

# **Preparing For New Enforcement Issues**

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# New DOJ Enforcement Developments

- Department of Justice (“DOJ”) Elder Justice Initiative looking at “nonexistent or grossly substandard care”
- Revisions to the US Sentencing Guidelines (9/2022): Compliance program effectiveness
  - Increased focus on individual accountability and cooperation
  - History of misconduct
    - ▶ 10 years for criminal conduct
    - ▶ 5 years for regulatory problems
  - Incentives for voluntary self-disclosure
  - Increased transparency for appointment of compliance monitors
  - Resourcing and integrated compliance into corporate culture

# Two-Step Preparation for Investigations

- Develop effective policies and procedures
  - ▶ Establish company policy
  - ▶ Train your employees

# Policy For Responding To Investigations

- Principles to include:
  - ▶ We will cooperate fully with any appropriately authorized investigation or audit
  - ▶ We will assert all protections afforded it by law

# Policy Regarding Investigations

- We will instruct all employees to tell the truth in all circumstances
- We will never tell employees not to cooperate or not to speak to investigators
- We will not retaliate against anyone who cooperates with the investigation or who reports possible wrongdoing, improper or illegal activity

# Policy For Responding To Investigations

- Establish a procedure for the orderly response to government investigation
  - ▶ Protect the organization's and its employees' rights and interests
  - ▶ Ensure appropriate cooperation

# Policy For Responding To Investigations

- Proper procedures protect both the organization as well as its employees
- Implement policy directing all employees to report any and all illegal activity or contacts about possible illegal or improper activities to their supervisor or the Compliance Officer

# Proactive Protections

- Examine existing reporting and record systems to identify potential operational challenges
- Identify potential internal risk factors
- Involve counsel
- Enhance compliance initiatives

# Regulatory Risks



# Regulatory Enforcement Initiatives

- New guidance from Centers for Medicare and Medicaid Services (“CMS”) for Phase 3 of the Requirements of Participation (“ROPs”) effective October 24, 2022
- Increased use of per day penalties
- Increased cross-linkage of potential Ftag violations
- Federal and state civil money penalties (“CMPs”) and sanctions
- Directed plans of correction (“DPOC”) and discretionary denial of payment for new admissions (“DDPNA”) for F880 infection control deficiencies

