



## Health Care Regulations & Compliance

### From health information privacy to fraud and abuse prevention, Hinshaw helps you stay within the lines.

Ask any executive, pharmacist or billing-department employee: health care is more highly regulated and scrutinized than virtually any industry. While most will agree that quality care, patient privacy, cost-efficiency and other standards are necessary, the complex web of health care laws and regulations can, at times confound even the most sophisticated health care companies.

The experienced regulatory lawyers of Hinshaw's health care team do more than cut the red tape. We help providers, insurers and other parties to understand the many state and federal requirements that govern their operations and to establish effective processes and systems to ensure compliance. When disputes with regulators or law enforcement officials arise, our experienced litigators rise to the occasion, helping clients cooperate with audits and investigations and, when necessary, defend their interests in court.

From structuring strategic transactions, to advising on scope of practice, licensure requirements, patient care, billing, data privacy, documentation and other day-to-day business operations, we help clients minimize risk and exposure to audits, investigations or regulatory challenges. We have significant experience assessing fraud and abuse and self-referral concerns, and regularly represent clients who have been investigated by or received a complaint from state licensing boards.

Among other activities likely to trigger fraud and abuse and other compliance issues, we assist clients with:

- Anti-Kickback Statute, False Claims Act, and the Ethics in Patient Referral Act matters
- Billing practices
- Clinical research, and trials
- Collections and payment disputes
- Environmental matters
- HIPAA privacy and security, and state data privacy laws
- Joint venture agreements
- Licensure, accreditation, and certification
- Medicare/Medicaid reimbursements
- Pharmacy regulatory compliance
- Physician compensation and financial arrangements
- Professional responsibility/liability
- Provider enrollment

### Industry Area Contact

Adam S. Guetzow  
312-704-3129  
aguetzow@hinshawlaw.com

### Attorneys

Roy M. Bossen  
Michael A. Dowell  
Robert J. Finley  
Elizabeth V. Heredia  
Noah Jussim  
Frank A. Mazzagatti, Ph.D.  
Stephen T. Moore

### Related Industries

Health Care  
Health Care Corporate Transactions  
Health Care Defense  
Health Care Human Resources  
Health Care Information, Privacy & Security  
Health Care Operations  
Health Care Pharmacy



- [Provider/physician relationships](#)

We have a successful record representing the interests of insurers and health care providers in litigation. We recognize that, in some cases, the breadth of our representation can give rise to potential conflicts of interest. We take great care to ensure that no such conflicts exist before agreeing to an engagement and take full advantage of our experience to represent all clients to our utmost ability.

## News

[Hinshaw Expands Health Care Practice on East Coast](#)

May 15, 2024

[Three Hinshaw Attorneys Co-author Chapter in Fourth Edition of Enterprise Risk Management for Health Care Handbook](#)

April 2, 2024

[Scott Seaman Recognized as a Top Insurance Author in JD Supra 2024 Readers' Choice Awards](#)

March 4, 2024

[Adam Guetzow and Elizabeth Heredia Co-Author a Chapter in 2023 Edition of the "Long-Term Care Litigation" IICLE Handbook](#)

November 15, 2023

[Michael Dowell Recognized as a Top Health Care Lawyer by The Daily Journal](#)

November 21, 2022

[Michael Dowell Discusses Cybersecurity and Cyberattack Prevention Strategies for Pharmacies](#)

May 16, 2022

[Telemedicine Legal Issues and Compliance Best Practices for FQHCs and RHCs](#)

April 30, 2019

[Ken Yeadon Talks to HealthcareDive about \\$1.3bn Federal Health Care Fraud Takedown](#)

July 18, 2017

[The OIG Issues New Safe Harbor Rule for Free or Discounted Health Care Transportation Services](#)

February 15, 2017

[Michael A. Dowell Published in Journal of Health Care Compliance](#)

July 10, 2014

[Michael A. Dowell Published in Journal of Health Care Compliance](#)

March 10, 2014

[Daniel Purdom Quoted in Mainstreet.com on Medicare Fraud: The Dirty Truth](#)

November 4, 2013

Mainstreet.com

[Michael Dowell Quoted in Hospitals & Health Networks Magazine](#)

October 13, 2013

Hospitals & Health Networks Magazine



## Events

Hinshaw's Jason Winslow Will Present NBI Seminar on Common Electronic Medical Records Mistakes and Related Medical Malpractice Risks

