



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.

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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

Publications

FTC's Policy Statement on breach notifications in mobile health apps: a new, broad approach that may face legal challenge

27 September 2021

The Policy Statement highlights the FTC's intention to step up enforcement consistent with these broad new interpretations.

The global landscape of data privacy: Important points about new laws in three key jurisdictions

21 September 2021

PRACTICAL COMPLIANCE

New data privacy requirements in three important jurisdictions – the European Union, China, and Brazil – with an emphasis on action steps for compliance officers.

The Hidden Cost of Price Control Policies with Kirsten Axelsen

15 September 2021

An interview with Kirsten Axelsen about what would change in biopharma if price controls were implemented.

President Biden announces new vaccination requirements – what private employers and federal contractors need to know

14 September 2021

Employers already struggling with a puzzling array of compliance challenges aimed at combating COVID-19 now face additional vaccination and testing requirements.

Split Seventh Circuit lowers the bar for pleading a False Claims Act violation

14 September 2021

Defendants are again at risk for False Claims Act liability for what appear to be mere breaches of contract or technical regulatory violations.

mRNA Technology: A New Approach to Therapeutics

8 September 2021

AT THE INTERSECTION OF SCIENCE AND LAW

Dr. Lisa Haile talks with Dr. Kathy Fernando about the study of mRNA and how COVID-19 catalyzed its advancement.

Seventh Circuit adopts objective reasonableness standard for False Claims Act liability

1 September 2021
Key details and takeaways.

Cybersecurity considerations for executives and boards of directors: How recent cyberattack trends and developments inform strategies for reducing cyber-risk

23 August 2021
We review recent trends and costs associated with cyberattacks and analyze how organizations can implement strategies for reducing cyber-risk.

Israel Group News August 2021

16 August 2021
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New workplace protections for medical cannabis patients in Puerto Rico

12 August 2021
The new law creates a new protected category under Puerto Rico antidiscrimination laws.

SCOTUS upholds the ACA: Next steps for employers

8 July 2021
All ACA provisions regarding the employer mandate for large employers continue in effect; in addition, ACA patient protection provisions have been expanded by the Consolidated Appropriations Act, 2021.

Global corporate benchmarking group seeks inputs on corporate human rights standards

22 June 2021
Comments are requested by June 25, 2021.

Whatever your sector, ransomware attacks are changing how to think about platform security risk: Action steps

14 June 2021
In an increasingly digitized economy, creating awareness of platform security risks is critical.

FDA solicits public comment on adding list of device materials to certain medical device labels

26 May 2021
The proposed change would apply to all medical devices that may be in contact with a patient long term.

Israel Group News May 2021

1 May 2021

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FDA warning letters: More warnings and closer scrutiny of COVID-19 and vaping products

26 April 2021

A large percentage of warning letters concern adulterated, unapproved or misbranded products related to COVID-19, and e-cigarette companies continue to be in the agency's crosshairs for selling unapproved products.

eSignature and ePayment News and Trends

2 April 2021

ESIGNATURE AND EPAYMENT NEWS AND TRENDS

Continuing the digital transformation into 2021.

Top employee benefits issues to watch

31 March 2021

The top 10 issues likely to impact plan sponsors in 2021 and beyond.

The Drivers of SPACs and Why They are Here to Stay

4 March 2021

HEALTHCARE Q&A SERIES

At the DLA Piper 2021 Healthcare Leadership Conference, both Josh and Jeff will join a panel to discuss the latest developments in capital markets for healthcare companies including SPACs.

Telehealth's impact on low-income communities

3 March 2021

Ray Williams and Kirsten Axelsen are joined by Dr. Benson Hsu of the University of South Dakota Sanford School of Medicine for a frank discussion on disparities to engaging with telehealth and ways to better serve low income communities.

Making Compliance Part of Your Business DNA

2 March 2021

HEALTHCARE Q&A SERIES

At the DLA Piper 2021 Healthcare Leadership Conference, Charles will participate in the panel, *What is an effective compliance*

program. This session will explore the shift in the federal government's approach to compliance program effectiveness and how new trends will impact organizational and enforcement efforts in the future.

Legislators and regulators continue to support digital transformation

26 February 2021

Endorsing the movement towards digital transformation.

eSignature and ePayment News and Trends

26 February 2021

[ESIGNATURE AND EPAYMENT NEWS AND TRENDS](#)

How legislatures and regulators endorse the movement towards digital transformation.

Expectations for white collar enforcement under the Biden Administration

18 February 2021

Six key areas where the Biden Administration may focus its enforcement efforts.

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19 January 2021

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No Surprises Act creates new model for commercial payors and providers

7 January 2021

The act contains consumer protection and transparency requirements that may fundamentally change health payor and provider operations.

Supporting the health of your health system

4 January 2021

Helping you tend to healthcare system wellness throughout the business life cycle.

Senate approves bill eliminating antitrust exemption for health insurers

29 December 2020

New antitrust compliance challenges for the health insurance industry.

The EEOC breaks its silence on the COVID-19 vaccine

22 December 2020

Some of the most important questions answered by the EEOC's guidance.

When a threat actor strikes: Legal considerations and challenges in a ransomware attack

21 December 2020

Evidence suggests that having employees working remotely significantly increases the risk of a successful ransomware attack.

