 MAY 2017

The expected changes will shift the structure of the current regime closer to that followed in the United States under the Hatch-Waxman Act.

House passes health reform bill – three key amendments

4 MAY 2017

Republicans produced three amendments to the original version of the AHCA in an attempt to appease various factions of their membership and successfully pass the bill.

The New England Compounding Center: the CEO of a Massachusetts drug company on trial for murder

21 APR 2017

Eric Christofferson and Steve Hassink discuss NECC's contaminated drugs in *Pharmaceutical Law & Industry Report*.

FDA authorizes first direct-to-consumer genetic test panel for predisposition to Alzheimer's disease and other serious disorders

11 APR 2017

A significant step for the FDA, creating a new class of genetic tests.

Public-Private Partnerships in Puerto Rico

21 MAR 2017

For those considering participating in P3s in Puerto Rico, this handbook summarizes the applicable legal framework and discusses why Puerto Rico is a favorable jurisdiction for entering into P3s.

Healthcare sector takes note: DOJ heightens its expectations for effective corporate compliance programs

13 MAR 2017

The new guidance expands the types of inquiries that have been typical in assessing health industry compliance programs and demonstrates a concerted effort to look beyond form to substance.

Repeal and replacement of Obamacare begins; policy changes to unfold in coming months

9 MAR 2017

While Congress is currently focusing on the financing arm of healthcare reform, the actual substantive policy changes will unfold over the next six to twelve months.

Preserving executive health plan options under the ACA

22 AUG 2016

Universal Health Services: contractors take note – Supreme Court approves implied certification theory of False Claims Act liability

22 JUN 2016

The Court's recognition of "implied certification" theory resolves a circuit split in favor of a more expansive view of the Act.

DLA Piper's Guide to Restructuring Issues for Not-For-Profit Companies and Their Directors

29 OCT 2015

Understanding the financial challenges in preserving an NFP and its mission

Wellness innovators take note: FDA reveals risk-based approaches to the regulation of health IT and mobile medical apps

2 FEB 2015

[HEALTH SYSTEMS ALERT SERIES](#)

With these draft guidance documents, FDA indicates it will not take enforcement action in connection with low-risk general wellness products and establishes a new risk-based approach to medical device accessories

FDA's new menu labeling and vending machine requirements: 10 key answers for food businesses

2 DEC 2014

The new requirements apply nationwide and preempt existing state laws

Intellectual Property and Technology News (United States), Issue 23, Q3 2014

10 SEP 2014

INTELLECTUAL PROPERTY AND TECHNOLOGY NEWS SERIES

Our Intellectual Property and Technology News reports on worldwide developments in IP and technology law, offering perspectives, analysis and visionary ideas.

Big or small, it's all hardball: merger enforcement actions *below* the HSR threshold - top ten tips in non-reportable transactions

23 JUN 2014

No anti-competitive deal is immune from challenge, even if it is small - 10 important points to keep in mind in M&A transactions

First Lady and nutrition: USDA and FDA propose sweeping food labeling and marketing regulations

27 FEB 2014

Today, First Lady Michelle Obama and the Food and Drug Administration released two long-awaited proposed regulations that would for the first time in 20 years make significant changes to the nutrition information found on food and dietary supplement labels.

Offering healthcare solutions at consumers' fingertips? What you should know about FDA regulation of mobile medical apps

10 OCT 2013

Food safety from farm to fork: FDA publishes proposed rules aiming to ensure the safety and security of the food supply

24 JAN 2013

The proposed rules lay the foundation of the prevention-based, modern food safety system envisioned in the FSMA and have wide-ranging effects on many industries, including every link in the global food supply chain.

Revenue pressure climbs for skilled nursing facilities – what does this mean for healthcare REITs?

3 JUN 2015

Healthcare REITs must be mindful of the challenges they may face due to changes in the healthcare environment

EVENTS

Upcoming

Healthcare Leadership Insights Conference 2019

14 MAR 2019

Miami

Previous

DLA Piper luncheon during the 37th annual JP Morgan Healthcare Conference

8 JAN 2019

Antitrust aspects of big data and algorithms

21 FEB 2018

Webinar

Healthcare Leadership Insights Conference 2018

8 FEB 2018

Miami

Healthcare reform webinar series

13 APR 2017

NEWS

Richard Cheng joins DLA Piper's Corporate practice in Dallas

31 JAN 2019

DLA Piper announced today that Richard Cheng has joined the firm's Corporate practice as a partner in Dallas.

DLA Piper advises ResMed in acquisition of Propeller Health

4 DEC 2018

DLA Piper represented ResMed (NYSE: RMD), a world-leading connected health company, in its entry into a definitive agreement to acquire Propeller Health, a digital therapeutics firm, for US\$225 million.

