South Carolina Bar
Continuing Legal Education Division

2026 SC BAR CONVENTION

Health Law Section

"Health Law: Trials, Tribulations, Triumphs and Trends"

Thursday, January 22

SC Supreme Court Commission on CLE Course No. 260127

South Carolina Bar

Continuing Legal Education Division

AI Use and Abuse in Healthcare

Stephen Bittinger
Wayne van Halem
Bob Coffield
&
J. Keane Mossman

AI Use and Abuse in Healthcare

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Artificial Intelligence 101

"Once a new technology rolls over you, if you're not part of the steamroller, you're part of the road."

Stewart Brand

Source: https://www.socratic-method.com/quote-meanings-and-interpretations/stewart-brand-once-a-new-technology-rolls-over-you-if-youre-not-part-of-the-steamroller-youre-part-of-the-road

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How Does It Feel to Win a Nobel Prize? Ask the 'Godfather of A.I.'

The computer scientist Geoffrey Hinton spoke with The Times shortly after learning he had won the Nobel Prize for Physics.

"What do you believe your legacy will be when it comes to AI?"

"I am hoping AI will lead to tremendous benefits, to tremendous increases in productivity, and a better life for everybody. I am convinced it will do this in healthcare. My worry is that it may also lead to bad things and in particular when we get things more intelligent than ourselves. No one really knows whether we are going to be able to control them."

– Professor Geoffrey Hinton

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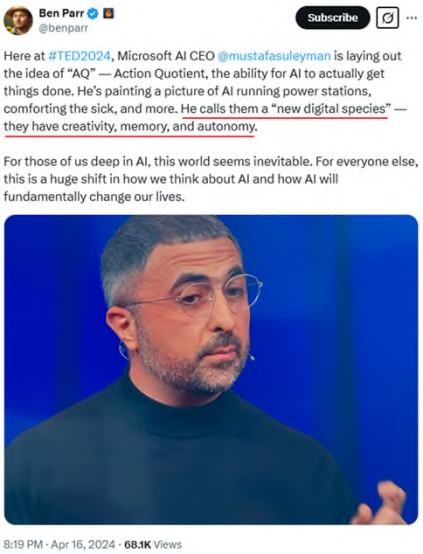
Why is Artificial General Intelligence Different?



Automobile = Machine
Airplane = Machine
Computer = Technology
Internet/Data = Technology
Smartphone = Technology
Robotics = Technology
Artificial Intelligence = Digital Species

nology connected and empowered us, and now
r understanding of what it means to be human
ing a new form of existence entirely.

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How are providers using AI?

- Medical Imaging and Diagnostics
  - AI algorithms are revolutionizing radiology by analyzing X-rays, MRIs, CT scans, and other medical images to detect abnormalities such as tumors, fractures, and signs of disease with high accuracy.
- Ambient Listening for Clinical Documentation
  - AI-powered ambient listening tools capture and transcribe patient-provider conversations in real time. This reduces the documentation burden on clinicians, improves accuracy in clinical notes, and helps meet billing and coding requirements.
- Predictive analytics
  - AI models are used to predict patient risks, such as hospital readmissions, disease progression, or adverse events. For example, AI can forecast heart attacks or strokes before symptoms appear

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How are providers using AI?

- Genomics and Precision Medicine
  - AI is enabling analysis of genomic data to identify disease risks and tailor treatments to individual patients. This is particularly powerful in oncology and psychiatric care, where understanding genetic variants can guide more effective therapies.
- Administrative Automation
  - AI is streamlining back-office operations like medical billing, coding, prior authorizations, and scheduling. These tools reduce human error, speed up workflows, and cut costs.
- Virtual Health Assistants
  - AI chatbots and voice assistants are being used to guide patients through care processes, answer questions, and monitor symptoms.

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How are providers using AI?

- Clinical Decision Support
  - AI systems provide evidence-based recommendations to clinicians by analyzing patient data and medical literature. This helps in making more informed decisions and improving treatment outcomes.
- Population Health Management
  - AI helps identify trends and risks across large patient populations, enabling healthcare systems to allocate resources more effectively and design targeted interventions

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Healthcare AI Vendor Contract Management

- How do AI vendor contracts differ from other provider/vendor arrangements
  - AI vendor platforms make decisions, evolve, and learn from data (updates, use outside data, bias, hallucinations)
  - AI vendor tools augment (or replace) human clinical decision making and can shift liability from provider to vendor

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Healthcare AI Vendor Contract Management

- Where does AI show up in the provider/vendor relationship
  - Clinical support tools (imaging, diagnostics, triage, medication adherence)
  - Documentation and ambient listening (EHR and virtual AI scribes)
  - Business and compliance (revenue cycle management, coding, utilization management)
  - Operations (scheduling, bed management, medication staffing, human resource management)
  - Patient engagement, education, chronic condition management

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Healthcare AI Vendor Contract Management

- Why contract terms matter so much with AI vendors
  - Allocates regulatory risks (privacy, security, licensure, fraud & abuse, FDA)
  - Allocates clinical risks (professional liability, licensure and regulatory compliance)
  - Controls data access, flow, use by provider or by third parties
  - Controls AI model training and commercialization
  - Show regulators your governance and oversight (or lack of it)

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Healthcare AI Vendor Contract Management

- Core contract clauses in AI negotiated contracts
  - Scope of use (what the AI tool does or does not do, data usage)
  - Performance (accuracy, response times, error handling)
  - Regulatory compliance (vendor reps on HIPAA privacy, security, fraud & abuse, AI laws, FDA)
  - Third-party terms (sub vendor identification and data flow-down legal protections)
  - Indemnification and liability caps (who pays if AI causes professional negligence, false claim, breach)
  - Insurance (scope, limits, exclusions, does vendor coverage match AI risk)

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Healthcare AI Vendor Contract Management

- Red flag warnings and emerging abuses in AI vendor contracts
  - Guaranteed revenue increases with no compliance discussion
  - Compensation tied to referrals or collections
  - Vendor unwillingness to provide transparency on how AI technology works
  - Contract silence on data use, training rights, and use for commercialization
  - Vendor resists audits, cooperation with oversight/investigations, or data extracts
  - Just click through and accept online terms and conditions with references to URLs

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Healthcare AI Vendor Contract Management

- Practical questions to ask your AI contract vendor
  - What decisions does this technology or tool influence?
  - If AI is wrong, who gets hurt – patient, payor, provider, etc.
  - How could this technology or tool create a false claim or kickback scenario?
  - Where is the data going?
  - Does the data leave our four walls?
  - What can the vendor do with our data?
  - If we decide to stop using the AI technology or switch software vendors – can we exit cleanly and cheaply?

