


Deloitte.



**Investigations, litigation,
and dispute consulting**

For life sciences and
health care companies



Life sciences and health care organizations are already under the microscope. But a range of factors are making this scrutiny even more intense, including:

- Heightened attention from state and federal regulators, consumers, and business partners
- Pressure to increase access to care, improve the quality of care, and reduce costs of health goods and services
- Continued focus from the federal and state governments to identify and contain fraud and abuse in the industry

These forces are also placing life sciences and health care organizations at greater risk of investigation or litigation.

Effectively and promptly responding to allegations and taking steps to reduce litigation risk often requires the assistance of highly experienced life sciences and health care specialists. Specialists who:

- Understand the industry and are accustomed to working closely with counsel
- Are dedicated to serving health care providers, health plans, and life sciences companies involved in investigations, litigation, and other business disputes
- Have deep industry skill sets and experience with investigations, litigation support, and dispute resolution capabilities
- Provide a multidisciplinary and integrated approach to problem solving

Specialists who work at Deloitte Risk and Financial Advisory.

Addressing your issues

Our professionals are dedicated to helping life sciences and health care clients face the litigation, investigation, and regulatory pressures of today's complex health care environment.

Health care providers

Health care providers are confronted with heightened regulatory and public scrutiny and increased litigation risk. Fraud detection, Civil False Claims Act (FCA), Stark Law, and Anti-Kickback Statute violations continue to be primary focuses of regulatory agencies.

Hospital pricing, pricing transparency, and quality of care have also been at the heart of numerous recent investigations and litigation matters. Our professionals have significant depth and breadth of experience within the health care provider sector to help clients address these types of issues.

Deloitte¹ works with:

More than 90% of the Fortune 500 life sciences and health care companies

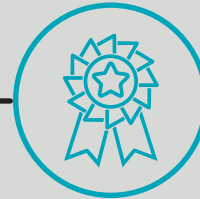


14 of the 15 best hospitals on US News and World Report's honor roll



10 of the 10 largest health care systems (as ranked by Modern Healthcare)

10 of the 10 largest secular not-for-profit healthcare systems (as ranked by Modern Healthcare)



10 of the 10 largest Catholic health care systems (as ranked by Modern Healthcare)



¹ "Deloitte" refers to Deloitte in the US, which includes one or more of Deloitte LLP and its subsidiaries.

Investigations of alleged Stark Law violations

The Stark Law prohibits physicians from billing Medicare when those physicians have a financial relationship, including ownership or compensation arrangements, in entities that provide certain designated health services, unless that financial relationship meets one of the several exceptions enumerated in regulations. The Stark Law is a strict liability statute that includes potential FCA liability as well as administrative sanctions, including civil monetary penalties and exclusion.

The Anti-Kickback statute prohibits the solicitation/receipt or the offering/payment of any remuneration, whether in cash or kind, for the purchase or lease of goods or the referral or performance of a service that might be reimbursed by a federal health care program.

In these investigations, we worked with counsel to assemble documents, read contracts, compile remuneration information, and quantify reimbursements associated with potentially tainted referrals. Deloitte Advisory has assisted counsel in the analysis of fair market value and commercial reasonableness of arrangements. We've also helped conduct interviews, employed data analytic techniques, and reported our findings and observations to counsel, the client, and regulatory bodies.

Breach of contract

The types of contracts being entered by health care providers and payers have increased in both nature and complexity—including joint ventures, partnerships, joint development arrangements, exclusive network agreements, risk-sharing arrangements, incentive arrangements, and more—for better managing care. These relationships may not always work out as planned, and they may occasionally result in disputes and litigation between the parties.

Deloitte Advisory professionals have advised clients on a wide range of disputes involving breach of contract claims, lost profit analyses, allocation of costs or profits among parties, and other damages assessments. Deloitte Advisory routinely provides assistance with:

- Electronic document and data discovery
- Analysis of transaction data, such as patient charge data
- Quantification of damages based on “but for” analyses
- Analysis and rebuttal of opposing party damages
- Preparation of expert witness reports and deposition testimony
- Expert witness testimony at trial or arbitration, including preparation of demonstratives of key analyses

Our professionals bring a powerful combination of industry specialization and experience working in dispute contexts.



