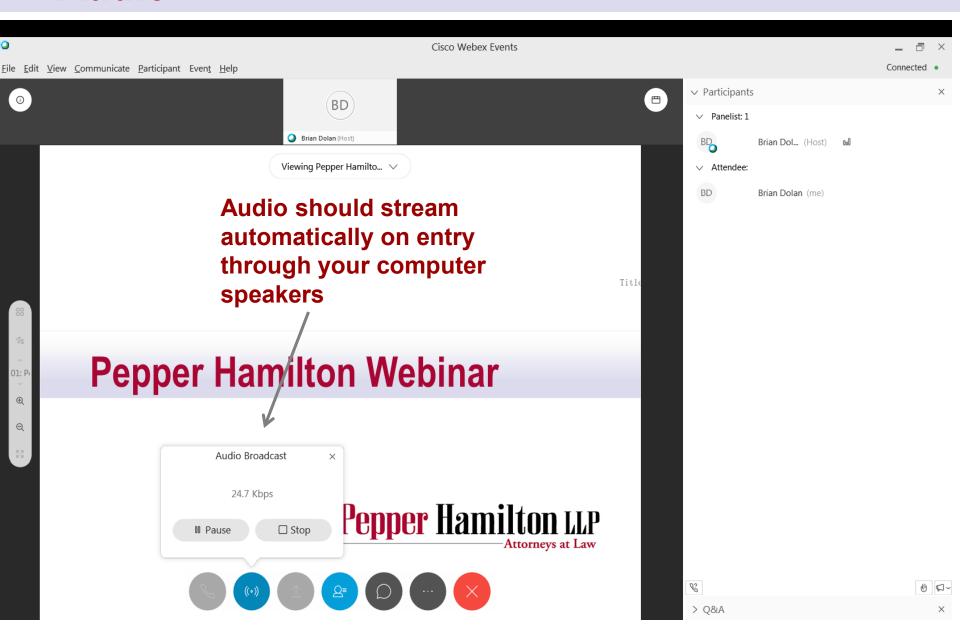
Skilled Nursing Facility and Nursing Home Staffing: Enforcement Risks & Compliance Considerations

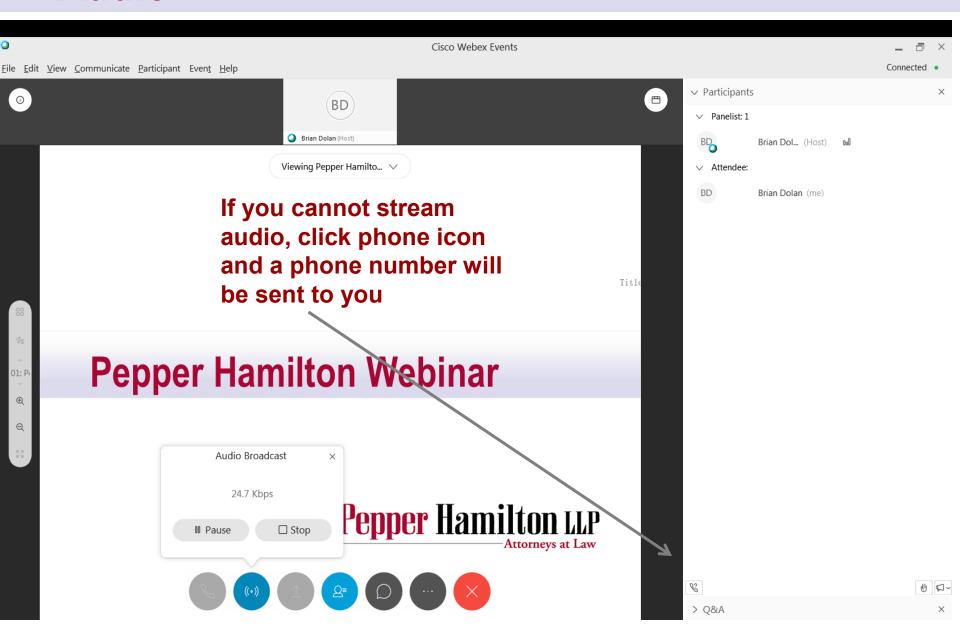
Thomas M. Gallagher Allison E. DeLaurentis