Silver linings for FCA defendants in new HHS Working Group

11 December 2020

The US Department of Health and Human Services is launching the Working Group to better protect taxpayer funds and deter "would-be fraudsters."

FDA seeks feedback on industry best practices for medical device cybersecurity communications

9 December 2020

The agency emphasizes the evolving responsibility of medical device manufacturers to promptly, clearly communicate cybersecurity issues to patients and healthcare providers.

Practical Compliance

8 December 2020

[PRACTICAL COMPLIANCE](#)

Q4 2020: Spotlight on real estate COVID-19 compliance.

CMS, OIG finalize Stark and AKS overhaul – paving the way for value-based care

25 November 2020

We highlight some of the most important ways in which HHS followed through on its ideas from 2019, as well as the instances where they pivoted in reaction to public comments.

HHS-OIG issues alert warning pharmaceutical and device manufacturers about the kickback risks of speaker programs

24 November 2020

Key details and takeaways.

The US Hemp Production Handbook

4 November 2020

A concise, high-level overview for businesses that are currently or are considering operating in this growing market.

Israel Group News October 2020

7 October 2020

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California on the verge of instituting new deidentification requirements, broader research exemptions for health data

23 September 2020

AB 713 has an emergency clause that means it will go into immediate effect once the governor signs it.

Four years later, federal court upholds convictions but harshly criticizes off-label prosecutions

23 September 2020

The decision will likely draw attention both in the First Circuit and beyond.

PREP Act immunity: federal courts weigh in

4 September 2020

The decisions suggest PREP Act immunity may apply broadly to manufacturers but may be more limited for hospitals, nursing homes, healthcare providers and others.

Food and Beverage News and Trends

10 August 2020

FOOD AND BEVERAGE NEWS AND TRENDS

FDA announces new food safety blueprint, plus cell-cultured meat, bioengineered foods, soda, onions and a white candy bar, a court says, is white.

Highlights from the Medicare Physician Fee Schedule proposal for CY 2021: Remote physiologic monitoring clarity, telehealth expansion, drug and vaccine pricing and more

10 August 2020

CMS is proposing that certain policy changes implemented on a temporary basis during the present public health emergency be carried forward permanently.

For the healthcare industry, seeking to incentivize restocking of elective surgery supplies may lead to civil and

criminal risk

6 August 2020

Discounts and incentives may have unforeseen consequences under certain federal anti-bribery laws.

The US-Mexico-Canada Agreement: A summary of changes in Mexico's laws

6 August 2020

Mexico makes sweeping changes to an array of laws.

New Executive Order forecasts permanent telehealth funding changes

5 August 2020

The Order implies a possible mechanism for making telehealth changes in spite of statutory confines and signals to Congress to take further action to permanently expand telehealth access in the Medicare program.

eSignature and ePayment News and Trends

30 July 2020

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OCC says national banks may provide cryptocurrency custody services – plus latest legal, regulatory and case law developments

HHS extends COVID-19 public health emergency declaration, preserving major Medicare changes (for now)

27 July 2020

The PHE declaration is an important prerequisite for certain major emergency measures the government has deployed to help address the pandemic.

Lessons learned about autonomous AI: Finding a safe, efficacious and ethical path through the development process

27 July 2020

A literature review of bioethical principles for AI and evaluation rules for autonomous AI, grounded in bioethical principles.

Momentum builds for permanent expansions in federal telehealth policy

21 July 2020

Recent legislative proposals and administrative initiatives suggest that the federal government may be moving to make permanent certain emergency fixes to the telehealth regulatory landscape.

Congress continues to signal interest in long-term telehealth

14 July 2020

Recent statements and proposals from members of Congress and state governments showing how interest in telehealth services generated by the pandemic may lead to lasting policy changes.

Digital health: Connecting patients and services in a COVID-19 world

13 July 2020

Telehealth technologies have emerged as a powerful tool to connect patients with vital services while reducing in-person interactions that can spread the virus.

Israel Group News July 2020

8 July 2020

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The legal challenges facing the vaping industry in the EU/UK and the US: An overview and a look ahead

7 July 2020

Notes as the industry matures.

CMS proposed rule aims to encourage value based purchasing for drugs, now open for comment

6 July 2020

The rule is intended to spur the development of contractual arrangements between insurers and biopharma companies that rely on the observed value from medicines in exchange for payment.

eSignature and ePayment News and Trends

2 July 2020

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Honoring National E-SIGN Day – plus latest legal, regulatory and case law developments

Therapies for COVID-19: Two major developments

25 June 2020

The developments, one negative and one positive, involve widely available medications.

Value-based payment in a pandemic: Will systematic changes to support the accountable care organization model be enough?

24 June 2020

It remains to be seen whether the adjustments from CMS are enough to change the minds of ACO leaders who have considered dropping out.

As COVID forces a telehealth boom, lawmakers weigh making certain emergency permissions permanent

12 June 2020

Some of the ways in which government actors have signaled openness to the possibility of longer-term telehealth solutions.

COVID-19 spurs digital transformation and electronic use and acceptance

3 June 2020

Steps to help to ensure enforceability and meet compliance obligations.

Managing the COVID-19 crisis in the healthcare sector

3 June 2020

We have selected key COVID-19 related alerts with the healthcare sector executive team and in-house counsel team in mind, categorized by key topics.