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Healthcare AI Vendor Contract Management

- Takeaways for counsel dealing with providers and AI vendors
  - Intake and scope of service (use case, data flows, clinical impact, risks)
  - Due diligence and risk assessment (technical, privacy/security, regulatory)
  - Term sheet and key deal points (data rights, liability, pricing)
  - Contract negotiations (detailed, documented, legal oversight/governance sign off)
  - Implementation and Go Live (testing, validation, training, operation change management)
  - Continued monitoring and renewal/amendment (performance review, audits, incident tracking, reassessment of risk)
  - Build a strong multidisciplinary and layered review process (clinical, operations, finance, IT, compliance, legal)

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How are payers using AI?

- Claims Processing and Fraud Detection
  - Real-time fraud detection: AI models flag suspicious billing patterns and identity mismatches. For example, Anthem uses Google Cloud AI to detect anomalies in claims.
  - Automated claims: AI enables near-instant claims processing, reducing delays and administrative burden. Some insurers have achieved claim approvals in seconds.
- Member Engagement and Personalization
  - AI-powered virtual assistants: Cigna and Elevance Health use generative AI chatbots to answer benefit questions and guide members through care options
  - Personalized care recommendations: Aetna's Care Paths and UnitedHealth's search tools use AI to tailor wellness programs and provider searches based on individual needs.

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How are payers using AI?

- Prior Authorization and Utilization Management
  - AI streamlines prior authorization workflows, making them faster and more transparent.
  - It supports utilization management by analyzing patient data to determine appropriate care pathways.
- Risk Assessment and Underwriting
  - AI enables risk scoring using real-time data, moving beyond traditional demographic-based models. This leads to fairer and more accurate premium pricing.
  - Agentic AI tools proactively assess risk and automate underwriting decisions without human intervention.

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How are payers using AI?

- Digital Experience and Tools
  - Insurers offer smart claim submission and real-time cost tracking features, improving transparency and ease of use for members.
  - AI enhances retail-like digital experiences, including intuitive navigation and simplified coordination of care.
- Governance and Compliance
  - Over 90% of insurers have adopted AI governance frameworks aligned with NAIC principles, focusing on transparency, fairness, and human oversight
  - AI is used to monitor model drift, bias, and data integrity, ensuring ethical and compliant use.

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How is government using AI?

- WISeR – Wasteful and Inappropriate Service Reduction Model
  - CMS estimates 25% of healthcare spending is wasteful
  - WISeR will harness enhanced technologies like AI and Machine Learning to streamline the review process for certain items and services that are vulnerable to fraud, waste and abuse
  - Will run from 1/1/2026 – 12/31/2031
- Participants will be AI companies that perform prior authorization services for other payers
  - They will be required to have clinicians with the expertise to conduct medical reviews to validate determinations

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WISeR Goals

- Focus healthcare spending on services that will improve patient well-being
- Apply commercial payer prior authorization processes that may be faster, easier and more accurate
- Increase transparency of existing Medicare coverage policy
- De-incentivize and reduce use of medically unnecessary care

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WISeR Focus

- Participants will apply their technology to help medical reviewers assess a set of services chosen by CMS that they determined:
  - May pose concerns related to patient safety if delivered inappropriately
  - Have existing publicly available coverage criteria
  - May involve prior reports of fraud, waste and abuse.
- Selected services include:
  - Skin and tissue substitutes
  - Implantable Electrical nerve stimulators
  - Knee arthroscopy for knee osteoarthritis
- Excluded services
  - Inpatient-only
  - Emergency Services
  - Services that would pose a threat if substantially delayed

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WISeR Initiative

- Impact on Providers
  - Optional for providers to participate
  - If they do not participate, they are subject to post-service/prepayment medical review through the same AI tool
- Model payment
  - AI Participants will be awarded based on the effectiveness of their technology for reducing spending on medically unnecessary or non-covered services
  - Participants will receive a percentage of the reduction in savings that can be attributed to their technology

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Model Performance Measures

- Process Quality
  - Number of non-affirmations and favorable appeal decisions
  - Volume of requests processed
- Provider/Supplier and Beneficiary Experience
  - Timeliness of response
  - Clarity of explanation of request determination
- Clinical quality outcomes
  - Use of alternative services
  - Evidence of ongoing urgent need to address the clinical issue

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FEDERAL REGULATORY BACKGROUND

Executive Order on the Safe, Secure, and Trustworthy Development and Use of Artificial Intelligence

MEDICARE ADVANTAGE (PROPOSED 12/10/24)

- CMS is concerned about algorithmic discrimination
- Requires that MA organizations using AI to aid in decision-making do so equitably
- MA organization compliance may be audited
- Defines "automated systems," "AI," "patient care decision support tool"

AI EXECUTIVE ORDERS

- EO 114110 (Rescinded 01/20/2025)
  - Included an "AI Plan" setting forth non-mandatory recommendations for the use of AI for automated and algorithmic systems
- EO 14179 (Issued 01/23/2025)
  - Sets forth recent policy of the US to sustain and enhance America's global AI dominance in order to promote human flourishing, economic competitiveness, and national security

