



Richard P. Church

Partner

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OVERVIEW

Richard Church is a co-leader of the firm's national health care practice group. He focuses his practice on health law regulatory issues and health care joint ventures, clinical integration and mergers and acquisitions. Richard handles complex 340B structuring, enrollment and compliance matters, Medicare and Medicaid enrollment and reimbursement issues, and health care operational matters. He also handles complex affiliations and transactions between health care providers, including legal compliance, change of ownership filings, and development of post-transaction reimbursement structures. He has been listed in *Chambers USA* since 2014 for Healthcare – North Carolina.

PROFESSIONAL BACKGROUND

Richard served as law clerk to the Honorable John T. Noonan, Jr., United States Court of Appeals for the Ninth Circuit. He also holds a Ph.D. in theological ethics from Duke University and previously taught medical ethics as an Assistant Professor of Religion at Wingate University.

ACHIEVEMENTS

- Listed in *Chambers USA* for Healthcare - North Carolina, 2014 - 2020
- Recognized in *National Law Review's* "Go-To Thought Leadership Awards" for the 340B Drug Pricing Program, 2020
- *Nightingale Healthcare News's* Outstanding Transaction Lawyer, 2009

PROFESSIONAL / CIVIC ACTIVITIES

- American Health Lawyers Association
- North Carolina Society of Health Care Attorneys

SPEAKING ENGAGEMENTS

- Health Information at the Crossroads: New Uses and Challenges for Integrated Clinical Records, presented to the Physicians and Hospitals Law Institute, February 2019
- More Data, More Problems: Big Data Issues for the Research Enterprise, presented to the National Association of College and University Attorneys, June 26, 2018
- Expanding the Scope of Integrated Health Information Records into the Clinical Research Arena: Lessons Learned (HIT), presentation to Physicians and Hospitals Law Institute, sponsored by the Health Lawyers Association, February 7, 2018
- Building a Compliant and Resilient 340B Program in the Midst of Regulatory Uncertainty, presented to the American Health Lawyers Association, National Association of College and University Attorneys, and Association of American Medical Colleges, January 26, 2018
- The Tail That Wags the Dog? How Different ACO Governance Structures Affect Operational Decision-Making, presentation to the Business Law and Governance Practice Group and the Accountable Care Organization Task Force, American Health Lawyers Association, January 11, 2017
- K&L Gates Triage Podcast: Section 603 Site-Neutral Payment: Overview and Payment Mechanism, January 2017
- 340B Mega-Guidance, presentation to the NC Bar Health Law Section Annual Meeting, April 29, 2016
- Changes to the 340B Program: What Covered Entities Must Know, Lorman webinar, March 3, 2016
- 340B Program Omnibus Guidance, webinar presented to the North Carolina Society for Health Care Attorneys, October 16, 2015
- Stark Compliance Advanced Discussion Group, Health Care Compliance Association's 17th Annual Compliance Institute, Washington, DC, April 2013
- Threat or Opportunity: The New Frontier of ACOs, North Carolina Hospital Association, September 2011
- Hostage to His Own Cure: Insights into American Medicine From What *Wasn't* in the Health Care Reform Bill, East Carolina University Brody School of Medicine Inaugural Lecture in Medical Jurisprudence, April 2011

EDUCATION

- Ph.D., Duke University, 2005 (*Religion*)
- J.D., Duke University School of Law, 1998 (*magna cum laude*; *Duke Journal of Law & Contemporary Problems*, *Staff Editor*; *Deans Advisory Counsel*; *Moot Court Board*; *Order of the Coif*)
- M.A., Duke University, 1998 (*Religion*)
- B.A., Calvin College, 1993

ADMISSIONS

- Bar of Illinois
- Bar of North Carolina
- North Carolina Superior Court, Wake County, District 10

