



Kristi Kung

Partner

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Kristi Kung focuses on the representation of healthcare clients in a range of regulatory, compliance and transactional matters. She is a member of the firm's Healthcare Industry team in the Northern Virginia and Washington, DC offices.

Kristi advises healthcare providers, emerging health IT companies, vendors and investors in the digital health industry on regulatory and strategic matters critical to her client's telehealth and other health technology products, platforms and services. She has worked with digital health startups, IT vendors and health systems to develop and implement telehealth networks throughout the United States and internationally.

Kristi also represents healthcare clients in a range of regulatory, compliance and transactional matters, including fraud and abuse, health information privacy and security, billing and reimbursement, and licensing and accreditation of healthcare providers and suppliers. She advises on the health regulatory requirements and risks related to mergers and acquisitions, insolvency and restructuring matters, private equity investment and healthcare lending transactions and has served as an independent compliance reviewer for entities under Corporate Integrity Agreements.

Her portfolio also includes the representation of hospitals, pharmacies and other covered entities with respect to 340B Drug Discount Pricing Program compliance, audits and appeals.

EXPERIENCE

Her experience includes:

Digital Health

Kristi has an active digital health practice advising healthcare startups on the appropriate business structuring and strategy to navigate complex and multijurisdictional regulatory challenges. Her background in privacy and security, licensing, reimbursement, fraud and abuse, registration and FDA enforcement and corporate practice of medicine provide her with the unique skillset to effectively guide her clients through the various legal and business obstacles confronting companies looking to develop and implement telehealth, mobile health, artificial intelligence, virtual and augmented reality, and other innovative health technologies. She has assisted clients in the development of regional, national, and international telehealth and mobile health programs and has

RELATED SERVICES

- Litigation, Arbitration and Investigations
- Cybersecurity
- FDA
- Corporate

RELATED SECTORS

- Healthcare
- Technology
- Life Sciences

advised health systems on the implementation of a cohesive telehealth strategy. She has also advised private equity sponsors with respect to digital health ventures and health IT acquisitions.

Healthcare Compliance, Investigations and Regulatory Counseling

Kristi has developed comprehensive compliance programs for a variety of healthcare providers and suppliers, including hospitals, physician practices, laboratories, DMEPOS suppliers, IDTFs, medical device manufacturers and specialty pharmacies. She also advises on the day-to-day healthcare regulatory and compliance matters confronting providers and suppliers in the healthcare industry. Kristi has developed and provided specialized training to her client's workforces and sales teams concerning fraud and abuse, privacy and security, and other client risk areas. In addition, she has served as an independent compliance reviewer for entities under Corporate Integrity Agreements.

She advises clients on fraud and abuse matters including Stark and Anti-Kickback as well as state law equivalents, HIPAA and other privacy laws, reimbursement and billing, licensing and corporate practice of medicine issues. She assists clients with respect to internal investigations and self-disclosure and refund obligations and has further represented clients under investigation by various federal and state agencies, including the Centers for Medicare and Medicaid Services, the Office of Inspector General for the US Health and Human Services, the Health and Human Service Office for Civil Rights, the Health Resources and Services Administration, the Virginia Department of Health, the North Carolina Department of Health, various Virginia professional licensing boards and the Washington, DC Board of Medicine.

Privacy and Security Compliance, Breach Reporting and Investigations

Kristi represents healthcare industry clients and stakeholders with respect to privacy and security matters, including the development of HIPAA compliance programs, website privacy policies and terms of use, breach investigation and reporting, government investigations and healthcare privacy and security matters arising during the due diligence process. She has extensive knowledge of state health information privacy and security laws and has assisted clients throughout the US in the investigation, remediation, and breach reporting, as required, of privacy and security incidents. She has also defended providers in investigations by the Health and Human Service Office for Civil Rights. She advises clients on privacy and security compliance issues related to big data, health information technology, business associate agreements data use agreements and the use of de-identified data.

340 B Drug Discount Pricing Program

Kristi has extensive experience advising hospitals, specialty pharmacies and other covered entities with respect to 340B Drug Discount Pricing Program compliance, audits and appeals. She assisted clients in this space with respect to the development of 340B compliance programs, internal audits and investigations, HRSA and drug manufacturer audits and inquiries and the submission of self-disclosures of 340B Program noncompliance to HRSA.

Healthcare Transactions

Kristi advises private equity sponsors in their healthcare acquisitions and divestitures, and the on-going representation of their healthcare portfolio companies, regarding healthcare regulatory issues identified in due diligence, including fraud and abuse matters (Stark, AKS, FCA), privacy and security, licensure matters, and Medicare and Medicaid billing issues. Her experience spans a wide range of specialty areas including health IT, specialty pharmacy, laboratory, hospitals, hospice, home health, ASCs, IDTFs, physician practice groups and specialty practices such as ophthalmology, oncology, urology, radiology, and dentistry.