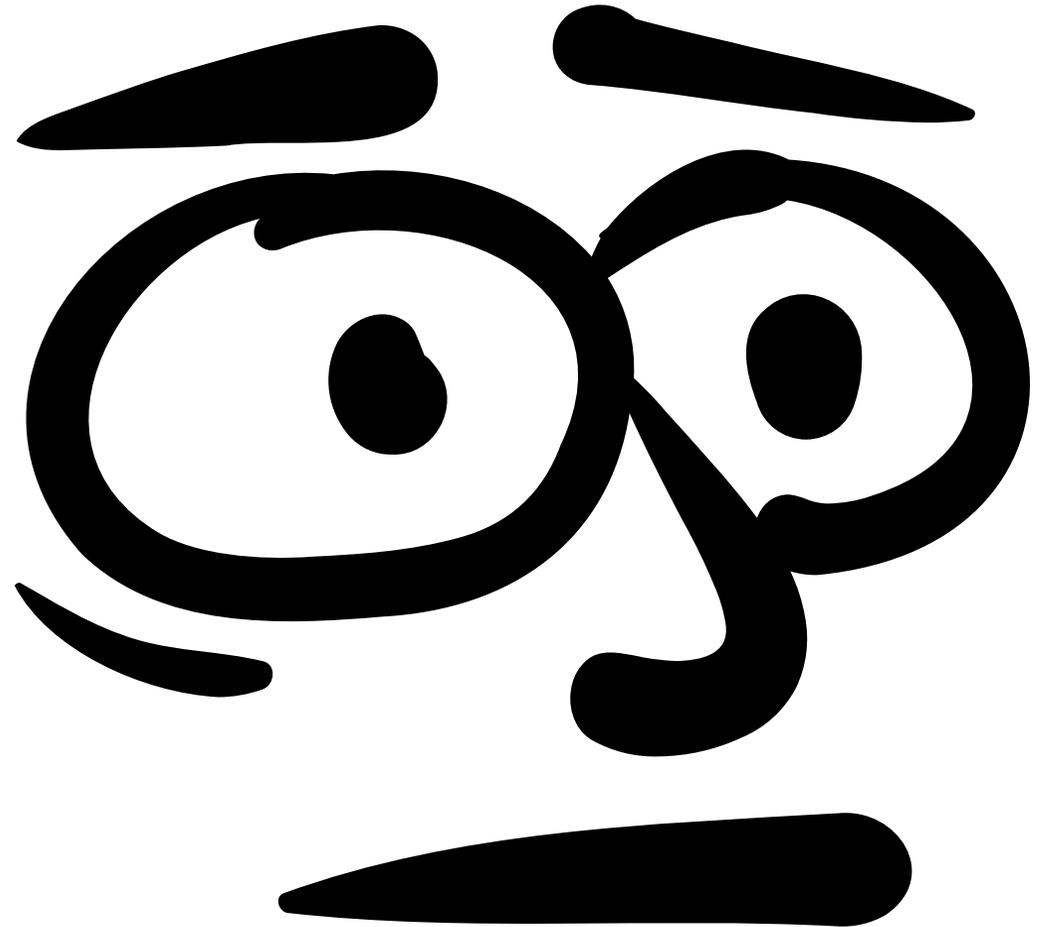
# Potential New Risk Areas

- Staff competencies
- Sufficient and competent staff
- Culturally informed care and care plans
- Trauma informed care
  - Post-traumatic stress disorder (“PTSD”)

# Potential New Risk Areas

- Admitting residents with behavioral conditions
- Admitting residents with substance use disorder (“SUD”) and/or opioid use disorder (“OUD”)
  - US Attorney sends letter 9/26/2022 to all Massachusetts SNFs warning that failing to admit person with OUD may violate the Americans with Disabilities Act (“ADA”)
  - 10 settlements, CMPs can start at \$92,383 for first violation
  - “evaluate each applicant individually to determine suitability for admission, rather than enacting a blanket policy denying admissions to all persons treated with MOUD” [<https://www.justice.gov/usao-ma/pr/us-attorneys-office-warns-skilled-nursing-facilities-not-refuse-treatment-people-opioid>]

- “Reasonable person” concept
  - What degree of actual or potential harm would one expect a reasonable person in the resident’s similar situation to suffer as a result of the noncompliance?
- Considerations
  - Resident may consider facility to be their “home,” where there is an expectation that he/she is safe, has privacy, and will be treated with respect and dignity
  - Resident trusts and relies on facility staff to meet his/her needs
  - Resident may be frail and vulnerable



# Psychosocial Harm May Not Be Readily Apparent

- Resident unable to express self due to medical condition and/or cognitive impairment
- Not able to recall what has occurred
- May not express outward signs of physical harm, pain, or mental anguish
- *"However, when a nursing home resident is treated in any manner that does not uphold a resident's sense of self-worth and individuality, it dehumanizes the resident and creates an environment that perpetuates a disrespectful and/or potentially abusive situation for the resident(s)"*

- Facility deprived residents of care related to failure of staff to respond timely to residents' requests and treat residents with dignity and respect which resulted in ongoing embarrassment, humiliation, and the failure to provide incontinence care as needed to meet the needs of several residents
- Family and resident group interviewed and complained that residents often waited a long time (up to an hour) before staff took them to the bathroom, resulting in residents urinating in their beds and lying in urine for long periods of time
- Residents indicated that this is a problem, especially on the night shift and said they were told by nurse aides to just urinate on their beds and staff would change the sheets in the morning
- Two night-shift staff members confirmed that they had seen other staff disconnect call lights in residents' rooms so that they were not functioning
- *"After investigation, it was determined that the nursing home failed to provide the necessary care. [NOTE: In this example, the surveyor had already identified noncompliance at dignity (F550) and urinary incontinence (F690)] It can be determined that the reasonable person in the residents' position would have experienced severe psychosocial harm (e.g., embarrassment, humiliation) as a result of the abuse."*

# IJ for Psychosocial Harm/Moving Call Bell

- Facility deprived R1 of care by failing to provide access for communication and response to R1's requests for necessary care resulting in R1's ongoing fear and anxiety
- During survey, surveyor observed that R1's call light was pinned to a privacy curtain that was out of reach of R1
- R1 said that staff removes the call light at night because nursing staff said he used it too much and they did not have time to answer the light all the time
- R1 began crying and expressed fear that something would happen and he would have no way of getting assistance as staff would not come if he called out for help
- *"Based on the resident's behavior, it can be determined that the resident experienced severe psychosocial harm as a result of the deprivation of care."*