Health plans

Health insurance plans, managed care organizations, and pharmacy benefit managers (“health plans”) are also under significant scrutiny from regulators, consumers, and business partners. Many health plans are under court-imposed and other pressures to bring transparency to their claims adjudication processes and consistency to medical necessity and coverage decisions.

In addition, many health plans have been accused of improper rescission of health care benefits, substandard quality of care,

improper credentialing decisions, and underpayment of out-of-network claims. Pharmacy benefit managers must walk a fine line between acting as both a payer and a provider, and they’re under the heightened inspection that comes with both roles.

Due to the many pressures placed on health plans to provide more access at reduced costs, disputes are rising at a fast pace. We work with health plans across the nation to help address, resolve, and mitigate such disputes.

Deloitte² works with:



Nearly 85% of the top 25 US health plans
(as ranked by the National Association of Insurance Commissioners)



80% of the largest provider sponsored plans
(as ranked by HealthLeaders)



Nearly 90% of the nation’s largest Blue Cross Blue Shield plans
(as ranked by AIS’s Directory of Health Plans)

² Ibid.

Provider versus payer disputes

Our professionals have worked with legal counsel on a variety of matters for hospitals or health insurers involved in disputes pertaining to rates, timely claim submission, timely payment, and claims denials for both contracted and non-contracted services. We've provided assistance with:

- Interpretation and application of contractual clauses, such as those regarding reimbursement for stop-loss claims and high-cost items
- Analysis of the appropriateness of the denial of services as non-covered, medically unnecessary, or provided without proper pre-authorization or referral
- Assessment of the appropriate reimbursement (usual and customary) rates for non-contracted providers
- Application of Medicare payment methodologies to commercial agreements

Claims in dispute have included claims and capitation payments for commercial, Medicare, and Medicaid beneficiaries. In each case, we have provided assistance with:

- Analysis of deposition testimony, contracts, contemporaneous correspondence regarding contract negotiations, and other documents produced through discovery
- Assessment of opposing side's damages claim and supporting documentation
- Identification of "at issue" claims populations and selection of one or more statistically valid sample(s) of claims
- Readjudication of sample claims and extrapolation of results to the population(s) of "at issue" claims
- Provision of other litigation support, such as assistance with depositions, production of an expert report, and assistance with settlement negotiations

Life sciences companies

Pharmaceutical manufacturers, medical technology companies, and biotechnology firms (“life sciences companies”) constantly face claims of antitrust, product liability, and improper sales and marketing techniques. They’re also under heightened scrutiny by federal and state regulators and the general public for the rising costs of pharmaceuticals and devices.

In addition, life sciences companies are spending an increasing amount of money on legal and litigation defense costs. Deloitte works with life sciences companies to help address a range of issues—from federal investigations to business disputes to managing legal expenses.

Pharmaceutical Manufacturers Compliance and Investigation Services

Deloitte Financial and Advisory professionals teamed with legal counsel to conduct an attorney-client privileged compliance program related to patient support services and other market access programs for pharmaceutical manufacturers. Deloitte helped these companies create an inventory of various activities performed by internal resources and third party vendors.

Some of the areas our team has provided support include:

- Donations to patient support foundations
- Donation of free drug to patients
- Coupons, vouchers, and co-pay programs
- Activities delivered by specialty pharmacies and hubs
- Field-based and home office patient support roles and reimbursement support roles

Our team had the experience to assess the relevant risks and controls, conduct a detailed risk assessment of current operations, and recommend changes to policies, procedures, systems, resources, governance, training, monitoring, auditing, and reporting. Deloitte Financial and Advisory also supported the implementation of the recommendations and change management with business stakeholders.

