



# 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**

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### **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

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 Assesments 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

# Health Care Reform: Health Insurance Exchanges and Private Insurance

April 9, 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

#### 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