US-based pharmaceutical manufacturing in response to COVID-19: new manufacturers face risks

3 June 2020

A rush to develop a new company to begin manufacturing is fraught with risk.

eSignature and ePayment News and Trends

3 June 2020

[ESIGNATURE AND EPAYMENT NEWS AND TRENDS](#)

COVID-19 spurs digital transformation and electronic use and acceptance, plus latest legal, regulatory and case law developments.

Preparing for global class actions arising from COVID-19

28 May 2020

The risk to companies of global and cross-border class action and collective redress proceedings is rising.

DOJ increasing scrutiny on coronavirus-related provider fraud

22 May 2020

Recent enforcement activity is focusing on providers, particularly on telemedicine companies.

Coronavirus testing and contact tracing: House Democrats' HEROES Act provides US\$75 billion to support testing and tracing to monitor and suppress COVID-19 transmission

21 May 2020

A major element for a successful, large-scale contact tracing program is data management and technology, and technology partners will play a major role in modifying existing systems as well as developing new data interfaces.

Helping patients during the pandemic

14 May 2020

Some important considerations for biopharma manufacturers.

[UPDATED] Therapies for COVID-19: What is in the pipeline?

11 May 2020

As of May 8, 2020, there are over 1,300 clinical trials investigating potential therapies for COVID-19, of which nearly 800 are interventional trials.

US takes action to abate tariffs and duties in wake of COVID-19

8 May 2020

US importers may consider navigating the various tariff exemptions and deferrals in several ways.

Latest round of CMS COVID-19 waivers includes telehealth expansion and other billing flexibilities

7 May 2020

Congress is permitting dramatic expansion of telehealth coverage for the duration of the public health emergency. These are the latest developments.

Life Sciences Top of Mind: COVID-19 sector insights

7 May 2020

Top COVID-19 considerations for the life sciences sector.

Protecting AI technologies through patents: A US guide

7 May 2020

A strong patent portfolio developed around a company's artificial intelligence innovations is an important asset.

COVID-19: New York and Other Northeast Council states take phased approach to reopening economy

6 May 2020

These developments raise a number of immediate questions and considerations for businesses operating in the region.

Post-COVID-19: What to expect in the "next normal"

30 April 2020

Issues that are front of mind, based on an informal survey of some of the largest companies and most influential global business leaders.

US telehealth update: New federal guidance to state Medicaid agencies suggests more coverage is coming

27 April 2020

A powerful signal that CMS is ready to support targeted interventions in favor of telehealth.

Connected care funding for healthcare providers from the CARES Act

24 April 2020

New funding to promote and support telehealth.

Coronavirus: reopening businesses – compliance risks

24 April 2020

Companies looking to reopen are urged to do so in compliance with varying, changing government restrictions to avoid longer term liabilities that could potentially outweigh short term gains

Coronavirus: State Attorneys General take action against alleged price gouging in personal protection equipment sales

21 April 2020

State Attorneys General coast to coast are taking aggressive action.

Opening Up America Again Guidelines signal relaxation in elective surgery restrictions

20 April 2020

For healthcare providers as they evaluate how the Opening Up America Again Guidelines pertain to their respective practices.

Clinical trials during the COVID-19 pandemic: A global guide

17 April 2020

The unprecedented situation resulting from the COVID-19 pandemic impacts the ability to conduct clinical trials on a global scale. Pharmaceutical companies need to address multiple challenges to ensure the continuity of trials on human medicines.

CMS issues temporary waivers to allow hospital services to be provided in community-based locations and clarifies the applicability of EMTALA for locations outside of the hospital

16 April 2020

These waivers permit patients to be triaged to a variety of community-based locales.

CMS regulatory waivers relax supervision and other requirements in an effort to address staff shortages caused by rising COVID-19 cases

16 April 2020

These changes are effective immediately.

FCC now accepting applications for CARES Act telehealth grants

16 April 2020

To ensure as many applicants as possible receive funding, the FCC noted it does not anticipate awarding more than \$1 million to any single applicant.

Immediate COVID-19 relief to Medicare providers arrives... with conditions

16 April 2020

For eligible Medicare providers who continue to suffer economic losses stemming from the pandemic, this program is welcome, but it comes with detailed conditions.

Courts allow False Claims Act cases to proceed despite providers' claims of honestly held clinical judgment

14 April 2020

These decisions will make it easier for relators and the government to successfully prosecute FCA cases.

COVID-19: New York State provides new guidance on essential businesses

13 April 2020

The Guidelines raise a number of immediate questions and considerations for New York businesses.

Coronavirus: Overview of healthcare funding stimulus and policy provisions in the CARES Act (United States)

10 April 2020

Among numerous health policy provisions in the CARES Act is one allowing BARDA to partner with private sector companies on R&D.

Families First Coronavirus Response Act – Health emergency leave and exempted health care providers

10 April 2020

The temporary health emergency leave measures include a key carveout for "Health Care Providers" and "Emergency Responders."

US \$2T stimulus COVID-19 package includes significant R&D funding

10 April 2020

A summary of R&D funding in the CARES Act broken out by federal departments and agencies.