April 9, 2019

Webinar

Robert Finley to Present "Medicare: Conditional Payment Claims" at the Claims & Litigation Management Alliance Training Program

June 22, 2016

Kemper, 3700 Arco Corporation Drive, Suite 200, Charlotte, NC 28274

William P. Grogan Presenting NBI Program on Bioethics Issues

October 2, 2014

Robert Finley to Present on Medicare Issues for the National Institute for Medicare & Medicaid Education Conference

June 26, 2014

Michael Dowell to Present at the California Society for Healthcare Attorneys Annual Meeting & Spring Seminar

April 11, 2014

CSHA Annual Meeting & Spring Seminar

HIPAA Webinar: Business Associate Agreements and Business Associate Requirements

August 7, 2013

Webinar

## Publications

California Prohibits PBM Discriminatory Practices Against 340B Program Covered Entities and Contract Pharmacies

December 15, 2023

Health Care Alert

California Expands "No Pharmacist Left Alone" Pharmacy Staffing Requirements and Also Enacts New Safety Measures

November 17, 2023

Health Care

OIG Advisory Opinion 22-08 Permits a Federally Qualified Health Center to Provide Smartphones to Patients to Promote Access to Telehealth and Social Isolation/Loneliness Benefits

May 20, 2022

Health Care Alert

Laboratory Testing Presents Business Opportunities for Community Pharmacies

January 11, 2022

Health Care Alert

District Court in Missouri Blocks Implementation of CMS Emergency Regulation Mandating Workforce COVID-19 Vaccinations

November 30, 2021 | Last Updated December 30, 2021

Health Care Alert

FAQs: CMS Issues Emergency Regulation Mandating Workforce COVID-19 Vaccinations by Medicare/Medicaid-Certified Providers and Suppliers

November 9, 2021

Health Care Alert

New California Law Prohibits Chain Community Pharmacy Productivity Quotas for Pharmacists and Pharmacy Technicians



October 27, 2021  
Health Care Alert

[California Appellate Court Rules That Federally Qualified Health Center Outreach Expenses Do Not Qualify For Cost-Based Reimbursement](#)

September 29, 2021  
Health Care Alert

[New OIG Guidance Permits Federally Qualified Health Centers to Offer Remote Patient Monitoring, Big-Box Store Gift Cards, and Other Incentives to Medicare and Medicaid Patients](#)

February 22, 2021  
Health Care Alert

[Change is on the Horizon for 340B Pharmacy Program's Administrative Dispute Resolution Process](#)

December 21, 2020  
Health Care Alert

[New Stark Regulations Further Clarify Definitions of Fair Market Value and General Market Value](#)

December 14, 2020  
Health Care

[Attention Pharmacies and Prescribers: New California Controlled Substances Prescription Form and CURES Reporting Requirements Are Coming](#)

November 19, 2020  
Health Care Alert

[California Board of Pharmacy Approves "No Pharmacist Left Alone" Regulations for Retail Pharmacy Chains](#)

September 21, 2020  
Health Care Alert

[Federally Qualified Health Center Agrees to Settlement for Failure to Implement](#)

August 26, 2020  
Health Care Alert

[OPA Program Update 2020 Highlights Changes to 340B Program Registration and Recertification Requirements](#)

August 13, 2020  
Health Care Alert

[Small Breaches Matter Too: OCR Broadens HIPAA Breach Investigations](#)

August 26, 2016  
Health Law Alert

[Significant Hospital Related Mid-Year Updated OIG Review Activities](#)

June 23, 2016  
Health Law Alert

[Supreme Court Case Expands False Claims Act Liability](#)

June 22, 2016  
Health Law Alert

[OIG Mid-Year Update Provides Insight To Its Concerns](#)

June 20, 2016  
Health Law Alert

[Groundbreaking Healthcare Nondiscrimination Rule Issued by HHS: What It Means for Covered Entities](#)

May 20, 2016  
Health Law Alert

[OIG Publishes 2016 Work Plan](#)



November 24, 2015  
Health Law Alert

[CMS Adopts Final Stark Rule Exceptions and Clarifications](#)

November 23, 2015  
Health Law Alert

[Budget Act Eliminates OPPS Reimbursement for New Off-Campus Hospital Departments](#)

November 12, 2015  
Health Law Alert

[OIG Scrutinizes Ambulance Billing Practices](#)

September 30, 2015  
Health Law Alert

[Illinois Eases Telehealth Use by Becoming 10th Member of Interstate Medical Licensure Compact](#)