Deloitte³ works with:

15 of the 15 largest pharmaceutical manufacturers

(as ranked by FiercePharma)



10 of the top 10 medical device manufacturers

(as ranked by Medical Product Outsourcing)

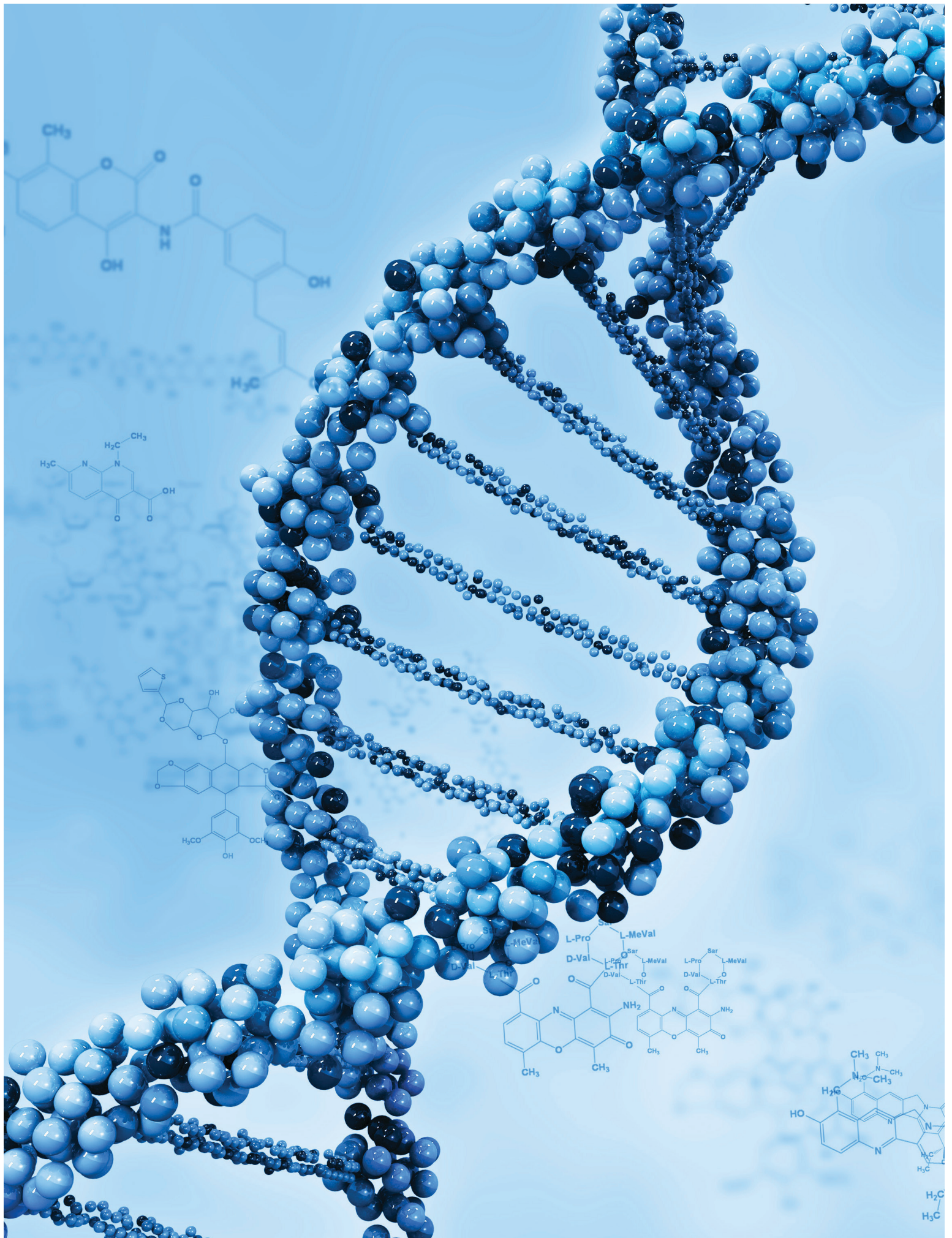
9 of the 10 largest biotechnology companies (as ranked by Med Ad News)



8 of the top 10 generic drug companies

(as ranked by Statista)

³Ibid.