DLA Piper advises ResMed in agreement to acquire MatrixCare for US\$750 million

7 NOV 2018

DLA Piper represented ResMed, a world-leading connected health company, in a definitive agreement to acquire privately held MatrixCare, a leader in US long-term post-acute care software, for US\$750 million.

Daniel Tobey joins DLA Piper's Litigation practice in Dallas

19 SEP 2018

DLA Piper announced today that Daniel Tobey has joined the firm's Litigation practice as a partner in Dallas.

DLA Piper advises BTG in acquisition of Novate Medical

10 SEP 2018

DLA Piper represented BTG plc, a global specialist healthcare company, in its acquisition of Novate Medical Ltd.

DLA Piper advises Maryland Proton Treatment Center in US\$277.4 million tax-exempt municipal bond financing

6 SEP 2018

DLA Piper represented Maryland Proton Therapy Center (MPTC) in its US\$277.4 million tax-exempt municipal bond financing.

DLA Piper advises Olive in US\$32.8 million Series D financing

31 JUL 2018

DLA Piper represented Olive, a technology company applying artificial intelligence to healthcare administration, in its US\$32.8 million Series D financing.

DLA Piper recognized again as a Top Global Outsourcing Advisor

28 JUN 2018

DLA Piper is pleased to announce that the firm has been selected for the 2018 World's Best Outsourcing Advisors list by the International Association of Outsourcing Professionals (IAOP).

Kristi Kung joins DLA Piper's Litigation and Healthcare practices in Northern Virginia and Washington, DC

27 JUN 2018

DLA Piper announced today that Kristi Kung has joined the firm's Litigation and Healthcare practices as a partner in Northern Virginia and Washington, DC.

DLA Piper named International Law Firm of the Year in Ukraine for fifth year running at The Legal Awards 2018

24 MAY 2018

DLA Piper has been named International Law Firm of the Year in Ukraine at the 2018 Legal Awards, held by Yuridicheskaya Practika Publishing House. This is the fifth time the office has won the award.

DLA Piper announces partnership promotions for 2018

3 APR 2018

DLA Piper is proud to announce that 62 lawyers have been promoted to its partnership. The promotions are effective as of 1 April 2018 in the United States and 1 May 2018 for EMEA and Asia Pacific. The promotions were made across many of the firm's practice areas in 42 different offices throughout 20 countries.

DLA Piper advises ICV Partners in acquisition of Outpatient Imaging Affiliates

15 MAR 2018

DLA Piper represented ICV Partners, LLC, a New York-based private equity firm focused on middle market companies, in its acquisition of Outpatient Imaging Affiliates, LLC, a leading provider of outpatient radiology services.

DLA Piper advises healthcare analytics company Protenus in \$11 million Series B investment

01 JAN 18

DLA Piper represented Protenus, a Baltimore-based healthcare compliance analytics company, in its \$11 million Series B financing round.

DLA Piper represents Vivo Capital in equity financing of Harmony Biosciences, LLC

13 OCT 2017

DLA Piper represented healthcare-focused investment firm Vivo Capital as the lead investor in a US\$270 million equity financing of Harmony Biosciences, LLC, a biopharmaceutical company that develops orphan and rare disease therapies.

DLA Piper announces healthcare enforcement response team

26 SEP 2017

To better serve the healthcare sector, DLA Piper has established a team of experienced professionals to address governmental enforcement proceedings arising from activity by HEAT and other regulators.

DLA Piper adds litigator Christopher Oprison in Miami

22 AUG 2017

DLA Piper announced today that Christopher Oprison has joined the firm's Litigation practice as a partner in Miami.

DLA Piper advises SoftBank Group in its Series E investment into Guardant Health

14 AUG 2017

DLA Piper represented SoftBank Group International, the investment arm of Tokyo-based telecommunications and internet company Softbank, in connection with its US\$360 million Series E investment and associated joint venture into Guardant Health, a Silicon Valley-based world leader in comprehensive liquid biopsies.

DLA Piper is #1 in Healthcare Private Equity

9 AUG 2017

DLA Piper was awarded the 2016 M&A Advisor Award in the Healthcare and Life Sciences Deal of the Year (under \$100 million) category and is ranked #1 in healthcare private equity work by *PitchBook* in 2016.

DLA Piper recognized for strong client relationships in *BTI Industry Power Rankings*

18 JUL 2017

DLA Piper has been recognized for the strength of its client relationships across a broad spectrum of industries in BTI Consulting Group's 2017 *BTI Industry Power Rankings*.

DLA Piper advises GreatCall in proposed acquisition by GTCR

8 June 2017

DLA Piper represented GreatCall, the largest provider of connected health and personal emergency response services for seniors in the United States, in its proposed acquisition by GTCR, a leading private equity firm. The transaction is expected to close in the third quarter of 2017.