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The White House Executive Orders on Artificial Intelligence

- October 30, 2023, the Biden Administration released Executive Order 14110 titled "Safe, Secure, and Trustworthy Development and Use of Artificial Intelligence"
- January 23, 2025, the Trump Administration released Executive Order 14179, titled "Removing Barriers to American Leadership in Artificial Intelligence"
- February 11, 2025, the Trump Administration released Executive Order 13859, titled "Maintaining American Leadership in Artificial Intelligence"
- July 23, 2025, White House released "Winning the AI Race: America's AI Action Plan (https://www.whitehouse.gov/articles/2025/07/white-house-unveils-americas-ai-action-plan/)
- CMS AI Playbook (Version 4), documents the agency's evolving approach to AI adoption and maturity and serves as a guidebook (https://ai.cms.gov/)

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Executive Order 14179, "Removing Barriers to American Leadership in Artificial Intelligence" (January 23, 2025)

- **Revocation of Previous AI Policies:** Eliminates existing AI policies and directives that are considered obstacles to U.S. AI innovation
- **Commitment to AI Leadership:** Affirms the U.S. policy to sustain and enhance America's global dominance in AI to promote human flourishing, economic competitiveness, and national security
- **Development of AI Action Plan:** Mandates the creation of an AI Action Plan within 180 days to achieve the stated policy goals
- **Review of Prior Directives:** Instructs relevant officials to review and identify any actions taken under the revoked Executive Order 14110 that may conflict with the new policy, and to suspend, revise, or rescind such actions as appropriate
- **Revision of OMB Memoranda:** Directs the OMB to update specific memoranda (M-24-10 and M-24-18) within 60 days to align with the new AI policy

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Executive Order 13859, titled "Maintaining American Leadership in Artificial Intelligence" (February 11, 2025)

- **Sustained Investment in AI R&D:** Encourages collaboration among industry, academia, and international partners to drive technological breakthroughs in AI
- **Access to Federal Data and Resources:** Aims to improve access to high-quality federal data, models, and computing resources for AI R&D, while ensuring safety, security, and privacy protections
- **Removing Barriers to AI Innovation:** Seeks to reduce obstacles to the safe testing and deployment of AI technologies
- **Training an AI-Ready Workforce:** Emphasizes the need to equip American workers with the skills necessary to develop and apply AI technologies
- **Promoting Trust in AI:** Focuses on fostering public trust and confidence in AI technologies by ensuring their development and application align with civil liberties, privacy, and American values
- **International Engagement and Protection of AI Technology:** Advocates for promoting an international environment that supports American AI research and innovation, while safeguarding critical AI technologies from acquisition by strategic competitors and adversarial nations

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White House Winning the AI Race: America's AI Action Plan (July 23, 2025)

Key policies in the AI Action Plan include:

- **Exporting American AI:** The Commerce and State Departments will partner with industry to deliver secure, full-stack AI export packages – including hardware, models, software, applications, and standards – to America's friends and allies around the world.
- **Promoting Rapid Buildout of Data Centers:** Expediting and modernizing permits for data centers and semiconductor fabs, as well as creating new national initiatives to increase high-demand occupations like electricians and HVAC technicians.
- **Enabling Innovation and Adoption:** Removing onerous Federal regulations that hinder AI development and deployment, and seek private sector input on rules to remove.
- **Upholding Free Speech in Frontier Models:** Updating Federal procurement guidelines to ensure that the government only contracts with frontier large language model developers who ensure that their systems are objective and free from top-down ideological bias.

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State Legislation of Artificial Intelligence

- **Regulatory Patchwork Emerging:** Many states are legislating AI use in healthcare – from insurance claim algorithms to clinical decision support
- Key Themes:
  - **Human Oversight Required:** Banning "AI-only" decisions in care and coverage by insurers and providers
  - **Transparency:** Patients and regulators must be informed when AI is used. AI-driven decisions impacting healthcare consumers
  - **Bias & Safety Checks:** Preventing discrimination and requiring quality controls in AI tools
  - **Appropriations and Education:** Allocating funds for AI initiatives to enhance research, development, and training

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State Legislation of Artificial Intelligence

- State Level – Mixed Momentum:
- **Passed Comprehensive Laws:**
  - **California**: Disclosure of AI use in patient communications and insurance coverage decisions
  - **Colorado**: Notification & anti-discrimination safeguards for high-risk AI systems (revised effective date June 30, 2026)
  - **Utah**: Mandatory AI use disclosure in healthcare interactions
  - **Texas**: Focus on protecting individual rights, notification, and prohibits discrimination

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State Legislation of Artificial Intelligence

- State Level – Mixed Momentum:
  - **Pending or Partial Legislation:**
    - States like NY, MA, CA, CT, NE, and NM considering similar bills.
    - Other states (e.g., AR, IL, KY, NJ, VA) have narrower or older laws.
  - **Industry Concerns:**
    - Multi-state compliance burdens.
    - Risk of "race to the bottom" in product design due to varying restrictions.
    - Startups may lack resources to comply with patchwork laws.