THOUGHT LEADERSHIP POWERED BY HUB

- 26 February 2021, What to Expect in Health Care in 2021 (*Podcast*)
- 19 January 2021, COVID-19: Provider Relief Funds: What to Expect as Reporting Begins in 2021 (*Alerts/Updates*)
- 29 December 2020, Federal Courts Block Implementation of Most Favored Nation Drug Pricing Rule (*Alerts/Updates*)
- 22 December 2020, 340B Update: Recent Supreme Court Ruling May Curtail 340B Program Discriminatory Pricing (*Alerts/Updates*)
- 15 December 2020, HRSA Publishes Long-Awaited (and Long-Overdue) 340B Program Alternative Dispute Resolution Process Final Rule (*Alerts/Updates*)
- 3 December 2020, CMS Issues Most Favored Nation Model Interim Final Rule: What to Expect Next (*Alerts/Updates*)
- 30 November 2020, Trump Administration Issues Flurry of Last Minute Healthcare Regulations: What Will the Incoming Administration Do Next? (*Alerts/Updates*)
- 16 November 2020, The Health Care Policy Landscape in 2021 and Beyond (*Webinar*)
- 2 November 2020, Healthcare Innovation Through In-house and Outside Counsel Partnerships | AHLA Health Law Disruption: 2030 and Beyond | K&L Gates and Parkview Health (*Video*)
- 16 October 2020, 340B Update: Ryan White Clinics Sue in Response to Contract Pharmacy Actions as Congress Requests Information on Ways to Improve the 340B Program (*Alerts/Updates*)
- 25 September 2020, 340B Update: Congress and the Administration Respond to Drug Manufacturers' 340B Contract Pharmacy Actions (*Alerts/Updates*)
- 5 August 2020, 340B Update: Appeals Court Upholds 340B Payment Reduction Under the OPPS as CMS Proposes Further Reductions for CY 2021 (*Alerts/Updates*)
- 27 July 2020, President Trump Signs Drug Pricing Executive Orders Reinforcing the Administration's Priorities (*Alerts/Updates*)
- 23 July 2020, K&L Gates Triage: Recent Developments in the 340B Drug Pricing Program (*Podcast*)

- 21 July 2020, 340B Update: HRSA Indicates it Lacks Authority to Enforce 340B Program Guidance (*Alerts/Updates*)
- 8 June 2020, COVID-19: 340B Update: HRSA Updates Guidance Granting New HOPD Flexibility (*Alerts/Updates*)
- 29 April 2020, COVID-19: Testing and Treatment to Uninsured Patients - Reimbursement Available Under New HHS Payment Program (*Alerts/Updates*)
- 27 April 2020, 340B Update: CMS Opens Acquisition Cost Data Survey for 340B Hospitals (*Alerts/Updates*)
- 24 April 2020, COVID-19: UPDATED HHS Announces Remaining Allocations of CARES Act Provider Relief Funding and Updates Funding Terms and Conditions (*Alerts/Updates*)
- 16 April 2020, COVID-19: UPDATED HHS Delivers Initial \$30 Billion of CARES Act Provider Relief Funding Directly to Medicare (*Alerts/Updates*)
- 16 April 2020, COVID-19: UPDATED HHS Delivers Initial \$30 Billion of CARES Act Provider Relief Funding Directly to Medicare Providers and Suppliers and Quickly Updates Terms and Conditions (*Alerts/Updates*)
- 9 April 2020, COVID-19: 340B Update - Hospitals Request Eligibility Flexibilities Amid COVID-19 Pandemic (*Podcast*)
- 26 March 2020, COVID-19: Healthcare Policy and Market Outlook (*Webinar*)
- 23 March 2020, COVID-19: 340B Update - HRSA Releases COVID-19 Guidance for 340B Covered Entities (*Alerts/Updates*)
- March 2020, COVID-19: Analysis of White House National Emergency Declaration and Implementation (*Webinar*)
- 13 March 2020, COVID-19: EMTALA Guidance on COVID-19 While Hospitals Await Potential EMTALA Waivers (*Alerts/Updates*)
- 12 February 2020, 340B Update: CMS Issues Updated Acquisition Cost Data Survey (*Alerts/Updates*)
- 5 February 2020, Antitrust Agencies Release Draft Vertical Merger Guidelines: A Healthcare Perspective (*Alerts/Updates*)
- 10 January 2020, 340B Update: Safety Net Providers Fight Back Against Two-Tier Pricing Models (*Alerts/Updates*)
- 20 November 2019, CMS Finalizes Hospital Price Transparency Rule and Proposes New Transparency Requirements for Health Plans (*Alerts/Updates*)
- 18 November 2019, Qui Tam Quarterly (*Alerts/Updates*)
- 4 November 2019, 340B Update: CMS Maintains Payment Reductions for 340B Drugs in CY 2020 OPPS Final Rule (*Alerts/Updates*)
- 1 October 2019, 340B Update: CMS Seeks Comments on Acquisition Cost Data Survey (*Alerts/Updates*)