# F609 Reporting Timetable

|   | 42 CFR 483.12(b)(5) and Section 1150B of the Act ("EJA")   | 42 CFR 483.12(c)  |
|---|--|---|
| <b>WHAT IS TO BE REPORTED?</b>  | Any reasonable suspicion of a crime against a resident or an individual receiving care from the facility   | <ol style="list-style-type: none"> <li>1. All alleged violations of abuse, neglect, exploitation or mistreatment, including injuries of unknown source and misappropriation of resident property</li> <li>2. The results of all investigations of alleged violations</li> </ol>   |
| <b>WHO IS REQUIRED TO REPORT?</b>   | Any covered individual, which means the owner, operator, employee, manager, agent or contractor of the facility  | The facility  |
| <b>TO WHOM?</b>   | State Survey Agency (SA) and one or more law enforcement entities for the political subdivision in which the facility is located (i.e., the full range of potential responders to elder abuse, neglect, and exploitation including police, sheriffs, detectives, public safety officers; corrections personnel; prosecutors; medical examiners; investigators; and coroner | The facility administrator and to other officials in accordance with State law, including to the SA and the adult protective services where state law provides for jurisdiction in long-term care facilities  |
| <b>WHEN?</b><br><br>* - Reporting requirements under this regulation are based on real (clock) time, not business hours | Serious bodily injury Immediately but not later than 2 hours* after forming the suspicion<br><br>No serious bodily injury- not later than 24 hours*  | <b><i>All alleged violations:</i></b> <ol style="list-style-type: none"> <li>1. Immediately but not later than 2 hours*- if the alleged violation involves abuse or results in serious bodily injury</li> <li>2. Not later than 24 hours* - if the alleged violation involves neglect, exploitation, mistreatment, or misappropriation of resident property; and does not result in serious bodily injury</li> </ol> Results of all investigations of alleged violations- within 5 working days of the incident |

# Strategies For Success



# Prepare Now For Increased Survey Scrutiny

- Review the new guidance and identify gaps
- Effective compliance programs will help identify and reduce risks
- Use the Critical Element Pathways for trainings and mock surveys
- Consider new onboarding procedures to capture education, training, background checks and competencies
  - “Staff” includes employees, medical director, consultants, contractors, volunteers, caregivers who provide care and services to residents on behalf of the facility, students in nurse aide training program, and students from affiliated academic institutions, including therapy, social, and activity programs

# Criteria of Past Non-Compliance

1. The facility was not in compliance with the specific regulatory requirement(s) at the time the situation occurred



2. The noncompliance occurred after the exit date of the last standard (recertification) survey and before the survey (standard, complaint, or revisit) currently being conducted



3. There is *sufficient evidence* that the facility corrected the noncompliance and is in substantial compliance at the time of the current survey for the specific regulatory requirements

# Knowing Your Residents



- SUD
- OUD
- PTSD
- Behavioral Issues
- Wandering

# The Facility Assessment

- Mentioned 100 times in SOM
- Capacity and capability to care for residents, including mental disorders, psychosocial disorders, trauma informed care/PTSD, SUD, respiratory, cultural characteristics, diet
  - Facility assessment must address the behavioral health needs that can be met and the numbers and types of staff needed to meet these needs
- Sufficient and competent staff based on number, acuity and diagnoses of resident population
- Integral to QAPI, ICPC, emergency preparedness; compliance & ethics program, training

# The Facility Assessment: Probes

- Does the facility assessment describe the type and level of staff required to meet each resident's needs?
- Does the type and level of the staff onsite reflect the expectations described in the facility assessment?
- Does the facility assessment describe the type of competencies required to meet each resident's needs?
- Do the competencies of the staff reflect the expectations described in the facility assessment?
- How are the administrator and the governing body involved with facility assessment?
- Interview medical director about his/her participation or involvement in conducting the Facility Assessment and the Quality Assessment and Assurance (QAA) Committee



At last he had found the Regulatory Guidelines.