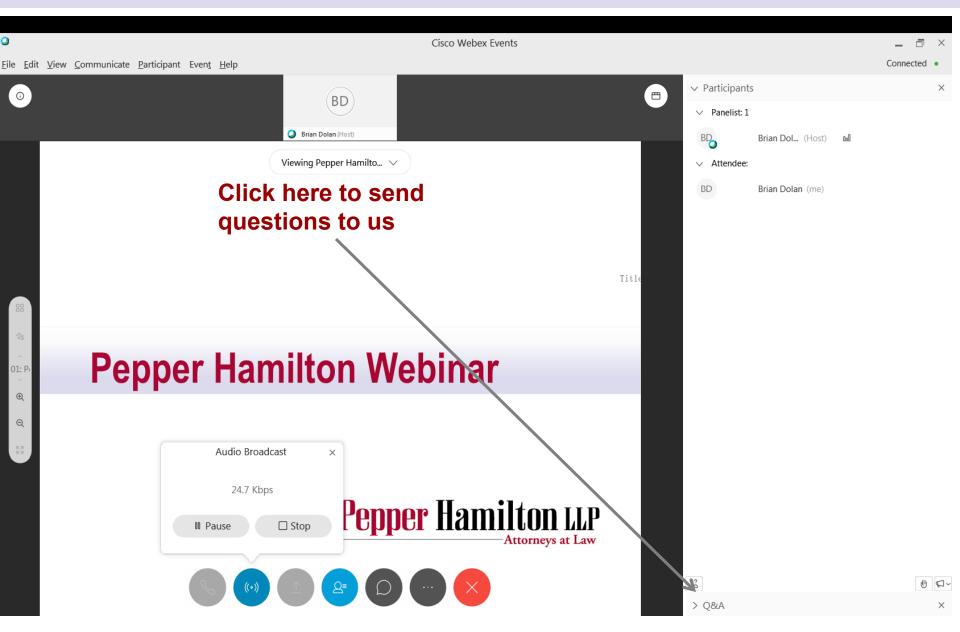
Audio



Audio



Q&A



Email dolanb@pepperlaw.com if interested in receiving a CLE form.



The webinar will be starting at approx. 12:00pm ET. There is currently no audio until we start.



We are on mute and will be starting in a few minutes.



Thomas M. Gallagher

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- Represents entities facing government investigations, particularly focused in the health care industry
- Also represents businesses and individuals facing investigation by federal and state law enforcement authorities, government regulatory agencies and congressional committees
- Has represented major pharmaceutical companies, medical device manufacturers, payors, providers, defense contractors and other entities and individuals





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- Focuses her practice in white collar defense and corporate investigations, particularly in the health care industry
- Advises health care industry clients on compliance with federal and state regulations
- Counsels clients on mitigating risks and implementing compliance programs





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ENTERTAINMENT

NONPROFIT ORGANIZATIONS AND

FOUNDATIONS

PHARMACEUTICAL AND MEDICAL DEVICE

RETAIL

TECHNOLOGY

TRANSPORTATION



Locations





Agenda

- Federal and State Staffing Requirements
- Litigation Related to Staffing and Substandard Care
- Recent Efforts to Enhance Nursing Home Staffing Oversight
- Enforcement Risks
- Compliance Considerations



Federal and State Staffing Requirements

Federal Requirements: 42 C.F.R. § 483.35

- ► "Facility must have sufficient nursing staff with the appropriate competencies and skill sets to provide nursing and related services to assure resident safety and attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident, as determined by resident assessments and individual plans of care and considering the number, acuity, and diagnoses of the facility's resident population"
- ► Facility must provide services by licensed nurses and other nursing personnel, including nurses aides, on a 24-hour basis
- Facility must use the services of a registered nurse for at least
 8 consecutive hours a day, 7 days a week



Federal and State Staffing Requirements

State Requirements

41 states have established higher, more specific staffing standards, including, for example:

Arkansas AR Code § 20-10-1403	•	At least 1 licensed nurse per every 40 residents during day and evening shifts; 1 licensed nurse per 80 residents during night shift At least 1 direct-care staff to every 6 residents during day shift; 1 direct care staff to every 14 residents during night shift
Florida Florida Statute 400.23(3)	•	Weekly average of 3.6 hours of certified nursing assistant or licensed nurse direct care per resident per day: minimum weekly average of certified nursing assistant and licensed nursing staffing
	•	Facility may not staff below one licensed nurse per 40 residents and one certified nursing assistant per 20 residents
Pennsylvania 28 Pa. Code § 211.12(i)	•	RN and LPN ratios depending on resident census
	•	At least 1 nursing staff employee per 20 residents
	•	Minimum of 2.7 hours of direct resident care provided by nurses in each 24 hour period
California Health and Safety Code §1276.65(B)	•	Minimum of 3.5 direct care service hours
	•	Of those, minimum of 2.4 hours provided by certified nurse assistants



Litigation Related to Staffing and Substandard Care

Recent Class Actions

Skilled Healthcare (2010)

Grace Healthcare (2017)

- 32,000 class member plaintiffs
- Alleged defendants failed to provide 3.2 nursing hours per patient per day and misrepresented the quality of care
- \$50 million settlement

3,400 class member plaintiffs

Golden Living (2017)

- Alleged defendants failed to properly staff facilities and did not meet minimum staffing requirements
- \$72 million settlement

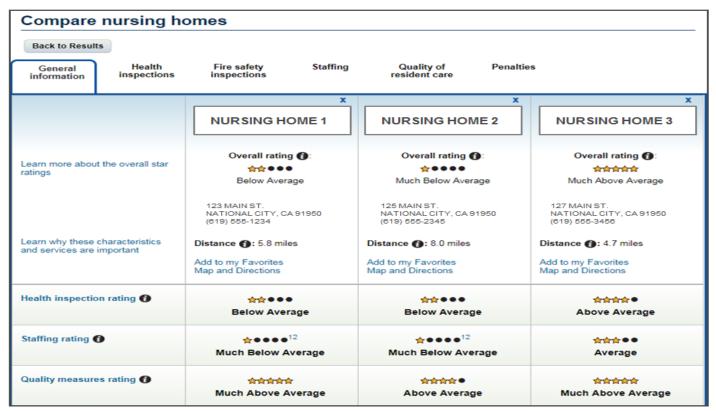
- 500+ class member plaintiffs
- Alleged defendants "chronically understaffed" their facilities
- \$8.4 million settlement



CMS Oversight

Nursing Home Compare

For the past ten years, CMS has posted information regarding facility staffing and other measures on *Nursing Home* Compare





CMS Oversight

Recent Enhancements

- ▶ In 2018, CMS enhanced efforts to report on, and enforce, staffing compliance
 - In April 2018, CMS started using daily payroll reports to calculate average staffing ratings
 - In November 2018, CMS announced it will use "payroll-based data to identify and provide state survey agencies with a list of nursing homes that have a significant drop in staffing levels on weekends, or that have several days in a quarter without a registered nurse onsite"
 - If surveyors identify insufficient staffing levels, the facility will be cited for noncompliance and required to implement a plan of correction



CMS Oversight

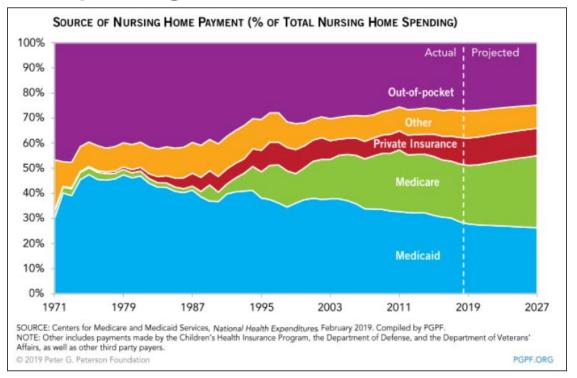
Special Focus Facility Initiative

- Initiated in 2007
- Federally mandated initiative to address persistent problems through enhanced oversight
- Once included in program, Special Focus Facilities have 18-24 months to improve quality and implement practices to ensure that poor performance does not reoccur
- Limited to 88 facilities nationwide, based on resources available for advanced oversight



