

# **2023 Long Term Care Provider State and Federal Legal Update**

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David C. Marshall, Esq.  
Jennifer Russell Spence, Esq.

# Introduction

- ▶ The latter part of 2022 and 2023 will see significant changes in the licensure/certification requirements for nursing facilities:
  - This year, the Pennsylvania Department of Health will be implementing the long-awaited updates to the Pennsylvania Long Term Care Regulations
  - What is the potential impact to long term care providers from the proposed Federal and White House initiatives?
- ▶ With the end of the public health emergency, will we “return to normal” governmental oversight of the long-term care industry?
- ▶ In this session, we will review current and pending laws/regulations and will provide recommendations for providers to maintain compliance with these changing rules.

# Introduction

## ▶ Industry Trends

- Sales, mergers and consolidations of long-term care providers
  - The last 2 years have seen a flurry of sales, mergers and affiliations of providers across the nation, including those among nonprofit organizations.
  - Lenders report that “per bed” prices are reaching all-time highs, and though access to funding has been limited for a time, it will likely come back in 2023.
  - This expanding activity has drawn the interest of federal and state regulators, as will be discussed further.
- Closures of facilities continue, as smaller facilities and those with census issues struggle to stay afloat
- Staffing continues to be one of, if not the main, operational challenge for the LTC industry, has been exacerbated by the pandemic and remains a significant focus for government.

**Pennsylvania Department of Health's  
New Licensure Regulations To Be  
Implemented in 2023**

# PA Department of Health Updates to the Long Term Care Regulations

- ▶ On December 24, 2022, the Pennsylvania Department of Health officially published its updates to the long-term care licensure regulations.
- ▶ The implementation of the new regulations will be done in stages:
  - February 1, 2023: Notice requirements under 201.12 associated with CHOW applications
  - July 1, 2023: Bulk of updates become effective
    - 2.87 minimum nurse staffing hours per patient day
  - October 31, 2023: Updated requirements associated with CHOW applications
  - July 1, 2024: 3.2 minimum nurse staffing hours per patient day

# PA Department of Health Updates to the Long Term Care Regulations

- **A few notes on the new regulations:**
  - Initially the Department attempted to incorporate the SOM into the regulations. The final form regulations do not do so.
  - With the incorporation of the 42 CFR 483 into the state regulations, now even non-Medicare/Medicaid facilities will need to comply for the most part with the federal regulations
    - The Department has clarified that the Federal standards for reporting of Minimum Data Set (MDS) reporting and the transmission of data to CMS are not required, unless a facility is participating in the Medicare or MA program.

# PA Department of Health Updates to the Long Term Care Regulations

- **Chapter 201**

- **201.12 Application for a License for New Facility or Change of Ownership**
- Significant changes to this section, particularly with respect to the sale of a facility (will not go into detail during this presentation)
- Most provisions go into effect October 1, 2023
- 2012.12a(a)(b) and (c)(1)-(3) went into effect February 1, 2023 (When filing an application for new facility or change in ownership, notice must be concurrently provided to residents, staff, state ombudsman)

# PA Department of Health Updates to the Long Term Care Regulations

- **Chapter 201**

- **201.13 Issuance of a license**

- The owner of the facility's name and address will now be listed on the license itself
    - Sets forth the requirements for regular, 201.13a and provisional licenses, 201.13b

- License Renewals 201.13c

- Will require financial reports be filed with the application for license renewal
    - License renewal applications shall be filed at least 21 days before the expiration of the license



# PA Department of Health Updates to the Long Term Care Regulations

- **Chapter 201**

- **201.14 Responsibility of a Licensee**

- Updates reporting requirements for serious incidents. Adds a provision requiring a facility to keep inspection reports on file and requires the facility-wide assessment to be completed quarterly (previously was required only annually under federal regulations).
  - Serious incidents must be reported as soon as possible but not later than 24 hours
  - Must include state long term care ombudsman in notifications regarding a staff strike notice
  - Facility wide assessments that meet the requirements of 483.70 must be conducted quarterly
  - A facility must have on file the most recent inspection reports relating to health and safety of residents, and upon request must make the most recent report available upon request to interested parties