COVID-19: Tort immunity for vaccines and antivirals – lessons from the swine flu of 1976

8 April 2020

While the common goal is to quickly develop countermeasures to combat COVID-19, it is important to consider the potential legal and reputational risks.

Contract analysis in a crisis: flowcharts

7 April 2020

Flowcharts providing considerations for analyzing commercial contracts in the context of the COVID-19 pandemic through a logical process flow that can serve as a practical checklist.

Cost-cutting considerations in the time of COVID-19 (Part 3 – employment issues outside the US)

7 April 2020

A deeper dive into various cost-saving measures and their viability for employers outside the US.

HHS issues notification of enforcement discretion under HIPAA for certain uses and disclosures by business associates

7 April 2020

This announcement permits business associates to share personal health information with public health authorities and agencies in accordance with HIPAA exceptions as part of COVID-19 relief efforts.

A balance between the government, the private sector and the needs of the people: Invocation of rarely used provisions to ensure public safety during the COVID-19 pandemic

6 April 2020

The Defense Production Act, compulsory licensing and march-in rights are means for authorizing the government to step in and assert rights against private companies.

COVID-19 and the "essential business" designation: Practical guidance for businesses that fall in the gray area between "essential" and "non-essential"

6 April 2020

Certain frequently asked questions as well as practical guidance.

COVID-19 emergency declaration allows Centers for Medicare & Medicaid Services to issue 1135 waivers, 1915(c) waivers and changes to survey and audit processes

6 April 2020

Issued in a public health emergency, the waivers help ensure healthcare items and services are available for individuals enrolled in Social Security Act programs.

Coronavirus: Supplier due diligence for vetting Chinese medical suppliers for quality, safety, fair pricing and anti-corruption compliance

6 April 2020

Some key risks, and potential solutions to reduce cross-border operational risks.

Coronavirus: The Defense Production Act's authorities and limitations in the fight against COVID-19

6 April 2020

The DPA has significant implications for companies receiving a direct order from the President and for the subcontractors and suppliers behind them; meanwhile, recent legislation has created procurement opportunities under the DPA.

[UPDATED] As device industry veterans and newcomers step up to the line, FDA swiftly adjusts regulatory hurdles for personal protective equipment during the COVID-19 pandemic

6 April 2020

A high level overview of the FDA's tiered, risk-based approach to masks, face shields and respirators based on developments to date.

CARES Act may offer relief for medical practices, but raises questions for private equity-backed practice management companies

3 April 2020

Medical practices and practice management companies are urged to consider options under the CARES Act.

CARES Act waivers from CMS provide additional flexibility for telehealth services and relief from certain Stark Law liabilities (United States)

3 April 2020

This latest relief further expands healthcare practitioners' ability to reach patients through telehealth, an important tool for addressing patient needs while reducing in-person contact.

Beyond social distancing: What employers need to know to keep their workplaces safe and manage privacy

obligations in the face of COVID-19

2 April 2020

Guidance from OSHA, EEO and CDC to help employers seeking to protect the health, safety and privacy of their on-site employees.

DOJ increases scrutiny of nursing home industry

1 April 2020

DOJ is doubling down on its commitment to investigate and prosecute allegations of elder abuse and of substandard quality of care.

Coronavirus: Cybersecurity considerations for your newly remote workforce (United States)

31 March 2020

Cyber risk management involves balancing the productivity of a workforce with ensuring confidentiality, integrity and availability of the company's own systems and data, as well as that of their supply chain.

Importing critical healthcare supplies during the COVID-19 pandemic: Recent US developments

31 March 2020

Practical guidance is critical to help importers of medical products efficiently navigate legal and regulatory hurdles so that admissible products with the potential to safeguard patients' health and well-being may be granted entry into US markets as expeditiously as possible.

Coronavirus: State Attorneys General and the New COVID-19 Stimulus

30 March 2020

With the president's signature on March 27, 2020, the government passed into law the Coronavirus Aid, Relief, and Economic Security Act (CARES Act), the largest economic stimulus package in American history. Passed in response to the coronavirus disease 2019 (COVID-19) pandemic, the CARES Act will have an enduring impact on the country for years to come, particularly so for the industries and businesses eligible for stimulus relief funds. The massive scale of the CARES Act immediately calls to mind questions about how the government will respond in its attempt to prevent fraud, waste, and abuse in carrying out the stimulus.

Top franchise developments of 2019

30 March 2020

Two top franchise developments in 2019 stand out from the rest.

Coronavirus: DHS Response to COVID-19 - What US Employers Need to Know

29 March 2020

Key questions and answers related to the new DHS guidance.

OCR issues guidance on permitted health information sharing to protect US law enforcement and first responders

27 March 2020

HIPAA-covered entity may, under certain circumstances, disclose protected health information about an individual who has been infected with, or exposed to, SARS-CoV-2 or COVID-19 without an individual's authorization.

Teledentistry update: Navigating teledentistry during the COVID-19 pandemic (United States)

27 March 2020

As part of its efforts to mitigate the spread of the COVID-19 pandemic, on March 18, 2020, the American Dental Association provided essential guidance on emergency vs. nonemergency dental care and the use of teledentistry.

COVID-19 prompts CMS to give new flexibility to participants in Medicare Quality Programs

25 March 2020

In light of COVID-19, participants in the Medicare Quality Payment Program will have extra time to report some quality metrics and can temporarily suspend other tracking and reporting activities altogether.

