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Regulatory Update and Current Themes in Litigation

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Presented to: FSA FRIENDS SERVICES ALLIANCE

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Agenda

- Regulatory Updates
- DOJ Investigations
- Federal & State Developments
- Litigation Updates

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Legislative and Regulatory Updates

(1) Moratorium on Staffing Standards

(2) Changes to Nursing Home Care Compare and Five Star Quality Rating System

(3) Medicaid Reimbursement

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Moratorium on Staffing Requirement

- In May 2024, CMS finalized a rule that set the minimum federal staffing requirements for LTC facilities
  - 24/7 Registered Nurse coverage
  - Overall minimum standard of 3.48 total nurse hours per day
  - Changes in the rule would require "more than 79 percent of nursing facilities nationwide" to increase staffing
- On July 4, 2025, President Trump signed a law that imposes a 10-year moratorium on the implementation and enforcement the increased staffing requirement.
- **CMS will not be enforcing the staffing requirements until September 30, 2034.**

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Updates to Nursing Home Care Compare and Five Star Quality Rating System

- ***Began July 2025***
- Post Performance Data for Nursing Home Chains – "Compare in a consumer-friendly format"
- Drop Third Cycle Standard Surveys from the Nursing Home Care Compare Health Inspection Rating
- Incorporate Updated Long-Stay Antipsychotic Measure on Nursing Home Care Compare
- Removing COVID-19 Vaccination Measures

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Medicaid Reimbursement

- OBBBA cuts $911 billion in federal Medicaid spending over 10 years
- Eligibility redeterminations every six months - instead of every year (starting 12/31/26)
  - The primary category for SNF care (aged, blind, or disabled) is exempt
- Reduced retroactive coverage time limits in the future (starting 1/1/27)
- Big Beautiful Bill could cause nursing homes to face funding shortfalls and reduced Medicaid reimbursement ***- Post-Acute and Long Term Care Medical Association (PALTmed)***

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Navigating the Evolving Landscape

- Prepare for increased staffing requirements
- Reduce Medicaid dependence - consider diversifying payer sources
- Monitor state specific changes
- Be proactive and prepare for potential changes
- Maintain the best quality patient care

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> The Health Care Fraud Unit and U.S. Attorneys' Offices stand united with our law enforcement partners in this fight, and we will continue to use every tool at our disposal to protect the integrity of our health care programs for the American people.
>
> - Matthew R. Galeotti,
>
> Head of the Justice Department's Criminal Division

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What the Enforcement Plan Means for Health Care Providers

- May 12, 2025, Matthew R. Galeotti, head of DOJ's criminal division, announced the first ever white-collar enforcement plan.
  - Focuses on several areas directly impacting the health care and life sciences industries
  - Incentivizes voluntary self disclosure
  - Reduces the length of investigations and prosecution decisions
- False Claims Act cases can be initiated by putative whistleblowers, creating an incentive structure that may generate substantial litigation even without direct government action
  - Reports can be related to private insures not subject to FCA or public health care programs
  - Revised policy incudes fraud against patients, investors, and other non-governmental entities in the health care industry

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- Healthcare organizations are uniquely at risk due the volume of claims they submit
  - Each claim submitted has the protentional to be a separate false claim
- The "Plan uses intentionally broad language to also capture 'fraud that threatens the health and safety of consumers,' which likely targets counterfeiting, misbranding, and adulteration theories in connection with the manufacture and sale of both pharmaceuticals and medical devices, as well as potentially direct-to-consumer advertising" – *Harvard Law School Forum on Corporate Governance*

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New Enforcement Branch

- The Office of Enforcement & Affirmative Litigation
  - On September 25, 2025, the DOJ announced the creation of this new Civil Division office
  - Dedicated to safeguarding public health and safety through high-impact affirmative litigation and enforcement actions.
  - The DOJ stated this new Branch will strengthen the Civil Division's ability to advance the Department's enforcement priorities, such as protecting individuals from pharmaceutical companies, healthcare providers, and medical associations from profiting off false and misleading claims.

False Claims Act (FCA) Explained

- FCA allows the government to penalize SNFs for submitting false or fraudulent claims for payment from government programs like Medicare and Medicaid.
- Common FCA violations include:
  - upcoding (billing for higher levels of care than provided)
  - providing medically unnecessary services (i.e. unnecessary rehab)
  - providing substandard or inadequate care (grossly substandard services)
  - falsely certifying services

Grossly Substandard Services

- Nuanced theory of liability as residents at the center for months to years - not isolated incidents
- Looking at comprehensive picture of care provided to residents
  - Failing to provide adequate staffing;
  - Failing to comply with "basic protocols" of hygiene and infection control;
  - Failing to provide adequate wound care;
  - Failing to meet the nutritional needs of residents
  - Withholding pain medication;
  - Overutilization of psychotropic medications for sedation;
  - Falsely documenting care provided that was not.