Hospitals and health systems

Kristi represents hospitals and health systems in a wide array of healthcare regulatory and transactional matters with a particular focus on digital health, fraud and abuse counseling, and the development of innovative shared risk arrangements.

Medical groups and physicians

Kristi represents multispecialty physician groups on regulatory matters and acquisitions, including the development of super groups to capture ancillary revenues and working with clients to satisfy their physician compensation goals in a manner that is compliant with the Stark Law and other healthcare regulations. She also assists medical groups and physicians with employment agreements, professional service agreements, administrative service agreements, compliance program development, business

associate agreements and a range of other transactional and regulatory matters.

CREDENTIALS

Admissions

- District of Columbia
- North Carolina
- Virginia

Recognitions

Kristi Kung has been named a Washington, DC Rising Star by *Super Lawyers* in 2016, 2017 and 2018 and a Virginia Rising Star in 2010.

Education

- J.D., Emory University School of Law
- B.S., Michigan State University

Memberships

- Center for Telehealth and e-Health Law (CTeL), Legal Advisory Board, 2019
- American Health Lawyers Association
- American Telemedicine Association
- Healthcare Information and Management Systems Society
- American Bar Association – Health Law Section
- DC Bar Association – Health Law Section

Teaching Experience

Law school courses taught:

- Adjunct Professor, American University Washington College of Law, "Healthcare Fraud and Abuse," 2014 - 2016 and 2018 (fall semester)
- Adjunct Professor, American University Washington College of Law, "Digital Health and the Law," 2015, 2016 and 2018 (summer institute)
- Subject Matter Coach, American University Washington College of Law, Health Law Competition Team, 2015 - 2018

INSIGHTS

Publications

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.

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.

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.

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.

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.

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.

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.

DOJ increasing scrutiny on coronavirus-related provider fraud

22 May 2020

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

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.

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.

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.

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.

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.

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.

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.

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.

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.

- "How Will Telehealth Change After the Pandemic?," *HealthTech*, June 5, 2020
- "New York Settles EmblemHealth Breach for \$575,000," *Eye on Privacy Blog*, March 2018
- "HHS-OCR Closes 2017 with Six Figure Settlement in PHI Data Breach," *Eye on Privacy Blog*, January 2018
- "Life in the Slow Lane? What Net Neutrality Repeal May Mean for Telehealth Services," *The National Law Review*, January 2018
- "Telehealth in 2017: What's Changed and What's Ahead," *Law360*, December 2018
- "Texas Telemedicine Saga Finally Over?," *SMRH Health Law Blog*, November 2017
- "New York AG Takes Enforcement Action Against Heart Monitoring Apps: Murmurs of Concern are Heard in mHealth App World," *SMRH Health Law Blog*, April 2017
- "Is a Truce in the Battle over Telemedicine in Texas Upon Us?," *SMRH Health Law Blog*, February 2017
- "Recent Relaxation of State-Level Challenges to the Expansion of Telemedicine but Barriers Remain," *SMRH Health Law Blog*, July 2016
- "CMS Proposes to Limit Site Neutral Payment Exceptions Applicable to Certain Off-Campus Hospital Departments Following Relocation, Service Expansion, or Certain Ownership Changes," *SMRH Health Law Blog*, July 2016
- "Disclosing 340B Program Non-Compliance and Negotiating Manufacturer Refunds – An Overview and Case Study, American Health Lawyers Association," *In-House Counsel Meeting*, June 2016
- "Assessing the Legal Risk of Unregulated Yoga Therapy," *Law360*, January, 5 2016
- "Health Care Fraud and Abuse Update," *Health Law Handbook*, 2014 – 2016 editions
- "340B Omnibus Guidance Would Significantly Narrow the Pool of Eligible Patients," *Law360*, September 3, 2015
- "FDA Draft Guidance Would Ease Regulatory Burdens for Certain mHealth Applications," *Law360*, August 1, 2014
- "OIG Releases Special Bulletin on the Effect of Exclusion from Federal Health Care Programs," E-Alert, AHLA Accreditation, Certification and Enrollment, Affinity Group, May 8, 2013
- "Impact of the American Taxpayer Relief Act of 2012 on Reimbursement for Health Care Services," E-Alert, AHLA Regulation, Accreditation and Payment Practice Group, January 4, 2013
- "Telemedicine Legal Hurdles - An Overview of Lesser Known Challenges," *Healthcare IT News – A Publication of the American Health Lawyers Association*, Vol. 15, Issue 3, Page. 7, November 2012
- "Qui Tam Counsel Sanctioned for Breaching Ethical Rules Relating to Review of Privileged Material – E-Alert on the *Frazier v. IASIS* case," AHLA Healthcare Liability & Litigation Practice Group, February 2012
- "CMS Issues Final Rule Updating Payment Policies Under ESRD PPS for CY 2012," E-Alert, AHLA Regulation, Accreditation and Payment Practice Group, November 7, 2011
- "Legal Practice in a HITECH Environment: An Overview of the HITECH Act and its Impact on Lawyers as Business

