

HEALTHCARE COMPLIANCE ENFORCEMENT: Recent Trends and Lessons Learned

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PRESENTED BY



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Leslie Boles is the Co-Owner & President of Revu Healthcare, with over 15 years of experience in healthcare coding, auditing, and compliance. She holds various credentials and has served in leadership roles, including on the Board of Directors at Engage NC and as Co-Chairman of the Board at Grateful Heart Church in Cary, NC. Previously, she was the Senior Director of Compliance & Audit at Waud Capital Partners, overseeing compliance programs for portfolio companies. Leslie earned her bachelor's degree from the University of Arizona and is certified by the American Academy of Professional Coders, American Health Information Management Association, and the Health Care Compliance Association.

Objectives

- Examine recent healthcare fraud enforcement actions
- Identify key trends in healthcare compliance
- Analyze diverse types of healthcare fraud schemes
- Provide strategies to strengthen compliance programs
- Discuss future focus areas for regulatory oversight

2024 National Health Care Fraud Enforcement Action

- 193 defendants charged across 32 federal districts
- 76 doctors, nurse practitioners, and other licensed medical professionals involved \$2.75 billion in intended losses,
- \$1.6 billion in actual losses
- Over \$231 million in assets seized

Key Trends in Enforcement

- Increasingly complex and large-scale schemes
- Exploitation of vulnerable populations
- Abuse of digital health platforms
- Fraud in response to public health crises
- Compromise of education and licensing processes
- Violations in teaching hospitals and complex procedures

Case Studies: Recent Enforcement Actions

Amniotic Wound Graft Fraud (\$900 million scheme)

- **Scheme Overview:**
 - Four individuals charged in the District of Arizona
 - Targeted elderly Medicare patients, many terminally ill
 - Applied medically unnecessary and expensive amniotic grafts
- **Fraudulent Practices:**
 - Indiscriminate application without coordination with treating physicians
 - Treatment of superficial wounds not requiring grafts
 - Use of graft sizes far exceeding wound size
 - Lack of proper infection treatment

Amniotic Wound Graft Fraud (\$900 million scheme)

- **Financial Impact:**
 - Medicare paid over \$600 million in just 16 months
 - Average of more than \$1 million per patient for unnecessary grafts
 - Two defendants received over \$330 million in illegal kickbacks
- **Enforcement Action:**
 - Charges filed against four individuals
 - Government seized over \$70 million, including luxury vehicles, gold, and jewelry

Amniotic Wound Graft Fraud: Lessons Learned

- Importance of medical necessity reviews for expensive treatments
- Need for coordination with treating physicians
- Risks of targeting vulnerable patient populations
- Importance of proper documentation for treatments
 - “What safeguards could prevent this type of fraud in your organization?”

Concurrent Heart Surgeries Fraud: Baylor St. Luke's Medical Center

- **Defendants: Baylor St. Luke's Medical Center, Baylor College of Medicine, Surgical Associates of Texas**
- **Scheme Duration:** June 3, 2013, to December 21, 2020
- **Fraudulent Practices:**
 - Surgeons running two operating rooms simultaneously
 - Delegation of key aspects of complex heart surgeries to unqualified medical residents
 - Failure to attend surgical "timeout" procedures
 - False attestations of physical presence for entire operations

Concurrent Heart Surgeries Fraud: Baylor St. Luke's Medical Center

- **Violations:**
 - Medicare teaching physician regulations
 - Informed consent requirements
- **Settlement:**
 - \$15 million to resolve claims
 - Largest settlement to date involving concurrent surgeries

Concurrent Surgeries Fraud: Lessons Learned

- Criticality of informed consent and transparency with patients
- Importance of adhering to teaching physician regulations
- Risks of inadequate supervision in teaching hospitals
- Need for accurate documentation of surgeon presence
- Importance of prioritizing patient safety over efficiency
- Billing compliance concerns:
 - Accurate coding and billing for concurrent surgeries
 - Proper use of modifiers for overlapping procedures
 - Compliance with Medicare teaching physician billing rules
 - Alignment of quality metrics with billing practices