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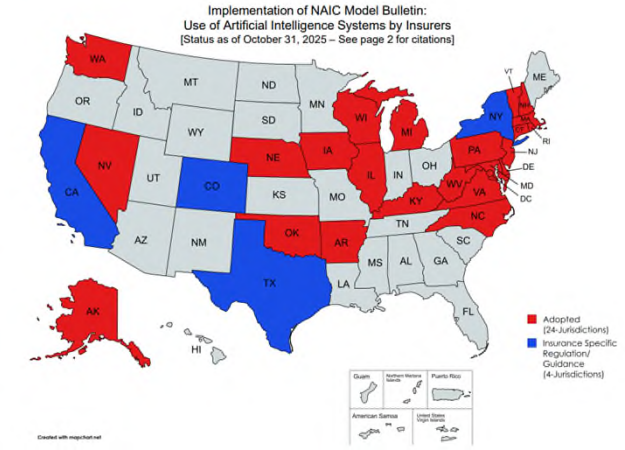
STATE REGULATION OF AI

Use of AI at the time of Patient Encounter



State regulation of AI in managed care

Via the National Association of Insurance Commissioners Model Bulletin

Adoption by state DOIs is ongoing

Delaware – Adopted February 5, 2025
New Jersey – Adopted February 11, 2025
Wisconsin – Adopted March 18, 2025

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Recent Cases

- ***Barrows, et al. v. Humana, Inc.*** **(W.D. Ky.)**
  - Barrows, who had post-acute care coverage terminated, filed a class action complaint alleging Humana's reliance on an AI model with a "90% error rate" to deny certain medical claims under Medicare Advantage plans constituted breach of contract, breach of the implied covenant of good faith and fair dealing, unjust enrichment, and insurance bad faith. The improper use of AI to make coverage decisions, while ignoring clinical determinations made by providers, can improperly deny elderly patients' coverage for care owed to them under Medicare Advantage.
  - Scheduling order entered October 10, 2025
- ***Estate of Gene B. Lokken, et al. v. UnitedHealth Group, Inc., et al.*** **(D. Minn.)**
  - Plaintiffs, estates of patients who had post-acute care coverage terminated, filed a putative class action complaint alleging the defendants improperly denied their medical insurance claims for medically necessary care based on artificial intelligence. This reliance on AI to deny certain medical claims under Medicare Advantage constituted breach of contract, breach of the implied covenant of good faith and fair dealing, unjust enrichment, and insurance bad faith.
  - Motion to Dismiss - Granted in Part and Denied in Part
    - State law claims for breach of contract and implied covenant of good faith and fair dealing could proceed forward.
    - Medicare Act's broad preemption barred other claims (unjust enrichment, insurance bad faith, state statutory claims under consumer-protection or unfair-insurance laws).
    - Court waived requirement that Plaintiffs must exhaust Medicare appeals process before filing a lawsuit.

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Recent Cases - Updates

- ***Kisting-Leung et al. v. Cigna Corporation, et al.*** **(E.D. Cal.)**
  - Plaintiffs, consumers in California, filed a class action complaint alleging that the denial of certain medical claims by the defendant using its PxDx algorithm constituted a breach of the implied covenant of good faith and fair dealing, unjust enrichment, intentionally interfered with contractual relations, and violated California's Unfair Competition Law. This reliance on AI to wrongfully deny certain medical claims allegedly deprives patients of their right to reasonable objective claim evaluation.
  - Discovery phase.
- ***Snyder, et al. v. Cigna Group, et al.*** **(D. Conn.)**
  - The lawsuit alleges that the defendant uses its PxDx (procedure-to-diagnosis) algorithm to automatically review claims without conducting a thorough medical review of the claims as required by law and contract. It alleges that over a period of two months in 2022, Cigna used PxDx to automatically review and deny over 300,000 claims, spending an average of just 1.2 seconds per claim. Further, it suggests that physicians employed by payers to review the insurance claims are signing off on denials without looking at them.
  - Discovery phase.

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Improper Use of AI & Postpayment Review

- ***Pinnacle Medical Solutions, LLC v. La. Healthcare Connections*** **(M.D. La.)**
  - Challenging an MCO's improper use of AI to perform post-payment review of medical records, without sufficient human oversight that generated improper denial bases used to assert an extrapolated overpayment.
  - MCO's AI software tool is alleged to have hallucinated the existence of requirements and documentation as the basis for denial of claims.
  - Plaintiff challenged the improper use of AI software tool as a violation of Federal Medicaid Act for not following statutory duties to beneficiaries.
  - Order to arbitration.

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Improper Use of AI & Price Fixing

- ***In Re Multiplan Health Insurance Provider Litigation*** **(N.D. Ill.)**
  - Plaintiffs allege that MultiPlan and third-party payors violated federal antitrust law by agreeing to fix prices for out-of-network healthcare services, constituting a per se violation of the Sherman Act.
  - Plaintiffs allege that when MultiPlan negotiates with providers, payment is conditioned on an agreement not to "balance bill" patients for the unpaid portion of their claims. In other words, providers cannot accept a third-party payor's payment and then recover the remainder from the patient.
  - The defendants filed motions to dismiss both the class action and direct-action complaints. The Court denied the motions to dismiss the federal and state antitrust claims and the state consumer protection claims but granted the motion to dismiss the unjust enrichment claims.
  - New trial date set for December 27, 2027.

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Disputes Over AI

KEY ISSUES BEING LITIGATED AGAINST GOVERNMENT PAYORS' USE OF AI: DUE PROCESS CHALLENGES

Medicare beneficiaries have a protected **due process property interest**.

Beneficiaries are the primary parties in interest to the Medicare program. Providers are parties in interest as **"assignees"** of the beneficiaries.

When medical providers furnish services to Medicare beneficiaries, the providers submit a claim for reimbursement based on the beneficiaries property right in the program.

Providers generally collect an **Assignment of Benefits** ("AOB") at the time of the first item or service is furnished to a beneficiary or assignment assumed by operation of law (e.g. emergency services).