Associates," Defensively Speaking, International Society of Primerus Law Firms, February 12, 2010

- "Annual Survey of Virginia Law: Health Care Law," 44 U. RICH. L. REV. 473, 2009

Events

Upcoming

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

Previous

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

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

DLA Piper White Collar CLE Series: Take 5

6 April 2020
Webinar

Healthcare Leadership Insights Conference 2019

14 MAR 2019
Miami

- Panelist, CTeL Telehealth Spring Summit – "Workshop: Telehealth Claims and Denials Management – Medicare, Medicaid, and Private Payors," The Washington Hilton, Washington, DC, June 13, 2019
- Panelist, Sensus Healthcare - American Academy of Dermatology Annual Meeting Dinner, The Willard Hotel, Washington, DC, March 1, 2019
- Faculty, TMCx Accelerator, Texas Medical Center, "Digital Health Regulation," February 25, 2019, with Danny Tobey
- Presenter, "Mitigating Legal Risks in Digital Health Adoption," with Danny Tobey, November 13, 2018
- "What the Net Neutrality Repeal May Mean for Telehealth," CTeL Executive Telehealth Spring Summit, June 14, 2018
- "Healthcare Disruptions," American University Washington College of Law Summer Health Law Institute Lunch and Learn Panel, June 6, 2018
- "Data Breach Simulation," Association of Corporate Counsel – San Diego Chapter, April 25, 2018
- "Hot Topics in Healthcare Compliance and Regulation," University of Minnesota Master of Business Administration – Healthcare Executive Track, March 2017
- Health Law Panel: "Where We Are and Where We Are Going," District of Columbia Bar Association, Health Law Section, March

2017

- "Hacking Health: Addressing mHealth Privacy and Security Risks," Lorman Webinar, September 2016
- "Specialty Pharmacy and the 340B Program," National Association of Specialty Pharmacy – Legal Day, Washington, DC, September 2016
- "Avoiding Fraud and Abuse Pitfalls Under Expanded Reimbursement for Telehealth Services," mHealth and Telehealth World Congress –, Boston, July 2016
- Co-Presenter, "HIPAA Compliance and the Use of De-Identified Data," June 25, 2016, with Lisa Shuman (Strategic Management Services)
- "Fraud and Abuse Issues in Telehealth," American Health Lawyers Association – Fraud and Compliance Forum, Baltimore, September 2015
- "Exploring the Current State of mHealth Privacy and Security," mHealth and Telehealth World Congress, Boston, July 2015
- "mHealth and Telehealth – Privacy and Security Issues," American University Washington College of Law, Washington, DC April 2015
- "Privacy and Security Issues," mHealth Applications Legal Issues Breakfast Series, Tysons Corner, Virginia, March 2015
- Federal and Virginia laws relating to pharmacy and prescribing; the Virginia State Board of Pharmacy structure, investigation and hearing procedures; risk management and documentation for preventing litigation, Medical College of Virginia, Pharmacy Residency Program, March 2011; April 2010; and March 2009
- "Electronic Health Records in Litigation," Martha Jefferson Hospital, September 2010
- "Moving Beyond HIPAA: Future Trends in Litigation in This New Electronic Age," American Bar Association National Teleconference, January 2010
- "Patients and Practitioners Beware: Mandatory Electronic (Medical) Records and What You Need to Know," American Bar Association - Young Lawyers Division Fall Conference, October 2009
- Moderator and Speaker, The American Recovery and Reinvestment Act, HITECH provisions, Electronic Medical Records and Health Information Exchanges, and the E-Discovery of Electronic Medical Records in Litigation, Lorman Education Services, July 2009
- Health Information Portability and Accountability Act (HIPAA) and Virginia Medical Records Law, Lorman Education Services, October 2008

NEWS

DLA Piper advises Haemonetics in its acquisition of Cardiva Medical

21 January 2021

DLA Piper represented Haemonetics Corporation (NYSE: HAE), a global medical technology company focused on delivering innovative medical solutions to drive better patient outcomes, in its acquisition of Cardiva Medical, Inc., an industry-leading manufacturer of vascular closure systems based in Santa Clara, California, for US\$475 million at closing and up to an additional US\$35 million in contingent consideration based on sales growth.

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

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