- 11 September 2019, K&L Gates Triage: Recent Developments Impacting Drug Pricing and the 340B Program: Part 2 (*Podcast*)
- 6 September 2019, K&L Gates Triage: Recent Developments Impacting Drug Pricing and the 340B Program: Part 1 (*Podcast*)
- 6 August 2019, 340B Update: CMS Addresses Ongoing Litigation and Reimbursement Changes for 340B Drugs in CY 2020 OPSS Proposed Rule (*Alerts/Updates*)
- 28 February 2019, K&L Gates Triage: A Discussion of Labor and Employment Issues in the Health Care Industry (*Podcast*)
- 11 February 2019, HHS Issues Proposed Rule to Remove Safe Harbor for Drug Rebates (*Alerts/Updates*)
- 4 February 2019, Employment Law in the Health Care Industry: 2018 Year in Review (*Alerts/Updates*)
- 31 January 2019, Approaching Integrated Health Information Databases in 2019 — Data-Sharing , Clinical, Quality, and Research Collaboration (*Alerts/Updates*)
- 8 January 2019, 340B Update: D.C. District Court Overturns OPSS 340B Reimbursement Cut for CY 2018 (*Alerts/Updates*)
- 19 December 2018, K&L Gates Triage: 340B Program: A Conversation with Chris Hatwig, Apexus President Part 3 (*Podcast*)
- 13 December 2018, K&L Gates Triage: 340B Program: A Conversation with Chris Hatwig, Apexus President Part 2 (*Podcast*)
- 6 December 2018, CMS Proposes Changes to Medicare Advantage and Part D Drug Pricing (*Alerts/Updates*)
- 4 December 2018, K&L Gates Triage: 340B Program: A Conversation with Chris Hatwig, Apexus President Part 1 (*Podcast*)
- 2 November 2018, Trump Administration Drug Pricing Plan Would Tie Medicare Part B Reimbursement to International Prices (*Alerts/Updates*)
- 2 November 2018, 340B Update: HRSA Accelerates Implementation of Long-Delayed 340B Pricing and Manufacturer Penalties Rule (*Alerts/Updates*)
- 27 September 2018, 340B Update: AHA Proposes Voluntary 340B Program Transparency Efforts (*Alerts/Updates*)
- 19 September 2018, 340B Update: Hospital Groups File (...and Refile) 340B Program Litigation (*Alerts/Updates*)
- 14 August 2018, CMS Solicits Comments On Part B Drug Reimbursement Changes Following On President's Drug Pricing Blueprint (*Alerts/Updates*)
- 30 July 2018, 340B Update: CMS Proposes Changes to OPSS Reimbursement for Nonexcepted PBDs (*Alerts/Updates*)

