

MOMENTUM 2022 Annual Conference and Trade Show - August 30 - September 1, 2022 *LeadingAge Ohio*

Changing Focus: Legal & Regulatory Update

August 31, 2022

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Janet K. Feldkamp



Janet focuses her practice in the area of health care law, including long-term care survey and certification, state and federal regulation, physician and nurse practice, and fraud and abuse involving hospitals, suppliers, insurers and physicians. She retains active licenses as a registered nurse and a nursing home administrator and has extensive health care experience.

Janet is a member of the editorial advisory board of *Caring for the Ages*, a monthly newspaper for long term care practitioners. She has been a frequent speaker, particularly in the area of long term care. She is also co-author of *The Long Term Care Handbook: Regulatory, Operational and Financial Guideposts* published by the American Health Lawyers Association.

Janet is also a board member of the American Association of Post Acute Care Network (AAPACN). AAPACN represents more than 15,000 post-acute care nurses and professionals.

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Objectives

- Gain knowledge regarding current regulatory requirements and challenges for post-acute care facilities including new transmittals, guidance and other issuances from the Centers for Medicare and Medicaid Services
- Comprehend the need for proactively addressing facility challenges facing the post-acute care industry and analyze the impact of the Office of Inspector General's work plan on post-acute care providers and multiple agencies focus on fraud enforcement and prevention

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2022 & Changing Focus

- CMS Issuances June 2022
- Survey Updates
- Financial Updates
- Recent Reports & Potential Impact
- Governmental Enforcement
- Miscellaneous



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CMS 2022 Strategic Plan


- Six potential trends to watch:
 - Medicare and Medicaid beneficiaries will be moved ACOs by 2030
 - Providers will have more pre-authorization processes
 - Continued scrutiny for nursing home staffing
 - Expects MANY new and revised regulations
 - Ensuring prescription drug accessibility by increasing use of generics, biosimilars and interchangeable biologics
 - CMS to improve access to behavioral health services
- CMS Strategic Plan: <https://www.cms.gov/cms-strategic-plan>

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Telemedicine: Positive Outcome from Pandemic

- Telehealth services were limited in reimbursement prior to the pandemic
- Previously, most encounters took place in rural health as a way for specialty physicians to treat rural patients
- Benefits are numerous for telehealth particularly during the pandemic
- Being used for acute care as well as for chronic health condition monitoring and treatment
- Limitations:
 - Some patient concerns about privacy
 - Regulatory issues can vary state by state
 - Need cultural acceptance by some for telehealth
- **Everyone expects telehealth to be here to stay!**
- Selected fraud and abuse investigations related to telehealth



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Nursing Home Compare & Others

Doctors & clinicians Hospitals Nursing homes including rehab services Home health services

Hospice care Inpatient rehabilitation facilities Long-term care hospitals Dialysis facilities

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Nursing Home Compare Update

- PBJ staffing domain with changes July 2022
- 1/3 of nursing homes with decline in staffing star rating
- Staffing star rating also impacts overall star rating
 - RN hours per resident per day
 - LPN hours per resident per day
 - Nurse aide hours per resident per day
 - Total nurse staffing per resident per day (RN, LPN and nurse aide)
- Per resident per day represents the average over the last reported 3 month quarter
- Staff turnover: Understand the details regarding turnover rates and how individuals have the potential to be counted more than once in turnover rates!

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Survey Updates

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CMS QSO-22-19-NH


- Importance of keeping up with the QSO (Quality/Survey)
 - Used to be issued as S & Cs
 - <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Policy-and-Memos-to-States-and-Regions>
 - Filter to find the most recent

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Surveyor Vaccinations

- QSO-22-10-All: January 25, 2022
 - Rescinded June 16, 2022
- Surveyors do not have to be vaccinated
- Facilities cannot require testing at entrance
- Surveyors must use appropriate PPE




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Survey Updates

- Annual Surveys slowly catching up. Ohio is still behind.
- LONG survey cycles
 - Multiple complaint surveys in a row
 - Many long cycles with Denial of Payment for New Admissions (DPNA)
 - Fines resulting in loss of NATCEP (nurse aide training) program for 2 years
- Cycles with no revisits for months