Significant Medicare and Medicaid Expenditure

- Medicare and Medicaid finance about half of all nursing home and skilled nursing facility spending in the United States
- Total annual spending rose to more than \$160B in 2016





Federal False Claims Act

 We have already seen staffing allegations raised by Relators in FCA cases involving upcoding, fraudulent billing, and substandard care

Cathedral Rock (E.D.Mo. 2010)

- "Between 2001 and 2005, the Nursing Facilities failed . . . to provide adequate care to residents."
- Staffing levels "were not adequate to provide nursing care to some residents in accordance with the residents' care plans"
- Qui tam complaint resulted in \$628,000 civil settlement, \$1 million criminal fine, and guilty plea

Kindred Healthcare (E.D.Pa. 2016)

- "Kindred's policies of admitting as many residents as possible and recruiting high acuity residents while understaffing its nursing homes resulted in residents not receiving necessary care"
- Defendant billed for therapies that were either not performed, or were unnecessary.
- Qui tam complaint resulted in \$125 million settlement

Genesis Healthcare (N.D.Ga. 2017)

- "Defendants systematically bill Medicare for services they do not perform"
- Defendants failed to provide beneficiaries with "adequate medical equipment, appropriate medication, adequate protective oversight"
- Defendants "failed to provide adequate nursing staff in all of the required areas...to adequately care for beneficiaries"
- Qui tam complaints resulted in \$53.6 million civil settlement



Federal False Claims Act

- Recent CMS, legislative, and patient focus on staffing suggests a potential uptick in DOJ enforcement actions and qui tam litigation
- Evidentiary Issues:
 - Nursing Home Compare data identifies facilities with low staffing scores and publishes average staffing levels based on payroll data
 - Additional discovery needed to prove fraud
- Defense Considerations:
 - Qui tam claims based on publicly available staffing data will be subject to public disclosure bar
 - But, where a whistleblower has independent knowledge that materially adds to that publicly available information, they may qualify as an original source



State Attorney General Actions

As state staffing requirements are often more demanding than the federal requirement, and Medicaid covers a significant proportion of nursing home expenditures, state AG suits also may increase

Golden Living (PA)

Allegations that 25 Golden living Nursing Homes violated Unfair Trade Practices and Consumer Protection Law by exaggerating the level of care provided to its customers and understaffing its facilities

Reliant Senior Care Holdings (PA)

Pennsylvania AG announced \$2 million settlement against nursing home operator that allegedly "promised...to provide basic care to residents in its facilities, but failed to do so by leaving its facilities understaffed"

Preferred Care Partners Management Group & Cathedral Rock (NM)

New Mexico sued one of the largest nursing home chains in the nation "over inadequate resident care, alleging that thin staffing made it numerically impossible to provide good care"

Chandler Care Center (NY)

 Facilities pleaded guilty to seconddegree larceny charges resulting from failure to provide an adequate level of skilled nursing care to patients



What's at stake?

- Treble damages and civil penalties per claim
- Corporate integrity obligations, including potential quality of care CIA
- Potential exclusion
- Criminal penalties and fines
- Individual liability



2000 OIG Compliance Program Guidance for Nursing Facilities

- At a minimum, a comprehensive compliance program should include:
 - Implementing written policies, procedures, and standards of conduct
 - Designation of a compliance officer and compliance committee
 - Conducting effective training and education
 - Creating and maintaining effective lines of communication
 - Conducting internal monitoring and auditing
 - Enforcing standards through well-publicized disciplinary guidelines
 - Responding to detected offenses and developing corrective action initiatives