How we can help

Deloitte Risk and Financial Advisory has a dedicated team focused on litigation and dispute services within the life sciences and health care industry. Our professionals have devoted years of service to helping clients and their outside counsel address and resolve investigations, litigation, and disputes. We're intimately familiar with the intricacies of health care transactions and industry standards from regulatory, contractual, and data perspectives.

We provide a broad spectrum of litigation support and dispute resolution services, from the initiation of a dispute to the final distribution of damage awards. Our services include:

Pre-litigation/investigation assistance

Whether an investigation is launched internally or a client is responding to a government investigation, it's crucial that relevant facts and information are uncovered quickly and the appropriate response is made. Our seasoned professionals work with clients, their counsel, and outside regulatory agencies in a wide range of phases of an investigation, from the initial data and document discovery to voluntary disclosure.

Discovery services

Our professionals have deep experience in the discovery process. We offer services to assist in-house and outside counsel in facilitating discovery, should the need arise. Our professionals can help clients create or re-engineer processes designed to identify, preserve, collect, process, analyze, and produce electronic and paper data in discovery, whether that discovery is intended for litigation or regulatory purposes. We've developed the system capabilities and knowledge to help identify, gather, and produce active and archived data from multiple legacy systems and platforms. Our professionals can also provide testimony regarding the chain of custody of discovery documents and data.

Department of Justice investigations of acute-care providers and its executives

Deloitte assisted in the investigation of several acute-care providers all of which were accused of improperly manipulated charge masters for the purpose of maximizing outlier reimbursement. The engagement involved assistance with the analysis of \$1.5 billion of hospital claims to the Medicare program.

Deloitte Financial and Advisory assisted the client with:

- Econometric and regression analyses
- Pro forma claims repricing
- Analysis of the providers financial models
- Investigating revenue recognition and loss contingency recognition practices
- Development of alternate models under the DoJ's Ability-to-Pay methodology.
- Supported the clients and counsel with settlement negotiations
- Assisted the clients in negotiations with creditors
- Performed internal control and compliance program gap assessments
- Assisted clients as they prepared for IRO inspections.

Our qualifications

Our professionals' backgrounds and qualifications include:

- Actuaries
- Appraisers
- Former prosecutors
- Certified coders
- Chartered financial analysts
- Certified fraud examiners
- Certified public accountants
- Computer forensic specialists
- Economists
- Former federal law enforcement professionals
- Former industry executives
- Professional engineers
- Statisticians

Data and document management

Once data and documents are produced, our professionals can help manage them by providing secure, catalogued, and searchable access to the information. In cases where the allegations involve the need to assess large volumes of health care transactional data, data warehouses can be created to allow efficient management and analysis of the data. The databases can be designed to be accessed and analyzed by our Deloitte Forensic team or external experts retained by counsel.

Class certification defense

We have assisted numerous clients in defending against class certification. We have experience with the requirements for class certification under Rule 23 of the Federal Rules of Civil Procedure and similarly adopted state requirements. Our professionals have been successful on numerous occasions in using the client's internal data in conjunction with publicly available data to help demonstrate that a proposed class doesn't meet the requirements of numerosity, commonality, typicality and/or adequacy. We've also assisted outside counsel in demonstrating that classes as proposed by plaintiffs weren't manageable and that common issues didn't predominate individual issues.

Economic damages modeling

Depending on the type(s) of analysis required, we can use statistical, economic, financial, and/or industry specialists to help develop damages theories and models to support those theories. Our models are based on sound and reasonable assumptions and methodologies. Using our deep industry knowledge, we're also able to incorporate industry standards and account for other industry-specific issues.

Non-testifying litigation consulting

While our professionals have years of experience testifying as experts in litigation and dispute matters, we're also adept at

assisting clients and their outside counsel as non-testifying litigation consultants. Our work can be used for case strategy purposes or to support the analysis and testimony of an outside expert.