Medicare providers are then subrogated to the statutory entitlement of reimbursement for services rendered to Medicare beneficiaries. **42 U.S.C. § 1395l**

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Disputes Over AI

KEY ISSUES BEING LITIGATED AGAINST ALL PAYORS' USE OF AI

- **Overlap between statistics and AI: Bayesian Statistics**:
  - **Bayes' Theorem** – a fundamental rule that describes how to update the probability of a hypothesis given new evidence.

$$P(A \mid B) = \frac{P(B \mid A) \cdot P(A)}{P(B)}$$

A, B = events
$P(A|B)$ = probability of A given B is true
$P(B|A)$ = probability of B given A is true
$P(A), P(B)$ = the independent probabilities of A and B

- **Bayesian Reasoning and Machine Learning**:
  - Can mathematically calculate confidence in model predictions
  - Determine a range of possible outcomes for a given input
  - Uses prior domain knowledge to improve model performance

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Challenges for Courts

VITAL LEGAL ISSUES THE COURTS MUST DETERMINE ON HOW AI WILL BE VALUED AS EVIDENCE

- *Artificial Intelligence as Evidence*, Paul W. Grimm, Maura R. Grossman, and Gordon V. Cormack, 19 Nw. J. Tech. & Intell. Prop. (2021)
  - Advocates that the Federal Rules of Civil Procedure, *if followed*, are sufficient to provide fair outcomes
  - Currently no case law squarely addressing admissibility of AI evidence in federal courts
  - Judges must learn what AI is, the types of AI that presently exist, challenges AI can pose, what governs whether AI produces valid and reliable output, evidentiary value of AI at trial
  - "Judges cannot evaluate AI from a state of fundamental ignorance"

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A BACKDROP

Generative AI ("gAI") as estimative evidence[1]

- The essence of AI technology boils down to the data and algorithms that were developed to govern it
- Algorithms are a set of rules or procedures for solving a problem or accomplishing an end
- Knowing the problem it was designed to solve is critical to assess the following:
  - Validity – AI's accuracy in performing its functions
  - Reliability – the consistency with which the AI produces the same or substantially similar results when applied under substantially similar circumstances
  - Function creep – whether the AI is being used for purposes for which it was not designed
- These foundational principles equally apply to the use of statistical sampling and extrapolation in post-payment audits and self-audits

[1] *Artificial Intelligence as Evidence*, Paul W. Grimm, Maura R. Grossman, and Gordon V. Cormack, 19 Nw. J. Tech. & Intell. Prop. (2021)

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gAI and Data Analytics, Audit Process, and Estimates

CMS and AI

CMS GUIDANCE RELATED TO USE OF AI BY MEDICARE ADVANTAGE PLANS FOR:

- Coverage Criteria
- Utilization Management
- Not on Post-Payment Review

KEY CONCEPTS:

- Medical Necessity Must Be Patient Specific
- gAI Can Assist Qualified Personnel
- gAI Predictive Analytics Cannot Be Sole Source
- gAI Cannot Be Discriminatory
- gAI can be biased by the training data set

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gAI and Data Analytics, Audit Process, and Estimates

gAI as Estimative Evidence?

NO LEADING DECISIONAL LAW

A LEADING SCHOLARLY SOURCE

- *Blame It on the Bot: Health Care Fraud and Compliance in the Age of AI*, Joshua Robbins and Daniel Pietragallo, AHLA Health Law Weekly, 7/11/25
  - "The AI taught itself to game the billing system."
  - "AI-powered health care fraud represents an evolution not a revolution in illegal schemes."
  - Another example of the "Pygmalion Effect."

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Proposed Rule 707, FRE

- Approved by the Committee of Rules of Practice and Procedure on June 10, 2025
- Purpose—to ensure that machine-generated evidence meets reliability standards set for expert witness testimony under Rule 702, FRE and *Daubert*
- To be admissible, the proponent of the evidence must show that the AI output is based on sufficient facts or data, produced through reliable principles and methods, and demonstrates a reliable application of the principles and methods to the facts

"When machine-generated evidence is offered without an expert witness and would be subject to Rule 702 if testified to by a witness, the court may admit the evidence only if it satisfies the requirements of Rule 702 (a)-(d). This rule does not apply to the output of simple scientific instruments."

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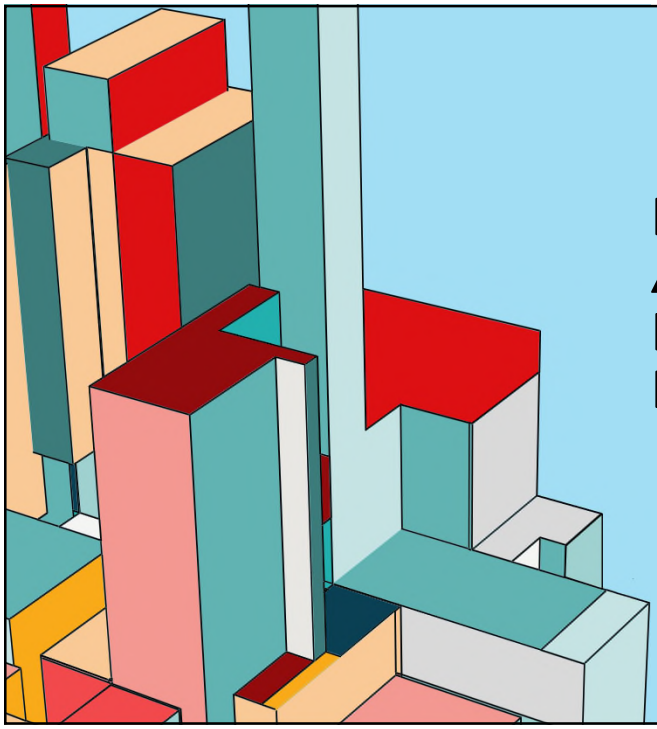
South Carolina Bar