Coronavirus: Cyber hygiene practices

25 March 2020

While the world is responding to the coronavirus disease 2019 (COVID-19), and individuals are increasingly focused on personal hygiene and social distancing, augmenting cyber hygiene efforts at home and at work are increasing in importance too.

Coronavirus: Employee furloughs, reductions-in-force and similar temporary cost-saving measures (Part 2 – Employment issues outside the US)

25 March 2020

A general overview of key employment issues to consider outside of the US in light of COVID-19.

Coronavirus: Employee furloughs, reductions-in-force and similar temporary cost-saving measures in the US - Part 1

25 March 2020

Key employment-related issues for US-based employers in relation to cost-saving measures due to COVID-19.

Hotels and hospitals may find new partnerships to solve for bed capacity issues and vacancies

25 March 2020

The impacts of COVID-19 upon the hospitality sector as well as hospital systems and the healthcare industry have been sudden and dramatic.

CMS Emergency Preparedness Rule: Planning during COVID-19 (United States)

24 March 2020

As healthcare providers continue to face a variety of challenges during the coronavirus disease 2019 (COVID-19) pandemic, healthcare providers and suppliers should be aware of the Centers for Medicare and Medicaid Services Emergency Preparedness Rule and its resources.

US HHS-OCR Clarifies Waiver of HIPAA Sanctions for Telehealth Services during COVID-19

24 March 2020

On March 20, 2020, the Office for Civil Rights (OCR) at the US Department of Health and Human Services (HHS) issued FAQs to follow its Notice of Enforcement Discretion (notification). The FAQs address several questions and clarify OCR's intended broad application, including that the notification has no expiration date; rather, OCR will issue a new notice to the public when it is no longer available.

Coronavirus: Several state and local governments issue "shelter in place" orders (United States)

23 March 2020

Between March 17 and 22, state and local governments have promulgated at least a dozen "Stay-at-Home" / "Shelter-at-Home"-type Orders. This alert provides details on a number of state and local government orders.

90-day deferral for US federal income tax payments

20 March 2020

Those who decide to defer their federal tax payments will be able to do so on a penalty-free and interest-free basis, with penalties and interest beginning to accrue for payments submitted after July 15, 2020.

Potential paths forward amidst the challenges to COVID-19 therapeutic and vaccine development; collaboration and communication among clinical trial stakeholders takes on heightened importance (United States)

20 March 2020

In a March 19, 2020, briefing and press release, the US Food and Drug Administration outlined ways that existing regulatory options may make it possible to expedite access to therapeutics and vaccines with the potential to treat or prevent coronavirus disease 2019 (COVID-19).

COVID-19: The benefits of US chapter 11 relief in a time of economic crisis

19 March 2020

Highlighting some of the most significant benefits of US chapter 11 for companies facing severe challenges under the current circumstances.

Coronavirus: business resilience and continuity planning

19 March 2020

Prudent companies understand that their response to the COVID-19 pandemic should be consistent with their business resilience plans.

Coronavirus: Congress passes revised paid leave law (United States)

18 March 2020

Congress passed a revised version of The Families First Coronavirus Response Act requiring employers with fewer than 500 employees to provide COVID-19-related paid sick and family leave to eligible employees.

Telehealth update: COVID-19 prompts emergency Medicare coverage and other seismic shifts (United States)

18 March 2020

Multiple federal agencies have issued regulatory waivers and released additional funding to loosen the constraints on telehealth services and encourage widespread adoption.

US HHS issues waiver of certain HIPAA sanctions and penalties amidst COVID-19

18 March 2020

The HHS Secretary uses emergency authority under the Social Security Act to waive sanctions and penalties for certain provisions of HIPAA for certain covered hospitals.

Coronavirus: Congress expected to pass expanded paid leave (United States)

16 March 2020

The paid leave requirements in the current version of the Families First Coronavirus Response Act.

Coronavirus: federal and state tax relief (United States)

16 March 2020

Congress and state legislatures and administrative agencies are working hard to provide necessary tax relief for those affected by the coronavirus disease (COVID-19) pandemic.

Coronavirus (COVID-19): ten practical steps for global employers, right now (Global)

13 March 2020

These steps are not based on laws of any one jurisdiction but rather are designed to provide a global employer with themes to consider, understanding that what may be suitable for each employer may vary greatly depending on the employer's unique circumstances.

HIPAA and the coronavirus (United States)

13 March 2020

Key questions businesses may consider asking.

Life sciences market remains strong despite uncertainty in an election year

11 March 2020

The current state of life sciences financing – thoughts from the JPMorgan panel

Healthcare market proves strong as investors embrace new technological advancements

3 March 2020

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

FTC issues 6(b) orders to tech companies – healthcare companies could be next

14 February 2020

The agency seeks information on unreported acquisitions with the goal of deepening its understanding of the competitive tech sector landscape.

New obligations targeting human trafficking for employers in California – and across the US

11 February 2020

Employers across the United States should consider these new obligations and carefully determine what actions they may be required to take in the workplace.

Broad's CRISPR/Cas9 patent EP2771468 revoked by the European Patent Office

17 January 2020

In the ongoing CRISPR patent battle, the European Patent Office has upheld the earlier EPO Opposition Division ruling revoking Broad Institute's European patent EP2771468.