# New CMS Guidance For Phase 3 Of The Requirements Of Participation

- §483.10 Resident Rights
  - F557: Respect, Dignity/Right to Have Personal Property
  - F561: Self-Determination
  - F563: Right to Receive/Deny Visitors
  - F582: Medicaid/Medicare Coverage/Liability Notice
- §483.12 Freedom From Abuse, Neglect, Exploitation
  - F600: Free From Abuse & Neglect
    - ▶ Resident-to-resident abuse
    - ▶ Sexual abuse
    - ▶ Past abuse noncompliance
    - ▶ Neglect
    - ▶ Abuse or neglect citation templates
  - Psychosocial Outcome Severity Guide
  - F604: Right to Be Free From Physical Restraints
  - F607: Develop/Implement Policies
    - ▶ QAPI coordination
  - F608: Deleted
  - F609: Reporting of Alleged Violations
    - ▶ Reporting of suspected crimes
    - ▶ Reporting of alleged violations
    - ▶ Contents of facility reports of alleged violations

# New CMS Guidance

- §483.15 Admission, Transfer, and Discharge Rights
  - F622: Transfer and Discharge Requirements
  - F623: Notice Requirements Before Transfer/Discharge
  - F626: Permitting Residents to Return to the Facility
  - F622, F623, and F626: Against medical advice (“AMA”) discharges
- §483.24: Quality of Life
  - F675 not automatically an immediate jeopardy (“IJ”) citation

# **New CMS Guidance – §483.25: Quality of Care**

- F686: Treatment/Services to Prevent/Heal Pressure Ulcers
- F687: Foot Care
- F689: Free of Accident Hazards/Supervision/Devices
- F690: Bladder/Bowel Incontinence, Catheter, Urinary Tract Infection (“UTI”)
- F694: Parenteral/IV Fluids
- F695: Respiratory/Tracheostomy Care & Suctioning
- F697: Pain Management

# New Guidance – §483.25: Quality of Care

- F699: Trauma Informed Care
  - F656: Develop/Implement Comprehensive Care Plan [for cultural preferences & trauma-informed care]
  - F656: Culturally competent and/or trauma-informed care plan interventions
  - F699: Outcomes or potential outcomes to resident related to culturally competent and/or trauma-informed care;
  - F726: Knowledge, competencies, or skill sets of nursing staff to provide culturally competent and trauma-informed care or services
  - F742: Treatment and services for residents with history of trauma and/or history of post-traumatic stress disorder (“PTSD”)
  - F700: Bedrails

# New CMS Guidance

- §483.40: Behavioral Health Services
  - F740: Behavioral Health Services
  - F741: Sufficient/Competent Staff—Behavioral Health Needs
- §483.45: Pharmacy Services
  - F755: Pharmacy Services/Procedures/Pharmacist/Records:
  - F757: Drug Regimen Is Free From Unnecessary Drugs
  - F758: Free From Unnecessary Psychotropic Medications/PRN Use
- §483.60: Food and Nutrition Services
  - F812 Food Procurement, Store/Prepare/Serve—Sanitary
- §483.70 Administration
  - F847: Enter Into Binding Arbitration Agreements
  - F848: Select Arbitrator/Venue, Retention of Agreements
  - F851 Payroll-Based Journal (“PBJ”)

# New CMS Guidance

- §483.75: Quality Assurance and Performance Improvement (QAPI)
  - F865: QAPI Program/Plan, Disclosure/Good Faith Attempt
  - F866: QAPI/QAA Data Collection and Monitoring
  - F867: QAPI/QAA Improvement Activities
  - F868: QAA Committee
- §483.80: Infection Control
  - F880: Infection Prevention and Control
  - F881: Antibiotic Stewardship Program
  - F882: Infection Preventionist Qualifications/Role
- §483.85: Compliance & Ethics Program
  - F895: Compliance & Ethics Program
- §483.90: Physical Environment
  - F519: Resident Call System

# New Guidance – §483.95: Training Requirements

- F940: Training Requirements—General
- F941: Communication
- F942: Resident’s Rights and Facility Responsibilities
- F943: Abuse, Neglect & Exploitation (no change)
- F944: QAPI
- F945: Infection Control
- F946: Compliance and Ethics Training
- F947: Required Inservice Training for Nurse Aides
- F948: Required Training of Feeding Assistants (no change)
- F949: Behavioral Health Training

# New Guidance – §483.35: Nursing Services

- F725: Sufficient Nursing Staff
- F727: RN 8 Hours/7 Days/Week, Full-Time DON
- F729: Nurse Aide Registry Verification, Retraining
- F732: Posted Nurse Staffing Information

# Questions?

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