Physical Therapy Fraud: Oahu Spine and Rehab Case

- **Defendant: Stephen Timothy Wells, 41, owner and operator of Oahu Spine and Rehab (OSR) Plea Date: 2024 (exact date not specified)**
- **Case Duration: July 2013 through early 2020**
- **Fraudulent Practices:**
 - Submission of false claims for physical therapy services to TRICARE and Medicare
 - Use of unique provider numbers of doctors, nurses, and physical therapists for services not personally provided by them
 - Services provided by unlicensed staff, including massage therapists, athletic trainers, personal trainers, and individuals with no professional certifications

Physical Therapy Fraud: Oahu Spine and Rehab Case

- **Scale of Fraud:**
 - Caused a loss between \$250,000 and \$550,000 to healthcare benefit programs
- **Financial Impact:**
 - Agreed to pay total restitution of \$392,157.20
- **Legal Consequences:**
 - Pleaded guilty to executing a scheme to defraud health care benefit programs
 - Facing a potential sentence between probation and two years in prison

Physical Therapy Fraud: Oahu Spine and Rehab Case

- **Investigating Agencies:**
 - Defense Criminal Investigative Service
 - Office of Inspector General of the Department of Health and Human Services
 - U.S. Department of Veteran Affairs, Office of Inspector General

Physical Therapy Fraud: Lessons Learned

- **Importance of proper credentialing and licensing verification:**
Implement rigorous processes to verify and regularly re-verify the credentials and licenses of all staff providing billable services
- **Risks of misusing provider numbers:** Establish strict protocols for the use of provider numbers in billing, including regular audits to ensure compliance
- **Necessity of clear delineation between licensed and unlicensed staff roles:** Develop and enforce clear policies on the scope of practice for different staff categories, ensuring alignment with state and federal regulations.

Physical Therapy Fraud: Lessons Learned

- **Importance of accurate service documentation:** Implement systems that require the actual service provider to document and authenticate their involvement in patient care
- **Risks of fraudulent billing practices in specialized clinics:** Conduct targeted audits and monitoring of specialized clinics or services, particularly those billing to multiple payers (e.g., TRICARE and Medicare)
- **Importance of whistleblower mechanisms (Speak-up Culture):** Establish and promote anonymous reporting systems for staff to report suspected fraudulent activities without fear of retaliation

Digital Health Company: Adderall Distribution

- **Defendants: Done Global Inc., Done Health P.C., and affiliated individuals**
- **Fraudulent Practices:**
 - Unlawful distribution of Adderall and other stimulants over the internet
 - Inadequate patient evaluations ("auto-refill" policy)
 - Prescribing without proper patient interaction
 - Continuing prescriptions after patient overdose deaths
- **Scale of Fraud:**
 - One Florida nurse practitioner prescribed over 1.5 million pills of Adderall and other stimulants

Digital Health Company: Adderall Distribution

- **Scale of Fraud:**
 - One Florida nurse practitioner prescribed over 1.5 million pills of Adderall and other stimulants
- **Impact:**
 - Potential harm to patients with drug addiction
 - Exacerbation of stimulant medicine shortage

Digital Health Prescription Fraud: Lessons Learned

- Importance of thorough patient evaluations in telemedicine
- Ensure robust protocols for remote consultations and follow-ups, particularly for outpatient clinics and post-discharge care
- Review and strengthen policies for medication renewals, especially for patients transitioning from inpatient to outpatient care
- Implement systems to track prescription patterns across departments and flag unusual prescribing behaviors
- Importance of robust prescription drug monitoring

Digital Health Prescription Fraud: Lessons Learned

- Integrate state prescription drug monitoring program (PDMP) checks into hospital EHR systems for both inpatient and outpatient prescribing
- Ensure proper vetting and ongoing monitoring of any third-party digital health platforms used for patient care or prescription management
- Risks of inadequate controls on prescribing practices
- Implement checks and balances in prescribing authority, particularly for high-risk medications, across all hospital departments
- Importance of staff education on proper prescribing protocols

Addiction Treatment Fraud (\$146 million scheme)

- **Location: Arizona and Florida**
- **Scheme Overview:**
 - Over \$146 million of allegedly false and fraudulent claims
 - Targeting vulnerable patients seeking addiction treatment
- **Fraudulent Practices:**
 - Payment of kickbacks for patient referrals
 - Recruitment from homeless population and Native American reservations
 - Billing for services never provided or substandard care

Addiction Treatment Fraud (\$146 million scheme)

- **Enforcement Action:**

- Charges filed against four defendants
- Allegations include money laundering and obstruction of justices