Continuing Legal Education Division

Private Equity and its Increasing Role in Healthcare

Pamela Coyle Brecht
Jake Shields
&
Tina Cundari



PRIVATE EQUITY AND ITS INCREASING ROLE IN HEALTHCARE

South Carolina Bar Convention
Health Care Law Section
January 22, 2026

1

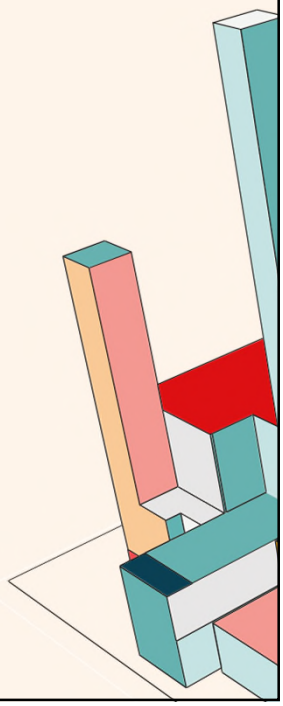
PANELISTS

Pamela Brecht

Pietragallo Gordon Alfano Bosick & Raspanti, LLP

Jake Shields

Gibson, Dunn & Crutcher LLP



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2

PRIVATE EQUITY IN A NUTSHELL

- PE firms manage money for investors and invest in private businesses.
- PE firms typically buy companies, oversee the investment, and sell for a profit.
- Structure:
  - PE Firm
  - Investment Fund
  - Investors in the Investment Fund
  - Portfolio Company
- Big business, including in healthcare

3

3

PE'S ROLE IN HEALTHCARE

- PE expanding into various healthcare industries
- Healthcare is an attractive target
  - Demand in healthcare
  - Risk/benefit analysis
  - Valuation Disparities
  - Profitability
- Pros and Cons of PE Involvement

4

4

FCA RISKS

- Common FCA violations in healthcare
- PE regulatory concerns
  - Management fees
  - Earnouts
  - Roll forward equity
  - Marketing/Advertising
- Risk to portfolio company, investment fund, and PE firm

5

5

FCA LITIGATION TO DATE

- DOJ's view that the FCA applies to PE in healthcare
- Case Results
  - Span various industries
  - Produced sizeable settlements

6

6

TRENDS IN CASELAW

- Sources of PE liability under the FCA
  - Direct involvement in management
  - Knowledge of fraudulent scheme
  - Failing to intervene and stop fraud

7

7

LITIGATION STRATEGIES

- Why do relator's counsel and the government pursue PE cases?
  - Theories of liability
- What are strategies for defending clients and cases?
  - Prevention
  - Motions practice
- Themes for trying PE cases

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FUTURE LEGISLATIVE/REGULATORY GUIDANCE

1. Bi-partisan Senate inquiry into private equity ownership on quality/accessibility of care in the ER
2. Multiple states are passing legislation regulating the surge of unchecked private equity investment in healthcare
   a. Nevada
   b. Massachusetts
3. Other legislation/regulatory guidance moving forward

9

9

QUESTIONS

10

10

THANK YOU

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RESOURCES

Cases and Settlements

Medrano & Lopez v. Diabetic Care Rx LLC, d/b/a Patient Care Am., No. 15-CV-62617 (S.D. Fla. Mar. 6, 2019).

Johnson v. Therakos, Inc., No. 12-cv-1454 (E.D. Pa. Nov. 19, 2020).

Martino-Fleming v. S. Bay Med. Health Ctrs., 540 F. Supp. 3d 103 (D. Mass. 2021).

Mandalapu v. All. Family of Companies LLC, No. 4:17-cv-00740 (S.D. Tex. July 9, 2021).

Martino-Fleming v. S. Bay Med. Health Ctrs., 540 F. Supp. 3d 103 (D. Mass. 2021).

U.S. ex rel. Schagrin v. LDR Indus. LLC & GB Holdings, Inc., 2019 WL 1254923 (N.D. Il. Mar. 19, 2019).

U.S. DOJ Settlement Agreement with Aero Turbine, Inc. and Gallant Capital Partners, LLC (Jul. 31, 2025), *available at* https://www.justice.gov/opa/media/1409651/dl.

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12

RESOURCES

Reports and Publications

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Kannan, Sneha, *Hospital Staffing and Patient Outcomes After Private Equity Acquisition*, Annals of Internal Medicine (2025), https://www.acpjournals.org/doi/10.7326/ANNALS-24-03471.

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Statement of Ethan Davis, Deputy Assistant Attorney General, DOJ's Civil Division (June 2020) (available at https://www.justice.gov/civil/speech/principal-deputy-assistant-attorney-general-ethan-p-davis-delivers-remarks-false-claims).

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A Look Back: 2025 Trends in Healthcare Fraud Enforcement

Brook Andrew
&
Stephanie Opet

A Look Back: 2025 Trends in Healthcare Fraud Enforcement

Stephanie Opet, SC Attorney General's Office
Brook B. Andrews, Nelson Mullins

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SOUTH CAROLINA
ATTORNEY GENERAL'S OFFICE

Vulnerable Adults and Medicaid Provider Fraud

Stephanie Opet, Director
South Carolina Medicaid Fraud Control Unit

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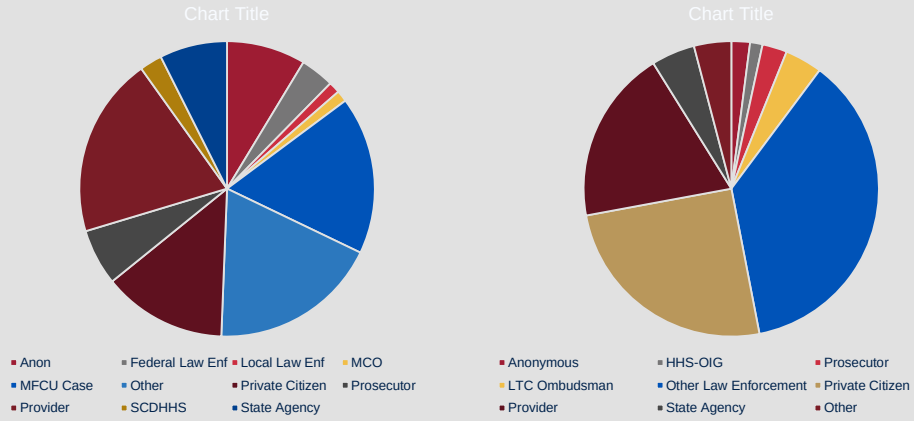
VAMPF Trends – Referral Sources