# PA Department of Health Updates to the Long Term Care Regulations

- **Chapter 201**

- **201.14 Responsibility of a Licensee**

- Note: 201.14(g) now requires a licensee to pay undisputed vendor bills in a timely manner so that resident health and safety is not jeopardized
  - Review your contracts to confirm what you should do with respect to disputed invoices (i.e. must they be disputed in writing? What are the notification requirements and deadlines to dispute a claim? You may need to provide such documentation to surveyors if they question why invoices aren't being paid).

# PA Department of Health Updates to the Long Term Care Regulations

- **Chapter 201**

- **201.17 Location**

- Allows a facility to be located in a building with other providers and to share services, with the approval of the Department.
  - The provider operates or provides other health related services, such as personal care, home health or hospice services
  - The shared services may include services such as laundry, pharmacy and meal preparations
  - The facility shall be operated as a unit distinct from other health related services
  - Note, though, the issues involved under the HCBS Settings Rule.

# PA Department of Health Updates to the Long Term Care Regulations

- **Chapter 201**

- **201.18 Management**

- Resident care policies must be reviewed annually
- Nursing Home Administrators must meet with and/or report at least monthly with governing body, medical and nursing staff and other professional supervisory staff
- If a facility accepts financial responsibility for a resident's financial affairs a facility must provide cash within 24 hours of a request for cash or 3 days for a request for a check
- The governing body of a facility shall adopt effective administrative and resident care policies and bylaws in accordance with legal requirements, they shall be in writing, shall be dated, and shall be reviewed and revised in writing as often as necessary but at least annually
- Sets forth requirements for facilities with less than 25 residents to share an administrator

# PA Department of Health Updates to the Long Term Care Regulations

- **Chapter 201**

- **201.19 Personnel records**

- Changes include a more detailed and comprehensive list of items that must be in the staff personnel files
- All personnel files must be kept current and available for each facility must contain the following information:
  1. The employee's job description, educational background and employment history
  2. Employee performance evaluations, including, documentation of any monitoring, performance, or disciplinary action related to the employee
  3. Documentation of credentials, which shall include, at a minimum, current certification, registration or licensure for the position assigned

# PA Department of Health Updates to the Long Term Care Regulations

- **Chapter 201**

- **201.19 Personnel records**

4. A determination by a health care practitioner that the employee as of their start date is free from communicable diseases or conditions
5. Records relating to a medical exam, if required by the facility or attestation that the employee is able to perform the employee's job duties
6. Documentation of the employee's orientation to the facility and the employee's assigned position prior to or within 1 week of the employee's start date
7. Documentation of the employee's completion of required trainings under this chapter, including documentation of orientation and other trainings

# PA Department of Health Updates to the Long Term Care Regulations

- **Chapter 201**

- **201.19 Personnel records**

8. A copy of the final report received by PSP and FBI as applicable in accordance with Older Adults Protective Services Act and the Adult Protective Services Act
9. In the event of a conviction prior to or following employment, documentation that the facility determined the employee's suitability for initial or continued employment in the position to which the employee is assigned "Suitability for employment" shall include a review of the offense; the length of time since the individual's conviction; the length of time since incarceration, if any; evidence of rehabilitation; work history; and the employee's job duties
10. The employees completed employment application

# PA Department of Health Updates to the Long Term Care Regulations

- **Chapter 201**

- **201.20 Staff development**

- Changes include a new requirement for staff training
- Topics required to be covered:
  - Topics outlined in 483.95
  - Accident prevention
  - Restorative nursing techniques
  - Emergency preparedness in accordance with 483.73
  - Fire and safety in accordance with 483.90
  - Resident rights, including nondiscrimination and cultural competency
  - Training needs identified through the facility assessment
  - Facility orientation shall include training on the prevention, detection and reporting resident abuse and dementia management and communication skills