Addiction Treatment Fraud: Lessons Learned

- Implement strict policies prohibiting any form of patient referral incentives
- Importance of ethical patient recruitment practices: Develop guidelines for ethical outreach to vulnerable populations
- Need for quality control in addiction treatment: Establish regular peer reviews and patient outcome assessments for addiction services
- Importance of proper documentation for services: Implement automated systems to track and verify service delivery
- Risks of targeting vulnerable populations: Provide specialized training for staff working with vulnerable populations

Nursing Education & Licensure Fraud: Asiegbunam Case

- **Defendant: Ejike Asiegbunam, owner of Nursing School**
- **Scheme Duration:** January 2018 to June 2021
- **Fraudulent Practices:**
 - Sale of fraudulent nursing diplomas and educational transcripts
 - Operating an unlicensed nursing school
 - Assisting purchasers in fraudulently obtaining nursing licensure

Nursing Education & Licensure Fraud: Asiegbunam Case

- **Financial Details:**
 - Charged \$15,000 to \$22,000 for false documents
 - Total Fraud Amount: At least \$1,390,332 from false document sales
- **Enforcement Action:**
 - Sentenced to 21 months in federal prison
 - Ordered to forfeit \$1,662,732 in fraudulent profits

Nursing Education Fraud: Lessons Learned

- **Importance of thorough credential verification for new hires:** Implement multi-step verification process, including direct contact with educational institutions
- **Risks of diploma mills and fraudulent educational credentials:** Maintain an updated database of accredited institutions and known diploma mills
- **Critical role of exclusion and sanction screening in hiring processes:** Conduct regular checks against OIG's LEIE and SAM for all staff, not just new hires

Nursing Education Fraud: Lessons Learned

- **Necessity of ongoing monitoring and periodic rescreening:** Implement annual re-verification of all clinical staff credentials and licensures
- **Importance of a comprehensive background check process:** Expand background checks to include international education and employment history

AI Misuse in Legal Filing: ChatGPT Generated Fake Cases

- **Defendants: Steven A. Schwartz and Peter LoDuca, lawyers from a New York law firm, (\$5,000.00 fine)**
- **Incident Date:** 2023
- Case Background: Personal injury lawsuit against Avianca airline
- **Fraudulent Practices:**
 - Submission of a legal brief containing six fake court cases generated by ChatGPT
 - Initial false claims that the non-existent cases were real
 - Use of AI to find supporting legal precedents without proper verification

AI Misuse in Legal Filing: ChatGPT Generated Fake Cases

- **Scale of Misuse:**
 - Six entirely fabricated court cases cited in a formal legal filing
- **Impact:**
 - Potential sanctions against the lawyers
 - Damage to the lawyers' and firm's credibility
 - Raised concerns about AI use in professional settings
- **Discovery of Fraud:**
 - Avianca's lawyers couldn't find any records of the cited cases
 - Upon questioning, the lawyers admitted to using ChatGPT

AI Misuse in Legal Filing: Lessons Learned

- **Importance of AI output verification:** Implement mandatory cross-checking procedures for any AI-generated content used in clinical or administrative decision-making
- **Risks of using unfamiliar technology without proper training:** Develop comprehensive training programs on AI tools before their implementation in any healthcare process
- **Need for clear guidelines on AI use in professional settings:** Establish and regularly update policies on appropriate AI use in various healthcare contexts (e.g., diagnosis, treatment planning, coding)

AI Misuse in Legal Filing: Lessons Learned

- **Potential legal and ethical implications of AI misuse:** Include AI-related scenarios in ethics training and legal compliance programs for healthcare professionals
- **Importance of transparency about AI use:** Implement protocols for documenting and disclosing when AI tools have been used in patient care or administrative processes
- **Risk of over-reliance on AI without human oversight:** Establish clear processes for human review and approval of AI-generated recommendations, especially in high-stakes decisions.