Provider Fraud



Patient Abuse

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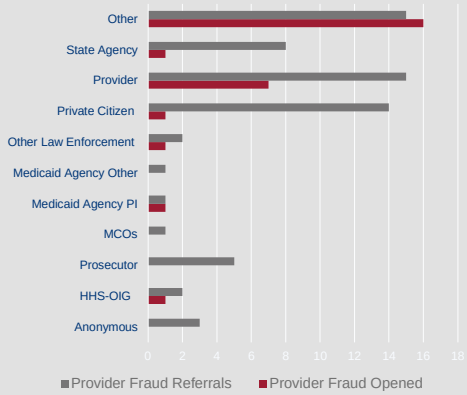
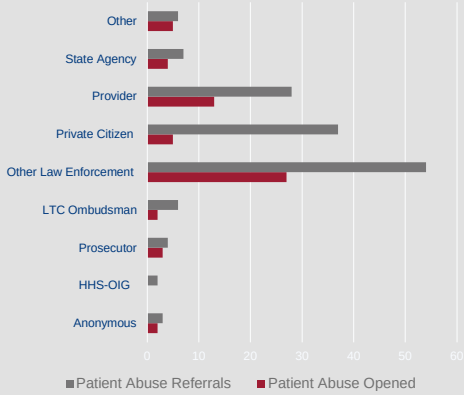
VAMPF Trends – Referral Sources

Provider Fraud



Patient Abuse



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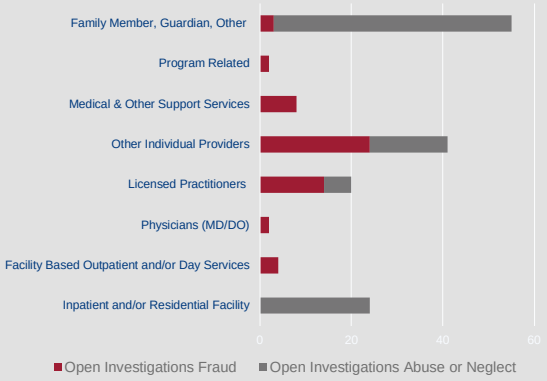
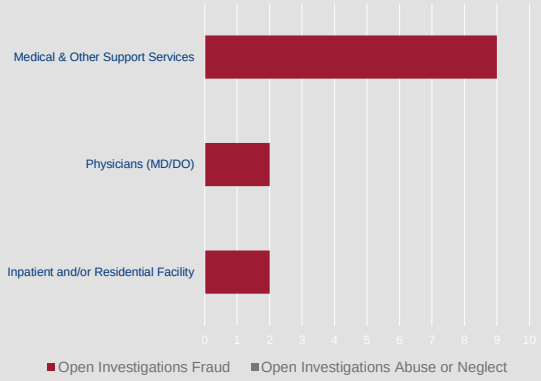
VAMPF Trends – Open Case Mix

Criminal



Civil



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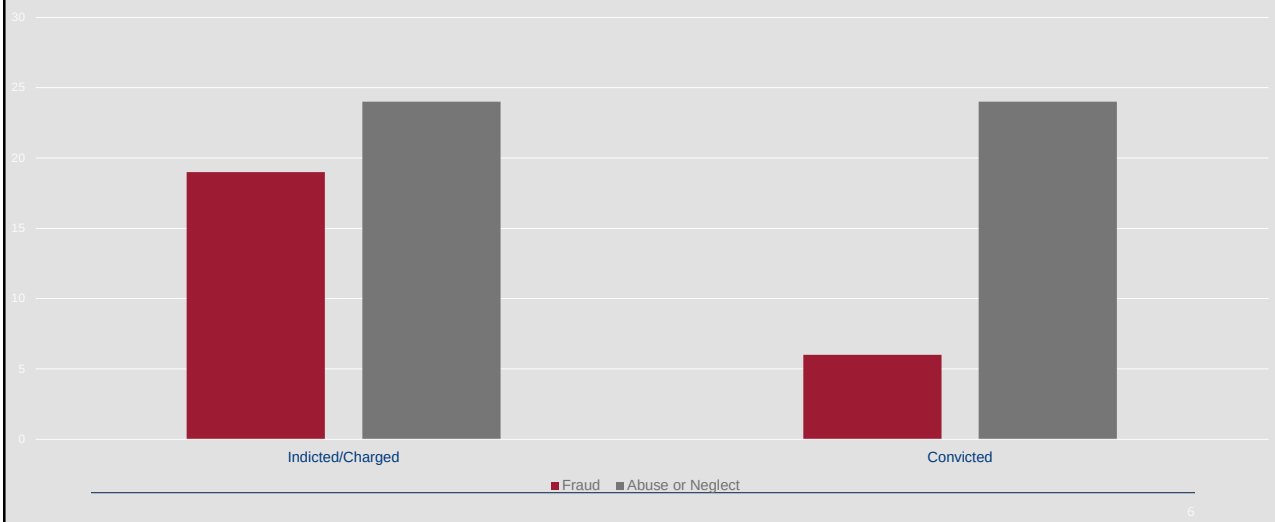
VAMPF Trends – Arrests & Convictions



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VAMPF Case Study

Operation Border War

Federal And State Officials Announce Efforts To Crack Down On Healthcare Fraud Schemes

Criminal Charges Filed Against Individuals Accused of Stealing Millions from the South Carolina and North Carolina Medicaid Programs; Civil Enforcement Actions Result in Nearly $5 Million in Settlements & Judgments to Resolve False Claims Act Allegations