Deposition assistance

Our professionals are experienced in helping outside counsel prepare for fact witness and expert witness depositions in litigation and dispute matters. We've assisted counsel in preparing outlines and potential questions based on our understanding of the issues in the case; our industry knowledge; the results of our analysis; and our assessment of the opposing side's expert report(s), affidavits, and/or testimony. We've also joined counsel at depositions to provide real-time assistance, feedback, and follow-up.

Expert witness testimony

Our professionals are experienced in providing expert witness testimony in deposition, at trial, and in other dispute resolution forums. When sought by clients, we identify Deloitte professionals with the credentials and industry experience to serve as expert witnesses. In addition to possessing the facts, knowledge, and industry experience, our professionals are skilled communicators often with years of experience testifying before judges, juries, and arbitrators in complicated areas of business, economics, and finance. We can simplify complex technical information in support of the client's case, as applicable.

Settlement support

Our professionals have assisted clients and their counsel on numerous occasions with settlement negotiations and support. We can articulate our work and findings as it relates to methodologies and assumptions used in our analysis. We help develop forward-looking and flexible models so that our clients can analyze the impact of different settlement scenarios in an efficient manner to facilitate negotiations.

Agency experience

Our professionals understand the different agencies involved in the complex health care environment and are familiar with the issues and pressures facing life sciences and health care companies. We have agency experience with:

- US Department of Health and Human Services (HHS)
- Centers for Medicare and Medicaid Services (CMS)
- Food and Drug Administration (FDA)
- Office of the Inspector General (OIG)
- Department of Justice (DOJ)
- State departments of insurance and managed care
- State departments of health and human services

Claims administration services

Our claims administration services specialists have worked on some of the nation's largest and most intricate claims administration projects. We bring a wealth of knowledge in addition to state-of-the-art technology to assist our clients with their claims processing obligations. To simplify the administration of a settlement, our professionals can work closely with each client to help develop a custom design for the specific requirements and challenges of a project. Through our proprietary software and leading-edge methodologies, we streamline the complex components of the settlement process to deliver cost-effective and efficient services to our clients.

Why Deloitte Risk and Financial Advisory?

Our multidisciplinary and integrated life sciences and health care team possesses years of industry experience. We can help clients and their outside counsel:

- Uncover instances of potential fraud, mismanagement, and other misconduct
- Develop, manage, and respond to discovery requests
- Produce, manage, and analyze massive quantities of transactional data
- Address class certification issues
- Identify, isolate, and quantify potential areas of exposure
- Depose and rebut opposing experts
- Negotiate settlements prior to litigation or binding arbitration

We provide these services in a phased approach, allowing the client to analyze our findings along the way and change course in a timely manner if needed. We have an acute awareness of the importance of the issues related to maintaining attorney-client privilege and of protecting confidential client and patient information.

At Deloitte Risk and Financial Advisory, we work side by side with our clients and their counsel to help them effectively and efficiently address, manage, and resolve investigations, litigation, and business disputes. And we look forward to helping you realize similar results.

Allegations of the filing of false claims

The FCA has been a powerful and effective tool used by law enforcement and the relators' counsel against health care companies. Companies engaged in the investigation or litigation of FCA allegations are subject to increasingly punitive penalties and damages mandated by statutes. We have helped numerous clients and their counsel investigate, resolve, and remediate alleged submission of false claims for medical services, including:

- Short stay admissions
- Home health visits
- Targeted cardiac procedures
- Skilled nursing services
- Clinical labs
- Billing for physician services
- And more

We have assisted health care providers and payers with:

- Early case assessment
- Quantification of amounts received from Medicare and other government payers
- Statistical modeling and sampling
- Medical record inspection to assess documentation quality
- Coding and repricing analyses
- Assistance with interviews
- Damages modeling and analysis of alternative damages theories
- Assistance with settlement negotiations, including the Department of Justice Ability to Pay Protocols
- Expert witness reports and depositions
- Assessments of corporate compliance programs
- Remediation and readiness services
- Monitor and Independent Review Organization (IRO) services

In these matters, we work with the client and counsel to make sure protected health information (PHI) is handled in accordance with the requirements of the Health Insurance Portability and Accountability Act (HIPAA).

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About Deloitte

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