August 27, 2015  
Health Law Alert

[New National Practitioner Guidebook Released](#)

August 26, 2015  
Health Law Alert

[CMS Proposes New Stark Exceptions and Clarifications](#)

August 25, 2015  
Health Law Alert

[Physician Compensation Arrangements May Result in Significant Liability](#)

June 10, 2015  
Health Law Alert

[CMS Issues Proposed Revisions for Stages 1 and 2 Meaningful Use Standards](#)

April 22, 2015  
Health Law Alert

[CMS Issues Proposed Stage 3 Meaningful Use Standards](#)

April 6, 2015  
Health Law Alert

[OIG Vetoes Proposed Lab Fee Waiver Arrangement](#)

April 2, 2015  
Health Law Alert

[Seventh Circuit Upholds Criminal Conviction Under the Anti-Kickback Statute Utilizing a Broad Definition of "Refer"](#)

February 17, 2015  
Health Law Alert

[FDA Publishes Draft Guidance on Individual Patient Access to Investigational New Drugs](#)

February 9, 2015  
Health Law Alert

[HHS Announces Medicare Shift to Value-Based Payments and Promotion of Reform Among All Payers](#)

January 27, 2015  
Health Law Alert

[IRS Issues Final 501\(r\) Regulations for Federal Tax Exemption for Hospitals](#)

January 26, 2015

[Report of Hospital's Collection Practices Angers Senator Charles Grassley](#)



January 26, 2015  
Health Law Alert

[REMINDER: Compliance Deadline for all Business Associate Agreements is Monday, September 22, 2014](#)  
September 16, 2014  
Health Law Alert

[CMS Medical Staffing Rule Leaves Questions Unanswered](#)  
August 20, 2014  
Health Law Alert

[Special Fraud Alert Released by OIG Regarding Laboratory Payments to Referring Physicians](#)  
July 9, 2014  
Health Law Alert

[Physicians Beware: Identity Theft Is On The Rise](#)  
June 4, 2014  
Health Law Alert

[Stark Law Violations Stemming from Improper Incentive Compensation Paid to Employed Physicians Result in \\$85 Million Settlement](#)  
April 7, 2014  
Health Law Alert

[Opportunity to Provide Input to the Federal Trade Commission on Health Care Competition](#)  
March 4, 2014

[Antitrust Update: Court Rules Against Hospital's Acquisition](#)  
January 29, 2014  
Health Law Alert

[Two Early New Year's Gifts from CMS and the OIG Concerning the Donation of Electronic Health Records](#)  
January 7, 2014  
Health Law Alert

[CMS, ONC Propose Adjustments to Meaningful Use Implementation for EHR Incentive Program](#)  
December 12, 2013  
Health Law Alert

[Office of Illinois Attorney General Adopts New Rules Regarding Hospital Financial Assistance Applications and Policies](#)  
August 8, 2013  
Health Law Alert

[OIG Fraud Alert on Physician Owned Distributorships \(PODs\)](#)  
April 2, 2013  
Health Law Alert

[The Omnibus Rule: Changes to HIPAA / HITECH Enforcement and Penalties](#)  
February 19, 2013  
Health Law Alert

[Protections, Limitations, Prohibitions and More: Important Modifications to Privacy Rule](#)  
February 14, 2013  
Health Law Alert

[New Requirements for HIPAA Notices of Privacy Practices](#)  
February 11, 2013  
Health Law Alert

[New HIPAA/HITECH Breach Notification Rules for Covered Entities and Business Associates](#)



February 5, 2013  
Health Law Alert

[New HIPAA Requirements for Business Associates and Their Subcontractors](#)

February 1, 2013  
Health Law Alert

[HHS Modifies HIPAA Privacy, Security, Enforcement and Breach Notification Rules](#)

January 24, 2013  
Health Law Alert

[FTC Allows Hospital to Sell Discounted Drugs to EMS Provider During Shortage](#)

December 14, 2012  
Health Law Alert

[Recent False Claims Act Case Illuminates Scary Issues for Health Care In-House Counsel](#)

December 4, 2012  
Health Law Alert

[OIG Releases Advisory Opinion Regarding Per Diem Fees Paid to Physicians for On-Call Coverage to Emergency Departments](#)

November 8, 2012  
Health Law Alert

[Federal Court Rejects Challenge to Physician-Owned Hospital Restrictions](#)

August 23, 2012  
Health Law Alert

[Alaska Settles HIPAA Security Case for \\$1.7 Million; HHS Reinforces Need for Adequate Policies and Procedures for the Safeguarding of ePHI](#)