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VAMPF Case Study

Premier Medical

United States and the States of Georgia, Colorado, and South Carolina Obtain $114.5M in Judgments in a Sprawling Cancer Genetic Testing Lab Scheme

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VAMPF Legislative Requests

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Federal Healthcare Enforcement Trends: 2025 In Review

Brook B. Andrews
Partner, Nelson Mullins
Former Acting U.S. Attorney, SC

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2025 Federal Health Care Enforcement Landscape

- Key statutes & tools: False Claims Act (FCA), Anti-Kickback Statute (AKS), Stark Law, ACA program-integrity provisions, HIPAA
- Core enforcement actors: DOJ Criminal and Civil Division, U.S. Attorney's Offices, HHS-OIG, HHS-OCR, FBI, DEA, CMS's Center for Program Integrity,
- Data and whistleblower driven enforcement: Strike Force model, advanced data analytics, and contractor reviews (e.g., UPICs) identify high-risk billing and relationships.
- FCA qui tams and DOJ whistleblower initiatives continue to drive major civil health care enforcement actions.

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New Administration Priorities & Policy Initiatives

- Health care fraud is framed as the top white-collar enforcement priority under the new administration.
- DOJ and HHS relaunch a joint False Claims Act working group to coordinate civil and criminal fraud and abuse enforcement across DOJ components, HHS-OIG, and CMS.
- HHS advances stronger cybersecurity expectations through proposed HIPAA Security Rule updates
- CMS issues program-integrity rules for the ACA Marketplaces that tighten data verification and block certain advance premium tax credits where fraud and non-compliance are suspected.

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National Health Care Fraud Takedown & Operation Gold Rush

- DOJ announced the largest coordinated national health care fraud takedown to date, charging hundreds of defendants across dozens of districts with schemes involving billions in intended losses.
- Cases span telehealth and genetic-testing scams, DME fraud, hospice and wound-care schemes, opioid pill mills, and home health and personal care fraud.
- Operation Gold Rush targets a massive urinary-catheter scheme that used shell DME entities and stolen identities for more than a million Medicare beneficiaries and thousands of physicians.
- Investigators emphasize the central role of data analytics and interagency coordination, including a health care fraud “data fusion” approach that integrates CMS, OIG, and law enforcement data to stop payments earlier.

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Other Notable 2025 Federal Health Care Enforcement Actions

- Large retail pharmacy resolutions, including a major opioid-related settlement with a national chain and corporate integrity obligations tied to controlled-substance dispensing and federal reimbursement.
- Significant FCA settlements with Medicare Advantage organizations and related entities over alleged risk-adjustment fraud and false diagnosis coding (e.g., large-dollar MA risk-adjustment cases).
- FCA resolutions involving national pharmacy chains for allegedly manipulating days’ supply and dispensing quantities to maximize reimbursement for drugs such as insulin.
- Mid-sized FCA cases targeting hospitals, emergency-care groups, and telehealth providers for upcoding, unnecessary services, and charging federal payors more than cash-pay patients.
- Privacy and cyber-focused enforcement by HHS OCR, including settlements with providers and vendors over inadequate security controls, data breaches, and failures to safeguard PHI and substance use disorder records.

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Substantive Trends & Focus Areas

- The FCA remains the dominant civil enforcement vehicle, even as annual health care recovery totals fluctuate; DOJ continues to highlight health care fraud as a core mission of the Civil and Criminal Divisions.
- Expansion of FCA target areas into politically sensitive spaces, such as federally funded diversity, equity, and inclusion initiatives and gender-related care, alongside traditional billing and quality-of-care theories.
- Cybersecurity is increasingly framed as a program-integrity issue, linking weak security controls and incident response to risks for Medicare, Medicaid, and other federal health care spend.
- Telehealth, DME, clinical labs, and Medicare Advantage risk-adjustment remain in the crosshairs due to high dollar volumes, historical fraud patterns, and rich data for analytics-driven investigations.

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Staffing & Structural Trends (DOJ, HHS-OIG, CMS)

- DOJ Fraud Section continues to staff a large Health Care Fraud Unit and to expand its data-analytics capacity, including new and enlarged health care fraud strike forces in key regions.
- White-collar priorities are narrowed to emphasize health care and federal program fraud, even as FBI and other resources are redirected toward immigration and other national enforcement missions.
- HHS-OIG maintains a sizeable investigative and audit workforce and reports high volumes of exclusions, criminal and civil actions, and expected recoveries in its 2025 semiannual reporting.
- CMS's Center for Program Integrity and its contractors (including UPICs) are heavily leveraged for provider enrollment screening, targeted audits, and data-driven identification of high-risk billing patterns.
- At the same time, HHS experiences significant staffing and IT strain in some components, raising questions about the capacity to modernize cyber infrastructure even as AI and analytics initiatives accelerate.

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Practical Takeaways for Providers & Counsel in 2026

- Expect investigations to be data-heavy, and multi-agency: enforcement teams often arrive with detailed claims, referral, and prescribing data already analyzed.
- Concentrated risk areas include Medicare Advantage risk-adjustment coding, opioids and CSA compliance in retail pharmacies, telehealth and DME arrangements, information blocking, cybersecurity, and certain federally funded DEI or gender-related programs.
- Compliance programs should prioritize accurate documentation and coding, monitoring of outlier billing (especially in MA and telehealth), hardened cyber defenses, and active testing of EHR and interoperability workflows.
- Organizations should have clear protocols for engaging with DOJ and HHS-OIG, including self-disclosure, cooperation, and remediation strategies, recognizing that repeat offenders and board-level failures face heightened sanctions and oversight.
- Boards and executives should receive regular briefings on enforcement trends and ensure that compliance, privacy, and security functions are adequately resourced and integrated into business decisions.

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Legislation: What to Know

Kevin Horton

No Materials Available