- 20 July 2018, 340B Update: D.C. Court of Appeals Upholds Medicare Part B Reimbursement Cut (*Alerts/Updates*)
- 22 May 2018, 340B Update: President's Blueprint Includes 340B Reforms, the OPPI Litigation Continues, and Other Recent Developments (*Alerts/Updates*)
- 17 May 2018, K&L Gates Triage: Pharmacy Gag Clauses & Clawbacks (*Podcast*)
- 25 April 2018, K&L Gates Triage: 340B Update: State Medicaid 340B Billing Requirements (*Podcast*)
- 10 April 2018, 340B Update: HRSA Seeks Fifth Delay of Final Rule on 340B Pricing and Manufacturer CMPs; Budget Document Sheds Light on 340B User Fee and Other HRSA Priorities (*Alerts/Updates*)
- 20 March 2018, Increased Scrutiny of Patient Assistance Programs: Enforcement Overview and Considerations (*Alerts/Updates*)
- 16 February 2018, 340B Update: Trump Administration's 2019 Budget and White House Council of Economic Advisors Signal Further Changes to 340B Program (*Alerts/Updates*)
- 16 January 2018, 340B Update: Hospitals Appeal Ruling on OPPI Reimbursement Cut; House Committee Issues Report Recommending Changes to 340B Program (*Alerts/Updates*)
- 18 December 2017, 340B Update for Hospitals: CMS Publishes FAQs Clarifying Use of Modifiers in Connection with 340B Program Reimbursement Cut on Part B Drugs (*Alerts/Updates*)
- 16 November 2017, K&L Gates Triage: 340B Update: CMS Finalizes 340B Program Reimbursement Cut on Part B Drugs (*Podcast*)
- 6 November 2017, 340B Update: CMS Finalizes 340B Program Reimbursement Cut on Part B Drugs (*Alerts/Updates*)
- 23 August 2017, 340B Update: HRSA Delays Final Rule on 340B Pricing and Manufacturer CMPs Yet Again (*Alerts/Updates*)
- 2 August 2017, CMS Proposes Substantial Payment Reductions in CY 2018 for Off-Campus Hospital Outpatient Departments Subject to the Site-Neutral Rule (*Alerts/Updates*)
- 17 July 2017, 340B Update: CMS Proposes to Reduce 340B Drug Reimbursement; Draft Executive Order Could Mean Further Changes to the 340B Program (*Alerts/Updates*)
- 30 May 2017, 340B Update: Trump Administration Calls for New Legislation and Regulatory Authority; HRSA Delays Regulations on 340B Pricing & Penalties for Drug Manufacturers to October 1, 2017 (*Alerts/Updates*)
- 29 March 2017, 340B Update: HRSA Further Delays Regulations on 340B Pricing & Penalties for Drug Manufacturers (*Alerts/Updates*)
- 8 February 2017, 340B Update: Trump Administration Withdraws Omnibus Guidance, Delays Final Rule on 340B Drug Pricing and CMPs (*Alerts/Updates*)

- 18 January 2017, 340B Update: HRSA Finalizes 340B Pricing & Penalties for Drug Manufacturers (*Alerts/Updates*)
- 5 January 2017, K&L Gates Triage: Section 603 Site-Neutral Payment: Overview and Payment Mechanism (*Webinar*)
- 9 November 2016, CMS Announces Final Rule Implementing Site-Neutral Payment Rule for Certain Off-Campus Hospital Outpatient Provider-Based Departments (*Alerts/Updates*)
- 22 August 2016, HRSA Releases Proposed Rule Governing the Administrative Dispute Resolution Process for 340B-Related Claims (*Alerts/Updates*)
- 12 August 2016, CMS Proposes Changes to Medicare Shared Savings Program (*Alerts/Updates*)
- 19 July 2016, CMS Releases Details on Site-Neutral Payment Provision under Bipartisan Budget Act (*Alerts/Updates*)
- 14 March 2016, CMS Issues a New Medicare Shared Savings Program Proposed Rule and Aims to Encourage Existing Accountable Care Organizations to Renew their Participation in the Program (*Alerts/Updates*)
- 8 December 2015, New Law Excludes New Provider-Based Off-Campus Outpatient Hospital Locations from OPPTS (*Alerts/Updates*)
- 16 November 2015, CMS and OIG Issue Final Fraud and Abuse Waivers in Connection With the Medicare Shared Savings Program (*Alerts/Updates*)
- 22 October 2015, 340B Orphan Drug Interpretive Rule Struck Down by D.C. District Court: HHS and HRSA Lose In Second Round of Litigation Over 340B Orphan Drug Rules (*Alerts/Updates*)
- 3 September 2015, HRSA Issues 340B Program Omnibus Guidance (*Alerts/Updates*)
- 22 June 2015, 340B Update: HRSA Proposes Penalties for Drug Manufacturers that Overcharge Covered Entities (*Alerts/Updates*)
- 11 June 2015, CMS Releases Final Medicare Shared Savings Program Rule (*Alerts/Updates*)
- 9 June 2015, Federal Court Enjoins Texas Medical Board from Enforcing More Stringent Telemedicine Rules (*Alerts/Updates*)