July 18, 2012  
Health Law Alert

[IRS Issues Notice of Proposed Regulations on New Federal Tax Exemption Requirements for Hospitals](#)

July 2, 2012  
Health Law Alert

[Illinois Governor Patrick Quinn Signs Tax Exemption and Tax Credit Legislation Affecting Hospitals](#)

June 14, 2012  
Health Law Alert

[HIPAA Privacy and Security HITECH Act Enforcement Actions Begin](#)

April 11, 2012  
Health Law Alert

[CMS Issues Proposed Rules on Reporting and Returning of Overpayments Under Medicare](#)

March 6, 2012  
Health Law Alert

[Illinois Healthcare Providers See Conflict Between New State Law and HIPAA Privacy Rule](#)

March 1, 2012  
Health Law Alert

[Supervision by Unapproved Physicians Sufficient to Find Violation of False Claims Act](#)

February 28, 2012  
Health Law Alert

[CMS Announces No Change to EMTALA Obligations Toward Hospital Inpatients](#)



February 21, 2012  
Health Law Alert

[New Mandate on Coverage for Contraceptives: Strategies for Organizations](#)

February 3, 2012  
Health Law Alert

[HHS Adopts HIPAA Standards for Electronic Funds Transfers](#)

January 23, 2012  
Health Law Alert

[CMS Posts Accountable Care Organization Final Rule](#)

October 26, 2011  
Health Law Alert

[New Business Opportunity for Health Care Providers: The Medicare Bundled Payments for Care Improvement Initiative](#)

September 27, 2011  
Health Law Alert

[Wisconsin Supreme Court Clarifies What Types of Health Care Facilities Qualify for Property Tax Exemption](#)

July 22, 2011  
Health Law Alert

[Accountable Care Organization Waivers](#)

June 28, 2011  
Health Law Alert

[Medicare Shared Savings Program](#)

May 24, 2011  
Health Law Alert

[Accountable Care Organization Data Sharing](#)

May 19, 2011  
Health Law Alert

[Accountable Care Organization Application Requirements](#)

May 11, 2011  
Health Law Alert

[Changes Affecting Hospital and Critical Access Hospital Medicare Conditions of Participation Governing Telemedicine Credentialing and Privileging](#)

May 10, 2011  
Health Law Alert

[Accountable Care Organization Overview](#)

May 5, 2011  
Health Law Alert

[Illinois Supreme Court Rules Common Fund Doctrine Does Not Apply to Health Care Services Lien Act](#)

April 1, 2011  
Health Law Alert

[Wisconsin's Health Care Quality Improvement Act Broadens Protections for Health Care Providers](#)

February 28, 2011  
Health Care Alert

[Federal Government "Clarifies" When Health Care Providers and Insurers Need an Affirmative Action Plan](#)

February 4, 2011





Hinshaw Health Law Alert

[Illinois Rule Restricting Medicaid Reimbursement for Hospital Off-Site Outpatient Department Services May Be Relaxed](#)

January 26, 2011

Hinshaw Health Law Alert

[Health Care Providers Are Exempt From the Red Flags Rule](#)

January 4, 2011

Hinshaw Health Law Alert

[Wisconsin Department of Health Services Releases Final Implementation Plan for Wisconsin's Health Care Transparency Law](#)

December 27, 2010

Hinshaw Health Law Alert

[Wisconsin Department of Health Services Issues New Guidance on the Preparation of Consumer Reports Required Under the New Health Care Transparency Law](#)

December 20, 2010

Hinshaw Health Law Alert

[DOJ Challenges Insurer's Use of "Most Favored Nations" Clauses with Hospital Providers](#)

November 2, 2010

Hinshaw Health Law Alert

[2011 OIG Work Plan Targets New Risk Areas for Hospitals](#)

October 20, 2010

Hinshaw Health Law Alert

[Minnesota Supreme Court Overrules Iowa National and Announces New Rule: Primary Insurers Have the Right to Contribution for Defense Costs](#)

October 7, 2010

Insurance Coverage Alert

[CMS Publishes Stark Self-Disclosure Protocol](#)

September 24, 2010

Hinshaw Health Law Alert

[New Durable Medical Equipment, Prosthetics, Orthotics and Supplier Standards May Require Operational Changes](#)

September 21, 2010

Hinshaw Health Law Alert

[Achieving "Meaningful Use" for Electronic Health Records and Financial Incentive Payments](#)