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OEI-06-19-00460 OIG Report

- Office of Inspector General report: **CMS Should Take Further Action to Address States with Poor Performance in Conducting Nursing Home Surveys**, January 2022
- Over ½ of the states (28 of 50) failed to meet performance measure in 3 or 4 consecutive years from FY 2015-2018.
 - Failure with survey timeliness & other issues


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OIG Report on State Survey Agencies

- **OIG recommended:**
 - Actively monitor SA's corrective action plans,
 - Establish progressive enforcement,
 - Engage with senior State officials earlier and more frequently, and
 - Revised State Operations Manual (SOM) to reflect current CMS oversight practices.
- In June 2022, changes were made to complaint triage requirements in Chapter 5 of the SOM for the nursing home complaints



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CMS Response to OIG Report

- While CMS has taken a number of actions, as OIG noted, CMS has few practical options to address intractable problems, such as chronic staffing shortages.
- Multiple factors that can affect survey performance, such as training, staffing vacancies, the volume of complaint surveys, staff tenure, and others.
- Foundational issues, such as staffing, can frequently be tied to inadequate budgets. Many SAs are unable to offer salaries that are competitive.
 - Survey workloads, especially complaint surveys, have increased rapidly since 2015 (complaint investigations grew by over 5,500 cases between FY 2015 and FY 2018), while the level of funding has remained flat at \$387 million since FY 2015.
- Growing numbers of complaints inhibit the SAs' ability to address issues proactively through standard surveys.
- Without adequate funding, state issues will persist. CMS can impose sanctions against SAs for inadequate survey performance (42 CFR 488.320). Further restricting funds would be counterproductive towards ensuring the health and safety among nursing home residents.
- CMS continues to work with SAs individually to address their unique issues.
- (Page 33 of 42) OEI-06-19-00460

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CMS Report on Penalties

- Total amount of per-incident penalties have dramatically increased in the last 5 years
- Total amount of fines CMS has collected through per-incident penalties has increased more than **eight fold** from 2016 to 2020
- CMS collected less than \$5 million in 2016
- CMS collected about \$27 million in 2020

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Recent Changes

- **Past Non-Compliance:**
 - Removed 2017 policy of only "Per Instance" civil money penalties for past non-compliance
 - Reinstated the ability of CMS/State Agencies to implement per day CMPs for past non-compliance
 - Rationale: Should be able to utilize the regulatory discretion
 - Have not yet seen on implemented against a facility: Only occurred in late July 2021

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Drowning in Red Tape!!!

- ▶ CDC & CMS Changes
- ▶ OSHA
- ▶ State Agency changes
- ▶ A fast paced ever changing environment
 - ▶ Exhausted staff
 - ▶ Stressed families and residents---more complaints

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APPENDIX PP: NEW CHANGES FOR OCTOBER 2022



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Appendix PP Changes

- QSO-22-19-NH Issued June 29, 2022: Advanced Copy Appendix PP
- Will be implemented October 24, 2022
- 65 tags modified by changes
 - Some dramatically changed
 - Some with minor and/or technical changes
- Total 847 pages
- Many, many changes
 - *Changes in italics and red font*
 - Many significant changes
 - Some not so significant

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Handout: Client Advisory

MY BENESCH MY TEAM

Benesch
Healthcare+
CLIENT BULLETIN

July 2022

CMS Issues Updated Guidance for Nursing Homes
By Janet K. Feldkamp and Alan E. Schabas



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F699: Trauma Informed Care

- A Phase 3 requirement: Assess and implement interventions based upon culturally – competent and trauma – informed services
- Added 9 pages of definitions, discussion and references such as Substance Abuse and Mental Health Services Administration (SAMHSA)
- Discusses use of General Critical Element Pathway for interpretive guidance for compliance
- Care plans to address past trauma, triggers and interventions; individualized
- Critical element pathways: CMS-20067

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F600 – F610 Freedom from Abuse, Neglect & Exploitation

- 42 CFR 483.12: 10 tags for this condition of participation
- Pages 68-167
 - Many changes and addition with these tags and interpretations
- Psychosocial outcome severity guide utilized for determining severity of the psychosocial harm
 - Use of “reasonable person” concept to be used by the surveyor if resident is unable to express self
- Many changes and interpretations related to these 10 tags.
- A frequent set of tags for immediate jeopardies