Top of Mind: Life Sciences

16 January 2020

Eight big topics that life sciences businesses have been thinking about and how DLA Piper has been covering those stories.

Court rules that "personal benefit" not necessary for criminal insider trading liability under certain statutes

14 January 2020

Błaszczak is unlikely to be the last word on insider trading.

Supporting the health of your health system

6 January 2020

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

Street art raises novel copyright issues – or does it?

19 December 2019

Is street art less entitled to copyright protection than are traditional art forms?

Upcoming 12/31 deadline to comment on CMS and OIG proposed rule changes under the Stark Law and Anti-Kickback Statute

16 December 2019

The two highly consequential proposals are poised to change how HHS approaches fraud and abuse enforcement in federal healthcare programs.

Food and Beverage News and Trends

11 December 2019

[FOOD AND BEVERAGE NEWS AND TRENDS](#)

Nomination of new FDA head advances, plus rose chocolate, meat wars, cage-free hens, and the last near-beer state.

New federal overtime rule set to take effect January 1, 2020

10 December 2019

The new rule significantly modifies the legal landscape regarding wage-and-hour compliance.

What starts the avalanche? Earlier triggers for life sciences mass torts in the era of big data and social media

9 December 2019

The bar for safety issues to lead to claims that ultimately result in mass tort litigation has never been lower.

Food and Beverage News and Trends

15 November 2019

[FOOD AND BEVERAGE NEWS AND TRENDS](#)

The FDA addresses the future of food safety, plus labels for plant-based “meat”; vapes in the news; and cotton... for dinner?

Texas: New safeguards to protect sensitive information

4 November 2019

The new PIA amendments will change the grounds upon which organizations may object to the disclosure of their sensitive information.

Plaintiff attorney advertising in pharmaceutical and medical device litigation: addressing the risk of harm to the public

29 October 2019

Law firm advertising about pharmaceutical and medical device litigation is receiving heightened regulatory scrutiny.

New California law requires year-end account balance notices for Flexible Spending Account plans – action items

25 October 2019

Starting in 2020, FSA participants in California should be given account notices twice prior to the FSA plan year's end and in different forms.

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.

Precarious steps: patent eligibility for healthcare IT

26 SEP 2016

Three recent Federal Circuit decisions, along with new updates from the USPTO, offer guidance on which steps to take in patenting healthcare IT-related inventions.

Stop them in their tracks: key points in seeking a preliminary injunction against medical device infringers

22 SEP 2016

Three considerations to bear in mind when bringing or defending a preliminary injunction motion in a medical device infringement case.

Is your cybersecurity upgrade FDA reportable?

28 SEP 2016

Draft guidance lends insight into the way the FDA may apply existing postmarket regulatory requirements to evolving cybersecurity-related technological issues.

Cybersecurity: past is prologue

29 MAR 2016

During 2016, we will likely see another increase in cyberattacks, and we will see cybersecurity being taken more seriously by its potential victims.

Supreme Court Corner: Q1 2016

29 MAR 2016

Two cases to watch.

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

10 SEP 2014

INTELLECTUAL PROPERTY AND TECHNOLOGY NEWS

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

Substitution allowed? State biosimilars laws are evolving

10 SEP 2014

Biosimilar products have not yet reached the US market, but debates on the laws and regulations that will govern them have been raging for some time

Supreme Court Corner - Q3 2014

10 SEP 2014

A review of cases relevant to IPT decided or argued before the Court during Q3

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.

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

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

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

Previous

US employment law update

12 October 2021 | 1:00 – 2:00 ET

Webinar

False Claims and *Qui Tam* Summit for Life Sciences and Healthcare

24 September 2021

Webinar

The FCA and nursing homes: A target before and after the pandemic

24 March 2021

Webinar

2021 Healthcare Leadership Conference: Day 4 - Path to restructuring and recovery

11 March 2021 | 12:00 PM - 3:30 PM ET

[2021 HEALTHCARE LEADERSHIP CONFERENCE](#)

2021 Healthcare Leadership Conference: Day 3 - Washington roundtable

10 March 2021 | 12:00 PM - 3:30 PM ET

[2021 HEALTHCARE LEADERSHIP CONFERENCE](#)

2021 Healthcare Leadership Conference: Day 2 - Unlocking innovation and collaboration through digital health and technology

9 March 2021 | 12:00 PM - 3:30 PM ET

[2021 HEALTHCARE LEADERSHIP CONFERENCE](#)

2021 Healthcare Leadership Conference: Day 1 - The dealmakers, the visionaries and the advocates

8 March 2021 | 12:00 PM - 3:30 PM ET

2021 HEALTHCARE LEADERSHIP CONFERENCE

The changing business and legal landscape: Key considerations for companies in 2021

5 March 2021 | 1:00 – 2:30 ET

Webinar

Communication and information sharing in support of healthcare for vulnerable populations

22 February 2021

Webinar

Building a vaccination plan: Key considerations for businesses

18 February 2021 | 9:00 - 10:00 PT

Webinar

How technology is impacting healthcare delivery in a COVID-19 world

13 January 2021 | 1:00 - 2:00 EST

Webinar

The US Election and the Race for a Vaccine: A Roundtable Discussion with Gregory Zuckerman