The Critical Role of Medical Necessity

- **Definition: Services that are reasonable and necessary for the diagnosis or treatment of illness or injury**
- **Why it matters:**
 - Patient safety and well-being
 - Appropriate use of healthcare resources
 - Compliance with payer requirements
 - Prevention of fraud and abuse

The Critical Role of Medical Necessity

- **Red flags for medical necessity issues:**
 - High utilization rates for specific procedures
 - Consistent use of higher-level codes
 - Patterns of unnecessary or excessive testing
 - Lack of individualized treatment plans

Strategies for Ensuring Medical Necessity

- **Implement robust documentation practices**
 - Clearly articulate the medical rationale for each service
 - Use evidence-based guidelines to support decision-making
- **Conduct regular internal audits**
 - Focus on high-risk areas and providers
 - Use data analytics to identify outliers

Strategies for Ensuring Medical Necessity

- **Provide ongoing education and training**
 - Keep staff updated on current medical necessity criteria
 - Offer guidance on proper documentation techniques
- **Establish a medical necessity review committee**
 - Multi-disciplinary team to review complex cases
 - Develop and update medical necessity policies

The Rise of AI in Healthcare



Areas of AI implementation:

- Clinical decision support
- Diagnostic assistance
- Treatment planning
- Medical coding and billing
- Patient risk stratification



Compliance challenges:

- Ensuring accuracy and reliability
- Maintaining transparency and explainability
- Protecting patient privacy and data security
- Adhering to regulatory requirements
- Managing potential biases in AI algorithms

Strategies for Monitoring AI in Healthcare Compliance

- **AI Decision Path Audits**
 - Regularly review the logic and decision paths of AI systems
 - Ensure alignment with current clinical guidelines and compliance requirements
- **Bias Detection and Mitigation**
 - Implement tools to detect potential biases in AI algorithms
 - Regularly assess AI outcomes across diverse patient populations
- **AI-Assisted Outlier Detection**
 - Use AI to identify unusual patterns in healthcare delivery, utilization, or billing
 - Investigate outliers for potential compliance issues

Strategies for Monitoring AI in Healthcare Compliance

- **AI Ethics Committee**
 - Form a multidisciplinary committee to oversee AI implementation and use
 - Include perspectives from compliance, legal, clinical, and technical experts
- **AI Compliance Training Program**
 - Develop training modules on AI compliance for staff at all levels
 - Cover topics such as AI limitations, proper use, and when to seek human oversight
- **External AI Audit Partnerships**
 - Engage third-party experts to conduct independent audits of AI systems
 - Stay updated on best practices and industry standards for AI in healthcare

AG in Texas Is Nation's First to Bring Gen-AI Enforcement Action in Health Care

- **Case Overview:**

- Texas AG filed action against Dr. Faris Tanyos and HairRx LLC
- First enforcement action involving generative AI in healthcare

- **Violation:**

- Used AI to create over 2,400 fake patient reviews and testimonials
- Violated Texas Deceptive Trade Practices Act

- **Key Compliance Issues:**

- Misuse of AI for marketing purposes
- Lack of transparency about AI-generated content
- Potential to mislead patients in healthcare decision-making

AG in Texas Is Nation's First to Bring GenAI Enforcement Action in Health Care

- **Compliance Implications:**
 - Existing consumer protection laws apply to AI-generated content
 - Need for AI governance in healthcare marketing
 - Importance of auditing AI-generated materials
- **Action Items for Healthcare Organizations:**
 - Develop policies for AI use in external communications
 - Implement disclosure practices for AI-generated content
 - Conduct regular audits of marketing materials for AI misuse

Key Takeaways

- **Evolving Landscape of Healthcare Fraud**
 - Fraud schemes are becoming increasingly complex and diverse
 - New technologies present both opportunities and risks
- **Importance of Proactive Compliance**
 - Implement robust screening and verification processes
 - Regularly update policies to address emerging risks
- **Focus on High-Risk Areas**
 - Pay special attention to billing practices, especially in specialized services
 - Monitor telemedicine and digital health platforms closely

Key Takeaways

- **Integration of Compliance and Quality**
 - Align compliance efforts with quality improvement initiatives
 - Use data analytics to identify both compliance risks and quality issues
- **AI and Technology Governance**
 - Develop clear policies for AI use in clinical and administrative functions
 - Implement oversight mechanisms for AI-generated content, especially in patient communications

Key Takeaways

- **Continuous Education and Training**
 - Keep staff updated on latest compliance requirements and fraud schemes
 - Foster a culture of ethical behavior and transparency
- **Collaboration and Information Sharing**
 - Work closely with legal, IT, and clinical departments
 - Stay informed about industry trends and enforcement actions

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QUESTION & ANSWER



THANK YOU

FOR YOUR ATTENTION



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