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F880 and F882: Infection Control and Infection Preventionist

- Numerous changes including addition of new definitions
- Review the changes and update policies and procedures
- 5 detailed pages regarding requirements and activities
- Potential tags for additional investigation: 6 tags
 - Allows for multiple cross references
 - F838 Facility assessment
 - F867 QAA Committee
 - F868 QAA Committee
 - F880 Infection prevention
 - F881 Antibiotic stewardship
 - F945 Staff training

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F895 Compliance and Ethics

- Expect this to be a significant focus at selected times as it relates to preventing and detecting criminal, civil and administrative violations and in promoting quality of care.
- Many facilities have not effectively implemented the Compliance & Ethics program
- Dust off the binder, review and put it into place
- **REQUIREMENTS FOR ALL FACILITIES Compliance and Ethics Program** *The operating organization of each facility must have a compliance and ethics program that has been reasonably designed, implemented, maintained and enforced, so that it is likely to be effective in preventing and detecting criminal, civil, and administrative violations under the Act and in promoting quality of care.*


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SOM Chapter 5

- CMS revised the guidance in Chapter 5 of Operations Manual (SOM) to strengthen complaints and reportable incidents. CM Medicare-certified provider/supplier type State agencies in their communication to
- Revised Exhibit 23 provides a grid to com
- Complaint timing discussion



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F741: Mental Health and Substance Abuse Disorder (SUD)

- Sufficient, competent staff to meet behavioral health needs
- The facility must consider the acuity of the population and its assessment in accordance with §483.70(e). This includes residents with mental disorders, psychosocial disorders, or substance use disorders (SUDs), and those with a history of trauma and/or post-traumatic stress disorder (PTSD), as reflected in the facility assessment. Facility staff members must implement person-centered care approaches designed to meet the individual goals and needs of each resident. Additionally, for residents with behavioral health needs, non-pharmacological interventions must be developed and implemented.
- Discussed trauma, PTSD, SUD and other types of needs for residents
- Training is important as well as the staffing

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F725: Staffing: Payroll Based Journal (PBJ)

- Added guidance that uses PBJ staffing to trigger deeper investigations related to "sufficient staffing"
- Examples of noncompliance with adequate staffing
- Multiple surveyor probes

• Compliance with State staffing standards is not necessarily determinative of compliance with Federal staffing standards that require a sufficient number of staff to meet all of the residents' basic and individualized care needs. A facility may meet a state's minimum staffing ratio requirement, and still need more staff to meet the needs of its residents. Additionally, the facility is required to provide licensed nursing staff 24 hours a day, 7 days a week.

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Staff Questioning Probes for F725

- If the surveyor is made aware of the absences of licensed nursing staff in a 24 hour period :
 - Interview direct care staff;
 - Are you ever made aware of the absence of licensed nursing staff during your shift?
 - When was the last time that licensed staff was not available during your shift?
 - How often does this occur?
 - How does this impact residents in the facility?
- Are you aware of any residents that missed medications or treatments due to no available licensed nurse?
- Who do you notify in the event of an emergency and there is no licensed nurses available?
- Interview the Director of Nursing or Administrator;

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Staff Questioning Probes for F725


- When was the last time that licensed nursing staff were not available on a shift?
 - How often does the facility not have licensed nursing staff at all times?
- What is the facility's policy when there is not a licensed nurse available in a 24 hour period?
- How does the facility provide care to residents that require a licensed nurse if one is not available to work?
 - How does this impact residents in the facility?

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Immediate Jeopardy



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IJ Template

Date/Time IJ Template provided to entity: _____

IJ Component	Yes/No	Preliminary fact analysis which demonstrates why key component exists.
<p>Noncompliance: Has the entity failed to meet one or more federal health, safety, and/or quality regulations?</p> <p>If yes, in the blank space, identify the tag and briefly summarize the issues that lead to the determination that the entity is in noncompliance with the identified requirement. This includes the actions, errors, or lack of actions, and the extent of the noncompliance (for example, number of units). Use one IJ template for each tag being considered at IJ level.</p>	<p>Yes/No</p>	

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Ohio 1st Quarter 2022 Immediate Jeopardies:

- 1st Quarter Calendar Year 2022:
- Deaths reported 6
- Us: January- 14; February - 7; March - 14
- F689: Elopement; choking, water line burst, fall
- F679: CPR 3
- F600: Abuse & Neglect: 4
- F880: Infection Control: 12 **many Ks and Ls**
- F725 Sufficient Staffing: 1
- F695: RT, Trach & Vent: 2
- Others: 4 total IJ citations

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Weathering the Financial Crisis



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Costs have skyrocketed

- ▶ Employee turnover
 - ▶ Increased costs to obtain and retain employees
 - ▶ Agency costs
 - ▶ Overtime
 - ▶ Nurses leaving to work at vaccination clinics
 - ▶ Employees "retiring"
- ▶ PPE
- ▶ Fines, Penalties and Outcomes from Survey
- ▶ The list is endless



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Other Regulatory Issues



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Office of Inspector General & Other Governmental Oversight Bodies



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OIG Semiannual Report to Congress

- Period October 1, 2021 through March 31, 2022
 - Expected audit recoveries \$1.14 billion
 - New audit and evaluation recommendations 130
 - Expected investigative recoveries \$1.44 billion
 - Criminal actions 320
 - Civil actions 320
 - Exclusions 1043
- Very busy and active

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OIG & State MFCUs

- OIG very busy. Visit website: <https://oig.hhs.gov/fraud/enforcement/>
 - Georgia Nurse Practitioner sentenced to prison, ordered to pay more than \$1.6 million for complex telemedicine fraud scheme (8/9/22)
 - 5 individuals and 2 nursing facilities indicted on charges of conspiracy to defraud (8/9/22)
 - Durable Medical Equipment provider pleads guilty to health care fraud (8/4/22)

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OIG Report: Facility Discharges

- **Facility Initiated Discharges in Nursing Home Require Further Attention**
- (OEI-01-18-00250) Issued November 2021
- Report raises concerns in "weaknesses in the safeguards to protect nursing home residents from harm that may result from inappropriate facility-initiated discharges"
- Beware of citations related to facility-initiated discharges
 - ODH is required to refer those to CMS
 - Can impose a direct plan of correction and/or other sanctions for this type of citation

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OIG Report July 2022

- Nursing Homes may not have complied with federal requirements for infection prevention and control and emergency preparedness;
- A-01-20-00005
- Used survey citations as their data
- 25 of 48 cites regarding infection prevention and control
- 18 instances at 18 nursing home were noncompliance with emergency preparedness




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FBI Investigations


- More multi-agency investigations
 - FBI investigating staffing related issues that may result in sub-optimal/problematic care
 - May involve Medicaid Fraud Control Unit
 - May involve Attorney General's Office
 - May involve many other agencies
- Requesting multiple records from facilities
 - Civil investigative demand
 - Subpoena
 - Other ways of obtaining records



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Staffing: Short staffing v. Critical staffing




- Employees always state that the facility is "short staffed"
- Where is the line between short and critical/crisis staffing
 - Not a PPD or pure numbers
 - Depends upon staff type and skill sets and conditions of residents
- What is your facility's plan for crisis staffing?
- If you don't have a plan and are able to swiftly put in action, your facility can be at risk of dramatic negative outcomes

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USEFUL TOOLS



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Nursing Facility Scope & Severity Grid



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Critical Element Pathways

All are available in the CMS survey materials
<https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/GuidanceforLawsAndRegulations/Nursing-Homes>
 Sufficient and Competent Nursing Staff Review
 CMS-20062
 8 pages
 Use the questions for QAPI purposes

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Ripped from the Headlines



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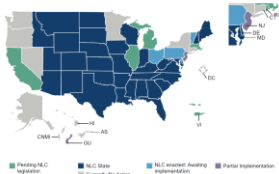
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Nursing Licensure

- Compact state licensure
- Important to have clear knowledge of requirements

Movement around the country
 Compact process only for nursing

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Know Licensure Requirements

- Who tracks all licensure
 - RNs, LPNs
 - PT, OT, ST, COTA
 - Physicians and APRNs
 - Dietary Manager
 - Others
- Why is it so important?
 - Lapsed licenses
 - Creates liability
 - State and federal regulation violations



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Miscellaneous Tidbits

- Drug Diversion
- Recommendations for Compliance and HIPAA review and updates
- Admission agreement reviews

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Caring for Our Seniors



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Questions



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