OTHER PUBLICATIONS

- Will CMS's Final Rule Really Make Hospital Prices Transparent for Consumers?, *Benefits Law Journal*, Spring 2020
- CMS Finalizes Hospital Price Transparency Rule and Proposes New Transparency Requirements for Health Plans, November 2019
- Enforcement Trends in False Claims Act Liability for Patient Assistance Programs, November 2019

- 340B Update: CMS Maintains Payment Reductions for 340B Drugs in CY 2020 OPPS Final Rule, November 2019
- 340B Update: CMS Seeks Comments on Acquisition Cost Data Survey, October 2019
- 340B Update: CMS Addresses Ongoing Litigation and Reimbursement Changes for 340B Drugs in CY 2020 OPPS Proposed Rule, August 2019
- HHS Issues Proposed Rule to Remove Safe Harbor for Drug Rebates, February 2019
- Employment Law in the Health Care Industry: 2018 Year in Review, February 2019
- Approaching Integrated Health Information Databases in 2019 — Data-Sharing , Clinical, Quality, and Research Collaboration, January 2019
- 340B Update: D.C. District Court Overturns OPPS 340B Reimbursement Cut for CY 2018, January 2019
- CMS Proposes Changes to Medicare Advantage and Part D Drug Pricing, December 2019
- 340B Update: HRSA Accelerates Implementation of Long-Delayed 340B Pricing and Manufacturer Penalties Rule, November 2018
- Trump Administration Drug Pricing Plan Would Tie Medicare Part B Reimbursement to International Prices, November 2018
- 340B Update: AHA Proposes Voluntary 340B Program Transparency Efforts, September 2018
- 340B Update: Hospital Groups File (...and Refile) 340B Program Litigation, September 2018
- CMS Solicits Comments on Part B Drug Reimbursement Changes Following on President's Drug Pricing Blueprint, August 2018
- 340 B Update: CMS Proposes Changes to OPPS Reimbursement for Nonexcepted PBDs, July 2018
- 340B Update: D.C. Court of Appeals Upholds Medicare Part B Reimbursement Cut, July 2018
- 340B Update: President's Blueprint Includes 340B Reforms, the OPPS Litigation Continues, and Other Recent Developments, May 2018
- 340B Update: HRSA Seeks Fifth Delay of Final Rule on 340B Pricing and Manufacturer CMPs; Budget Document Sheds Light on 340B User Free and Other HRSA Priorities, April 2018
- Increased Scrutiny of Patient Assistance Programs: Enforcement Overview and Considerations, March 2018
- 40B Update: Trump Administration's 2019 Budget and White House Council of Economic Advisors Signal Further Changes to 340B Program, February 2018
- 340B Update: Hospitals Appeal Ruling on OPPS Reimbursement Cut; House Committee Issues Report Recommending Changes to 340B Program, January 2018
- Site Neutral Payments - Transaction Concerns, ABA Business and Transactions Interest Group Business Wire, Fall 2016