21 December 2020

Webinar

2020 BioHealth Capital Region Virtual Forum

19 October 2020 | 4:30 - 5:00 EDT

Webinar

BRG Healthcare Restructuring Conference

12-13 October 2020

New York

Health tech market midst and post COVID-19

14 September 2020
Webinar

Considerations for drug pricing and demonstrating value in a post-pandemic environment

5 August 2020 | 12:00 – 1:00 ET
Webinar

ABI Healthcare Program

5 March 2020

The Fifth Circuit Bankruptcy Bench-Bar Conference

5-7 February 2020

J.P. Morgan Healthcare Conference

14 January 2020
[J.P. MORGAN HEALTHCARE CONFERENCE](#)

San Francisco

J.P. Morgan Healthcare Conference

13 January 2020
[J.P. MORGAN HEALTHCARE CONFERENCE](#)

NEWS

Ardith Bronson, Isabel De Obaldia and Rebecca Jones McKnight named to The American Lawyer's list of 2021 South Trailblazers

4 October 2021

DLA Piper is pleased to announce that Ardith Bronson, Irma Isabel De Obaldia and Rebecca Jones McKnight have been named to *The American Lawyer's* inaugural list of South Trailblazers. The list recognizes professionals in the South "who have moved the needle in the legal industry."

DLA Piper partner Jeff Baglio named a 2021 BTI M&A Client Service All-Star

9 September 2021

DLA Piper is pleased to announce that BTI Consulting Group has recognized partner Jeff Baglio for providing superior service to clients in its 2021 BTI M&A Client Service All-Star report.

DLA Piper achieves appellate victory for AMN Healthcare in antitrust lawsuit

24 August 2021

DLA Piper recently won a significant appellate victory on behalf of AMN Healthcare defeating a lawsuit seeking more than US\$50 million in damages that alleged violations of federal and state antitrust laws.

Deborah Samenow joins DLA Piper's Healthcare sector in Washington, DC

9 August 2021

DLA Piper announced today that Deborah Samenow has joined the firm's Litigation and Regulatory practice and Healthcare sector as of counsel based in Washington, DC.

DLA Piper advises underwriters of MaxCyte's upsized US IPO

30 July 2021

DLA Piper represented Cowen and Company, LLC, Stifel, Nicolaus & Company, Incorporated and William Blair & Company, L.L.C., as underwriters in the initial US public offering of 13,500,000 shares of common stock of MaxCyte, Inc. (Nasdaq: MXCT) (LSE: MXCT, MXCN), a leading provider of cell-engineering platform technologies, at an initial offering price of US\$13.00 per share.

DLA Piper recognized as one of the "Most Recommended Law Firms" by BTI Consulting Group

26 July 2021

Due to its ability to "exceed client expectations and consistently demonstrate deep business understanding," DLA Piper is pleased to announce that it has been named one of the 11 Most Recommended Law Firms by BTI Consulting Group for 2021.

DLA Piper advises Abry Partners in US\$400 million sale of Sentry Data Systems

16 July 2021

DLA Piper represented private equity investment firm Abry Partners in its US\$400 million sale of Sentry Data Systems, Inc.

DLA Piper advises Lionheart Acquisition Corp. II in US\$32.6 billion SPAC deal with MSP Recovery

13 July 2021

DLA Piper represented special purpose acquisition company (SPAC) Lionheart Acquisition Corp. II. in its agreement to merge with MSP Recovery LLC.

DLA Piper advises FastMed in its acquisition of CareSpot and MedPost Urgent Care

12 July 2021

DLA Piper represented FastMed in its recent acquisition of Tenet Healthcare's urgent care platform, which includes 87 CareSpot and MedPost clinics in Arizona, California, Florida and Texas.

DLA Piper advises emocha Health in US\$6.2 million Series A financing

7 July 2021

DLA Piper represented emocha Health in its recently completed US\$6.2 million Series A financing.

DLA Piper lawyers and practices ranked in latest edition of *The Legal 500*

17 June 2021

DLA Piper announced today that the firm received 42 individual lawyer rankings and 49 firm rankings in *The Legal 500 United States* 2021 guide.

DLA Piper advises CareMax in business combination with Deerfield Healthcare Technology Acquisitions Corp.

18 June 2021

DLA Piper represented CareMax Medical Group, L.L.C. in its business combination, along with IMC Medical Group Holdings LLC, with special purpose acquisition company Deerfield Healthcare Technology Acquisitions Corp. to create a publicly traded technology-enabled care platform providing value-based care and chronic disease management to seniors.

DLA Piper advises Harrison Street on US\$1.6 billion medical office and senior housing transactions

17 June 2021

DLA Piper advised Harrison Street on an integrated series of transactions through which Harrison Street agreed to purchase 24 senior housing assets and sell 14 medical office properties across eight states over numerous months for a total transaction value of approximately US\$1.6 billion.

DLA Piper lawyers and practices ranked in latest Chambers edition

1 June 2021

DLA Piper today announced that the firm received 216 lawyer rankings and 94 firm rankings in *Chambers USA's* 2021 guide.