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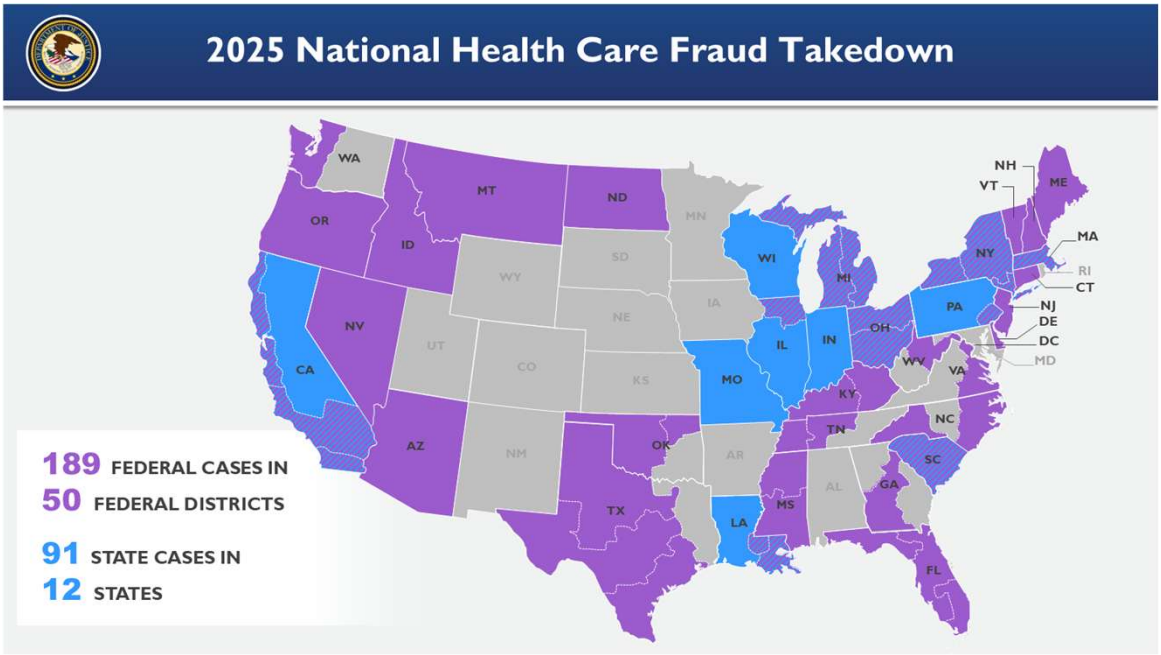

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Recent Investigations

- June 30, 2025 – Charges brought in 50 federal distracts
  - Largest health care fraud case by loss amount ever charged by the DOJ
  - 324 individuals charged with connection to 14.6 billions in fraud
  - Charges including conspiracy to commit money laundering, conspiracy to commit health care fraud, and wire fraud
    - Transnational Criminal Organizations → bought dozens of durable medical equipment companies (Scheme DME Companies) and submitted fraudulent claims, detected by through anomalous billing
    - Fraudulent Wound Care → applied medically unnecessary amniotic allografts to elderly patients
    - Other Fraud schemes included: Telemedicine Fraud, unnecessary treatment, prescription opioid trafficking

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Recent Investigations Continued …

- June 3, 2025 - Ohio
  - Nonprofit and affiliated nursing homes agreed to pay $3.61 million
  - Complaint alleged: grossly substandard services
  - Inadequate staffing, improper IC, pest-infested buildings, unnecessary medications, deprivation of dignity, lack of meaningful activities, failing to safeguard possessions, failing to provide psych care
- September 2025 - Pennsylvania
  - Nonprofit and affiliated nursing homes
  - Complaint alleged: “non-existent, grossly substandard “skilled nursing facility care or services
  - Inadequate wound care, lack of hygiene, lack of feeding assistance, severe weight loss in many cases, false documentation

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Recent Investigations Continued …

- May 28, 2025 – Maine
  - Operator of residential treatment programs agreed to pay $346,369 to settle
  - Alleged violation: billing for medically unnecessary services, failure to meet coverage requirements
- Jan 14, 2025 – California
  - Owner of CA based chain of skilled nursing facilities settled loan fraud claims for $18 million
  - Alleged violation: providing false information in support of Paycheck Protection Program (PPP) loan applications/loan forgiveness applications

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Non-profits v. For-profits

- Non-profits are not immune!
- Recent government investigations do not discriminate between non-profits and for-profits
- Same standards apply

"Grossly substandard care places nursing home residents at serious risk of harm and this suit sends a clear message that we will pursue health care providers who fail to meet their legal obligations to provide required care and who betray the trust of the residents they are meant to serve."

- Assistant Attorney General Brett A. Shumate of the Justice Department's Civil Division.