DLA Piper lawyers and practices ranked in latest Chambers edition

31 MAY 2017

DLA Piper today announced that 161 of the firm's lawyers and 62 of its practices were ranked in *Chambers USA's* 2017 guide.

Anna Spencer joins DLA Piper's Intellectual Property and Technology practice

3 May 2017

DLA Piper announced today that Anna Spencer has joined the firm's Intellectual Property and Technology practice as a partner who will work from the Atlanta and Washington, DC offices.

John Rah joins DLA Piper's Litigation practice in Washington, DC

20 APR 2017

DLA Piper announced today that healthcare and life sciences compliance lawyer John Rah has joined the firm's Litigation practice as a partner in Washington, DC.

Enforcement and Compliance

DLA Piper's Healthcare Enforcement and Compliance practice is a multi-disciplinary team that provides services in the areas of **prevention, compliance and advocacy** to members of the Healthcare community.

PREVENTION

- Providing "ready reference" compliance advice
- Assessing, building and strengthening compliance programs
- Anticipating and preventing legal and reputational risks
- Performing due diligence in healthcare transactions

COMPLIANCE

- Clarifying applicable standards, often in novel or esoteric areas
- Achieving compliance when it is in question
- Investigating potential non-compliance with applicable standards
- Taking appropriate remedial measures

ADVOCACY

- Defending lawsuits and investigations initiated by state and federal regulators and enforcers
- Defending whistleblower cases
- Responding rapidly when there is a government request for information
- Advocating in Recovery Audit Contractor (RAC), Medicare, Medicaid and payer audits
- Assisting with the defense, appeals and litigation of denied claims for reimbursement

OUR TEAM

We have lawyers across the United States and around the globe who have dedicated their careers to helping clients establish and maintain legal and regulatory compliance, and defend against government enforcement actions. Ten of our lawyers are Certified in Compliance, which we believe is more than any other law firm in the world.

OUR APPROACH

As we serve members of the healthcare industry in the current challenging environment, we provide value by using:

- Diverse teams that are best suited for the specific issue
- Diligent and focused assessments
- Rigorous, collaborative planning and execution
- Techniques to diminish internal client disruption and distraction from core activities
- Advice that provides clarity in the ever-changing healthcare climate
- Fresh perspectives and innovative strategies

WHAT WE DO

- Assess and enhance compliance program effectiveness
- Focus on industry-provider relationships and transparency
- Emphasize compliant physician-hospital relationships
- Assist with troublesome Medicaid issues, which are more prevalent in the post-reform environment
- Perform compliance due diligence in transactions
- Defend against regulatory enforcement and whistleblower actions and investigations
- Provide comprehensive privacy and security counseling
- Handle claims audits and reimbursement disputes

OUR CLIENTS

- Hospitals and health systems
- Academic medical centers
- Hospice, durable medical equipment, home health and long-term-care providers
- Physician groups
- Allied healthcare professionals
- Ancillary service providers

THE KINDS OF MATTERS WE HANDLE

- Government investigations and False Claims Act cases
- Internal investigations
- Whistleblower cases
- Stark Law and Anti-Kickback concerns
- Medicare and Medicaid issues
- Reimbursement disputes
- Exclusion proceedings
- Voluntary disclosures
- RAC and other government audits
- Privacy and security
- Drug Enforcement Agency (DEA) issues
- Clinical trials

OUR EXPERIENCES

A sampling of clients and matters:

- Hospitals, healthcare providers and physician groups in several investigations by the Department of Health and Human Services-Office of Inspector General (OIG) and the Department of Justice
- Health systems in the DOJ's national Implantable Cardioverter Defibrillator (ICD) investigation.
- Defense of whistleblower suits brought by disgruntled third parties
- Defense of allegations that hospitals' services were medically unnecessary and therefore not reimbursable
- A hospital in a dispute with former third-party billing and management companies related to alleged improprieties by those companies
- The operator of long-term-care facilities in parallel state and federal investigations
- A large academic medical center in government investigations relating to billings to federal healthcare programs
- Various clients in False Claims Act lawsuits alleging false billings to federal healthcare programs
- Allied health providers embroiled in parallel state and federal administrative, civil and criminal investigations into alleged billing for medically unnecessary services
- A public hospital regarding its voluntary disclosure of potential billing deficiencies
- A health system in a putative class action brought by former patients and an employee alleging improper billings to commercial payers
- A pharmacy provider in an investigation by the DOJ and the DEA
- Hospital systems in defending against RAC and other third-party payer audits
- A major children's hospital in regulatory, reimbursement and fraud and abuse counseling. The hospital ultimately refined its compliance program
- Stark and Anti-Kickback counseling for health providers

KEY CONTACT



Karen Nelson
Chair, Healthcare Regulatory Enforcement and Compliance Practice