Tracy Weir joins DLA Piper's Litigation and Regulatory practice and Healthcare sector in Washington, DC

17 May 2021

DLA Piper announced today that Tracy Weir has joined the firm's Litigation and Regulatory practice and Healthcare sector as a partner based in Washington, DC.

DLA Piper advises Denali Growth Partners in closing of US\$203 million growth equity fund

30 March 2021

DLA Piper represented Denali Growth Partners in the close of its US\$203 million inaugural fund, Denali Growth Partners Fund I, L.P.

DLA Piper advises ICV Partners in control investments in Total Access Urgent Care and Cherry Tree Dental

25 March 2021

DLA Piper represented ICV Partners, LLC in its control investments in Total Access Urgent Care (TAUC) and Cherry Tree Dental.

DLA Piper advises Truvian Sciences in oversubscribed US\$105 million Series C financing

24 February 2021

DLA Piper represented Truvian Sciences in its recent oversubscribed US\$105 million Series C financing.

DLA Piper advises EQ Health Acquisition Corp. in its upsized US\$220 million initial public offering

11 February 2021

DLA Piper represented EQ Health Acquisition Corp. in its recent upsized initial public offering of 21,999,960 units at a price of \$10 per unit.

DLA Piper advises Sidecar Health in US\$125 million Series C financing

3 February 2021

DLA Piper represented health insurtech company Sidecar Health in its recent US\$125 Series C financing, resulting in its subsequent valuation at US\$1 billion.

DLA Piper advises Unseen Capital Health Fund in US\$30 million investment from Eli Lilly and Company

25 January 2021

DLA Piper represented Unseen Capital Health Fund LP in a recent US\$30 million limited partner investment from global pharmaceutical company Eli Lilly and Company.

DLA Piper advises Stifel in Tastemaker Acquisition Corp.'s US\$276 million IPO and advises Stifel and Nomura in OCA Acquisition Corp.'s US\$149.5 million IPO

21 January 2021

DLA Piper represented Stifel as sole book-running manager of the US\$276 million initial public offering by Tastemaker Acquisition Corp., a special purpose acquisition company (SPAC) focused on the restaurant, hospitality, and related technology and service sectors globally.

The *Financial Times* ranks DLA Piper second Most Innovative and second Most Digital law firm in 2020 North America Innovative Lawyers report

16 December 2020

DLA Piper is pleased to announce it was ranked second by the *Financial Times* for both the Most Innovative and Most Digital law firm in the FT North America Innovative Lawyers 2020 report.

DLA Piper shortlisted by the *Financial Times* for five FT North America Innovative Lawyers awards

8 December 2020

DLA Piper is pleased to announce it has been shortlisted by the *Financial Times* for five FT North America Innovative Lawyers 2020 awards.

DLA Piper advises Abry Partners in its investment in Benefit Recovery Group

23 October 2020

DLA Piper represented private equity investment firm Abry Partners in its strategic investment in Benefit Recovery Group (BRG), a leading provider of healthcare subrogation services.

DLA Piper advises Edifecs in growth investment from TA Associates and Francisco Partners

24 September 2020

DLA Piper represented Edifecs, Inc. in a recent growth investment from TA Associates and Francisco Partners.

DLA Piper advises MEDNAX in its US\$885 million sale of MEDNAX Radiology Solutions to Radiology Partners

15 September 2020

DLA Piper represented MEDNAX, Inc. in the sale of MEDNAX Radiology Solutions to Radiology Partners for US\$885 million.

John Gibson joins DLA Piper's Litigation and Regulatory practice in Los Angeles

14 July 2020

DLA Piper announced that John Gibson has joined the firm's Litigation and Regulatory practice as a partner in Los Angeles.

DLA Piper advises Abry Partners in acquisition of HealthEZ

7 July 2020

DLA Piper represented private equity investment firm Abry Partners in its acquisition of a majority stake in HealthEZ.

DLA Piper advises Osceola Capital in the recapitalization of Central Medical Group

5 June 2020

DLA Piper represented Osceola Capital in the recapitalization of Central Medical Group, a New Jersey-based provider of outsourced equipment management solutions for hospices.

DLA Piper advises lovance Biotherapeutics in its US\$604 million common stock offering

4 June 2020

DLA Piper represented lovance Biotherapeutics, a late-stage biotechnology company developing novel T cell-based cancer immunotherapies (tumor-infiltrating lymphocyte, TIL and peripheral-blood lymphocyte, PBL), in a US\$603.7 million underwritten public offering.

Donna Thiel joins DLA Piper's Litigation and Regulatory practice and Healthcare sector in Washington, DC

11 May 2020

DLA Piper announced today that Donna Thiel has joined the firm's Litigation and Regulatory practice and Healthcare sector as a partner in Washington, DC.

DLA Piper advises OneSpaWorld in US\$75 million investment

5 May 2020

DLA Piper represented OneSpaWorld Holdings Limited, a global provider of health and wellness services and products on cruise ships and in destination resorts around the world, in an agreement to sell US\$75 million in common equity and warrants to Steiner Leisure Limited and its affiliates and other investors.

DLA Piper advises Osceola Capital in its acquisition of Healthcents

14 January 2020

DLA Piper is pleased to announce that the firm represented Osceola Capital in its acquisition of Healthcents, Inc.

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



Joshua Kaye
Chair, US Healthcare Sector