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Protect Your Communities

- Implement an effective and robust compliance and ethics program
- Ensure the company is in compliance with laws - conduct regular audits
- Encourage internal reporting system for employees and residents/families
- Fostering a culture of compliance
- Stay up to date on FCA regulations

Such steps will provide a defense for violations and mitigate the risks of serious fines and penalties*

Protect Your Communities

- We are all human and mistakes can occur
- Ensure employees feel comfortable reporting because it is important for the community to know of a potential issue as soon as possible
- Supervisors are in a good position to detect and report problems
- Have a non-retaliation policy
- Conduct yearly & as needed corporate compliance training

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Pennsylvania Updates

- Venue Rule change – 1/1/23
- PDPM Model – 11/1/25
- The Pennsylvania Health Care Association and SEIU Healthcare PA announced the collaboration to “solve the dire healthcare workforce challenges impacting residents across the state”
- Launching the PA CareKit – person-centered resource to support family caregivers by providing training, connection to respite services. With the intended goal of keeping elders in the homes and communities
- The Office of Long-Term Living announced an increase to the Personal Needs Allowance for individuals residing in long-term care facilities (Was $45 a month is now $60)

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New York Updates

- Introduced new bill S7954 - creates a new class of fiscal intermediaries with the same legal status as the statewide FI making it easier for individuals to choose their own home care
- June 2025, new committee has been appointed to review the state's current Certificate of Need (CON) process for nursing homes
  - Stated goals include expanding and clarifying ownership disclosures, strengthening the state's approach to character and competence reviews, and considering new review tracks for proposals that do not involve capital expenditures or changes in total capacity

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Maryland Updates

- HB 874 alters the requirements for assisted living managers, the training courses needed, the requirements for serving as interim manager, and reports needed to be submitted
- April 28, 2025 revised long-term care surveyor guide goes into effect
  - https://www.cms.gov/files/document/qso-25-14-nh.pdf

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Nuclear Verdicts

$30 MILLION DOLLAR CALIFORNIA VERDICT AGAINST SKILLED NURSING FACILITY FOR FAILURE TO PROVIDE PROPER CARE AND WRONGFUL DEATH CAUSED BY UNTREATED BEDSORES

Jury Returns $19M Verdict for Elderly Woman's Nursing Home Death

Philly jury hits home-care agency with $14 million verdict over death of Alzheimer's patient

24 Jul 2025

$5.5 MILLION VERDICT HIGHLIGHTS NURSING HOME NEGLECT IN COOK COUNTY

Florida assisted living home must pay $12.5M after woman's death

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Post Covid Trends

- Post-COVID, the admiration for our "healthcare heroes" has declined.
- Uptick nationally in large verdicts in nursing home negligence and medical malpractice cases.
- What are the trends that we are seeing?
  - Reptilian tactics;
  - Corporate negligence theories and narratives regarding staffing, profits, etc.;
  - Criticism regarding "stale" defenses; and
  - A need for flexibility and empathy.

Reptile Theory Explained

- Litigation strategy based on a behavioral theory that when people feel scared, they make decisions based on a primitive response to defend themselves from harm
- Used to persuade jurors to favor the plaintiff under the belief that punishing the defendants will protect the community
- **Safety rule + danger = reptile.** The brains of the jurors will "awaken" once they believe that a defendant has broken a safety rule.
- Once jurors see a broken rule, more likely to award damages to the plaintiff to protect themselves and society.

A New Playbook – Defense Strategies

- Innovation and fresh look at litigating cases differently than traditional approaches
- Tell the stories of the roles that providers play in the communities they serve – your employees are essential to tell this story
- Charity care and care to vulnerable communities
- Quality measures and outcomes
- Specialized care and treatments
- Highlight what this specific provider does to benefit the community at large.
- When appropriate, take responsibility and demonstrate empathy.

Diffusing the Reptile Theory

- Post-COVID, providers have unique stories to tell about the quality of healthcare provided in their communities
- Tell a broader story of the role of the healthcare provider in the community providing care to its neediest members
- An injured plaintiff pitted against a healthcare provider or healthcare system can be a powerful trial tool – the classic “David vs. Goliath” scenario
- Humanize the defense side through witnesses - healthcare is a person-centered industry

The Importance of Documentation

Chart

- Complete documentation of MARs and TARs
- Complete documentation of ADLs to show patient being cared for
- Timely and updated care plans
- Wound measurements documented
- Documentation of interactions with family

Incident Reporting

- Keep it factual
- If doing QA analysis, include in a separate section
- Gather witness statements
- Complete incident report
- Proper reporting to DOH or state agency

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Other Mitigation Strategies

- Admission documents
  - Forum selection
  - Arbitration agreements
- During litigation
  - Identify key witnesses for the defense
  - Deposition preparation and strategies
  - Highlight strong staffing levels, five star ratings, lack of deficiencies

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Thank you

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