- 340B Program Omnibus Guidance: Mega-Changes on the Horizon?, American Health Care Lawyers Association Rap Sheet, November 2015
- Preparing for Successful Medicare Shared Savings Program Enrollment, co-authored with Darlene Davis and Steve Pine, AHLA Connections, July 2015
- ACOs Continue to Expand in Both Public and Private Health Care Arenas, K&L Gates Global Government Solutions® 2015 Annual Outlook, April 2015
- Inside the Minds Managing Health Care Transactions “Enrollment Strategies for Managing Successor Liability in Health Care Transactions” Chapter Author, 2012, Aspatore Books
- Health Care Program Compliance Guide, Hospice and Nursing Home Relationships chapter, 2012, BNA
- Global Government Solutions 2011 Annual Outlook: Accountable Care Organizations: A New Frontier in Provider Integration, *K&L Gates Publication*, January 2011
- Global Government Solutions 2010: Mid-Year Outlook, *K&L Gates Publication*, July 2010
- Hurdles to Health Care Reform, co-authored with Mary Beth Johnston and Amy Garrigues, *National Law Journal*, September 2009
- Of the Good That Has Been Possible in This World: Lawyering in Port William, chapter in Wendell Berry and Religion: Heaven’s Earthly Life, The University Press of Kentucky, 2009
- First Be Reconciled: Challenging Christians in the Courts, Herald Press, 2008
- The Art of Description: How John Noonan Reasons, *76 Notre Dame Law Review* 849, 2001

NEWS & EVENTS

- 18 December 2020, K&L Gates Provides Insights Around Health Policy Landscape to EU Health Counsellors (*Practice & Regional News*)
- 7 October 2020, *Modern Healthcare*: 4 ways 340B discounts would change if the ACA is struck down (*Media Mention*)
- 20 August 2020, *Modern Healthcare*: Drugmakers crack down on 340B discounts, demand data (*Media Mention*)
- 23 April 2020, K&L Gates, Lawyers Recognized in 2020 Chambers USA Guide (*Rankings & Recognitions*)
- 26 April 2019, Chambers USA 2019 Guide Ranks K&L Gates, Lawyers Among Leaders (*Press Release*)
- 23 June 2016, K&L Gates, Lawyers Recognized as Leaders in Chambers USA 2016 Guide (*Press Release*)
- 20 May 2015, Chambers USA 2015 Guide Recognizes K&L Gates, Lawyers as Industry Leaders (*Press Release*)

MEDIA MENTIONS

- Quoted, "White House reviews rule for 340B dispute resolution," Modern Healthcare, 18 November 2020
- Quoted, "Hospitals will need Supreme Court's help to stop site-neutral, 340B cuts," Modern Healthcare, 19 October 2020
- Quoted, "HRSA Plans Several Audits of Provider Relief Fund; Reporting Requirements Raise Alarm," Report on Medicare Compliance, 12 October 2020
- Quoted, "4 ways 340B discounts would change if the ACA is struck down," Modern Healthcare, 6 October 2020

AREAS OF FOCUS

- Health Care and FDA

REPRESENTATIVE EXPERIENCE

- Engaged as special regulatory counsel in regard to a potential joint investment with a large national pharmacy company. Provided strategic advice on pharmacy operations, 340B Program compliance, and policy requirements.
- Led the development of a unique affiliation between an academic medical center and another local academic medical center in which certain clinical and pharmacy assets were acquired and professional and co-management services were contracted for the newly acquired hospital-based clinics.
- Advised on all aspects of structuring, creation, and launch of new "business to business" service line providing supply chain consulting services to third parties related to reducing supply chain spending and the creation of a group purchasing organization ("GPO").
- Served as regulatory counsel and provided advice in regard to various healthcare regulatory matters associated with internal compliance department reviews, structuring of new operations and services lines related to laboratory, and infusion services.
- Advised on member agreements and has negotiated several multi-million dollar agreements with large, national health care suppliers.