2008 Supplemental Guidance

- ▶ Discusses fraud and abuse risk areas to assist nursing facilities in efforts to identify operational areas that present risks, including quality of care, submission of accurate claims, the Federal Anti-Kickback Statute, and other risk areas.
- Emphasis on, among other things, sufficient staffing.
 - "OIG is aware of facilities that have systematically failed to provide staff in sufficient numbers and with appropriate clinical expertise to serve their residents. . . . nursing facilities must be mindful that Federal law requires sufficient staffing necessary to attain or maintain the highest practicable physical, mental, and psychosocial well-being of residents."
 - "Nursing facilities, therefore, are strongly encouraged to assess their staffing patterns regularly to evaluate whether they have sufficient staff members who are competent to care for the unique acuity levels of their residents."



2019 Nursing Home Compliance Program Mandate & Proposed Rule CMS-3347-P

- ▶ Beginning November 28, 2019, "the operating organization for each facility must have [a] compliance and ethics program . . . that meets the requirements of this section"
- ▶ 42 C.F.R. Section 483.85 provides for eight compliance program elements required for all facilities, as well as additional requirements for operating organizations with 5 or more facilities
- But, on July 16, 2019, CMS announced a proposed rule, Medicare & Medicaid Programs; Requirements for Long-Term Care Facilities: Regulatory Provisions to Promote Efficiency an Transparency (CMS-337-P), which if finalized, would remove requirements for participation identified as unnecessary, obsolete, or excessively burdensome
- If finalized, would remove requirements for a compliance officer and compliance liaisons and reduce program reviews from annual to biennial



Recommendations

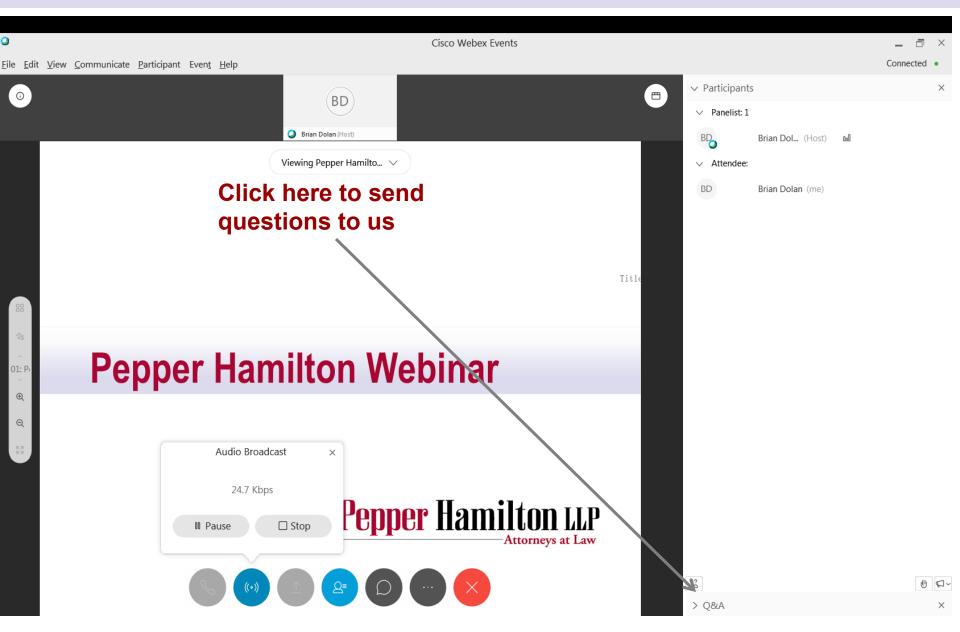
- Assess regularly and maintain comprehensive documentation regarding staffing patterns, staffing schedules, patient acuity, patient census, and employee job descriptions
- Cross-functional involvement in assessing staffing patterns and scheduling
- Train all employees on staffing requirements
- Communicate that instances of insufficient staffing can be reported through the facilities' anonymous reporting procedures
- Routinely monitor and audit payroll records and time sheets (not schedules) to ensure sufficient staffing
- Include compliance in management performance evaluations



Questions & Answers



Q&A



Email dolanb@pepperlaw.com if interested in receiving a CLE form.



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