August 5, 2010

Hinshaw Health Law Alert

[Court Strikes Down Budget Provision Authorizing Injured Patients and Families Compensation Fund Raid](#)

July 20, 2010

Hinshaw Health Law Alert

[Health Care Reform Law Changes Medicare GME for Hospitals and Allows GME Payments for FQHCs and RHCs](#)

July 19, 2010

Health Care Alert

[HHS Issues Draft Application for New Early Retiree Reimbursement Program](#)

June 8, 2010

Hinshaw Alert

[FTC Delays Enforcement of Red Flags Rule Until December 31, 2010](#)



June 3, 2010  
Hinshaw Health Law Alert

[Wisconsin Changes Laws Regulating Physicians](#)

June 2, 2010  
Hinshaw Health Law Alert

[Wisconsin Sets Statutory Fee Schedules for Copies of Health Care Records](#)

May 24, 2010  
Hinshaw Health Law Alert

[Patient Protection and Affordable Care Act Introduces Numerous Programs Focused on Quality and Delivery of Health Care](#)

May 20, 2010  
Hinshaw Health Law Alert

[The Impact of Health Care Reform on Medicare Advantage Plans and Medicare Prescription Drug Plans](#)

May 18, 2010  
Hinshaw Health Law Alert

[Health Care Reform Introduces Array of Cost Containment Measures](#)

May 6, 2010  
Hinshaw Health Law Alert

[Health Care Reform to Reduce Medicare DSH Payments](#)

April 29, 2010  
Hinshaw Health Law Alert

[Health Care Reform Increases Physician Transparency and Disclosure Requirements](#)

April 27, 2010  
Hinshaw Health Law Alert

[Wisconsin to Collect Assessments From Critical Access Hospitals, Use Funds for Rural Health Care Programs](#)

April 26, 2010  
Hinshaw Health Law Alert

[Health Care Reform Increases Federal Tax Exemption Requirements for Hospitals](#)

April 20, 2010  
Hinshaw Health Law Alert

[The Impact of Health Care Reform on Community Health Centers](#)

April 19, 2010  
Hinshaw Health Law Alert

[Health Care Reform Includes Initiatives to Promote Clinical Integration](#)

April 15, 2010  
Hinshaw Health Law Alert

[Health Care Reform Law Amends Many Existing Anti-Fraud Statutes, Increasing Need for Effective Compliance Programs](#)

April 14, 2010  
Hinshaw Health Law Alert

[Wisconsin Creates Statutory Presumption That Billing Statements and Invoices Reflect the Reasonable Value of Reasonably Necessary Health Care Services](#)

April 9, 2010  
Health Care Alert

[Health Care Reform: Health Insurance Exchanges and Private Insurance](#)



April 9, 2010  
Hinshaw Health Law Alert

[An Eagle's Eye View of the Health Care Reform Legislation](#)  
April 7, 2010  
Hinshaw Health Law Alert

[Joint Commission Releases Revised Medical Staff Bylaws Standard](#)  
March 24, 2010  
Hinshaw Health Law Alert

[Wisconsin Allows Cooperative Associations to Expand Health Care Services](#)  
March 23, 2010  
Hinshaw Health Law Alert

[Illinois Supreme Court Denies Property Tax Exemption for Provena Covenant](#)  
March 19, 2010  
Hinshaw Health Law Alert

["Health Care Transparency Bill" Signed into Law in Wisconsin](#)  
March 10, 2010  
Hinshaw Health Law Alert

[Wisconsin Expands Scope of Volunteer Health Care Provider Program](#)  
February 12, 2010  
Hinshaw Health Law Alert

[February 17, 2010, Deadline for Implementing HIPAA Privacy Rule Amendments and HIPAA Business Associate Compliance](#)  
February 9, 2010  
Hinshaw Health Law Alert

[DEA Approval Necessary to Act on Recent Amendments to Illinois Law Granting APNs and PAs the Authority to Prescribe Schedule II Controlled Substances](#)  
February 5, 2010  
Hinshaw Health Law Alert

[New Rules Increase Reporting Obligations and Access to the National Practitioner Data Bank](#)  
February 4, 2010  
Hinshaw Health Law Alert

[CMS and ONC Issue Regulations Defining "Meaningful Use" of EHR Technology](#)  
January 19, 2010  
Hinshaw Health Law Alert

[RAC Implementation Beginning January 10, 2010](#)  
January 7, 2010  
Hinshaw Health Law Alert