# PA Department of Health Updates to the Long Term Care Regulations

- **Chapter 201**

- **201.21 Use of Outside Resources**

- Modifications to make the requirements consistent with the requirements of 483.70(g) relating to administration, the responsibilities, functions, objectives and terms of agreements related to outside resources shall be delineated in writing and signed and dated by the parties
- If the facility acquires employees from outside resources, the facility shall obtain confirmation from the outside resource that the employees are free from the communicable diseases and conditions listed in 27.155 and are able to perform their assigned job duties
- This covers all personnel who provide services at the facility (staffing agencies, consultants, specific providers, etc...)
- Arrangements with outside vendors must in writing (contract, regular invoices)

# PA Department of Health Updates to the Long Term Care Regulations

- **Chapter 201**

- **201.22 Prevention, control, and surveillance of tuberculosis (TB)**

- Removes outdated provisions, specific requirements outlined have been removed
- Facilities must have a written TB control plan that complies with CDC guidance
- Will likely do away with the need for waivers or exceptions that have been currently approved by the Department

# PA Department of Health Updates to the Long Term Care Regulations

- **Chapter 201**

- **201.23 Closure of a Facility**

- New provisions include development of a closure plan that identifies and provides contact information for the individuals responsible for operations during the closure process, and a plan for identifying and assessing potential transfer facilities for residents and interviewing each resident to determine goals, preferences and needs
- Facility must develop a plan to securely transfer resident information
- DOH must be notified at least 75 days in advance of the closure
- In addition to the federal notice requirement of 60 days notice to residents and the long-term care ombudsman, the facility must also notify facility employees 60 days in advance of the closure and the Department of Human Services

# PA Department of Health Updates to the Long Term Care Regulations

- **Chapter 201**

- **201.24 Admission policy**

- Requires newly admitted residents to be introduced to at least one member of the professional nursing staff and to the direct care staff assigned to them within 2 hours of admission
- Requires orientation to the facility and essential services like the dining room, nurses' station, social workers and complaint officers within 2 hours of admission
- Within 24 hours a facility must provide a description of facility routines and discuss the resident's routines and preferences to be included in the care plan
- Within 72 hours the facility must assist the resident in creating a homelike environment and settling and securing their personal possessions in their room

# PA Department of Health Updates to the Long Term Care Regulations

- **Chapter 201**

- **201.24 Admission policy**

- A few notes:

- Review admission agreements, as the new regulations may require changes to admission agreements
- Cannot mandate a resident to name a Resident Representative if the resident is competent to manage his/her affairs
  - Note the “legal” meaning associated with the term “Resident Representative”
- Cannot utilize releases unless part of a formal litigation settlement

# PA Department of Health Updates to the Long Term Care Regulations

- **Note the definition of Resident Representative from Part 483**

For purposes of this subpart, the term resident representative means any of the following:

- (1) An individual chosen by the resident to act on behalf of the resident in order to support the resident in decision-making; access medical, social or other personal information of the resident; manage financial matters; or receive notifications;
- (2) A person authorized by State or Federal law (including but not limited to agents under power of attorney, representative payees, and other fiduciaries) to act on behalf of the resident in order to support the resident in decision-making; access medical, social or other personal information of the resident; manage financial matters; or receive notifications;
- (3) Legal representative, as used in section 712 of the Older Americans Act; or.
- (4) The court-appointed guardian or conservator of a resident.
- (5) Nothing in this rule is intended to expand the scope of authority of any resident representative beyond that authority specifically authorized by the resident, State or Federal law, or a court of competent jurisdiction.

# PA Department of Health Updates to the Long Term Care Regulations

- **Chapter 201**

- **201.29 Resident Rights**

- Development of written policies on resident rights and responsibilities must include residents
- The resident's written acknowledgement that they received personal notification of rights and responsibilities must be entered into the resident's record
- Facility Resident rights policies should include a mechanism for inclusion of residents and representatives in the development and implementation of policies and procedures regarding resident rights. This could be accomplished by working with resident groups should they exist. If no resident group exists, then perhaps an annual meeting with residents to discuss Resident rights policies could be scheduled
- Resident rights include rights to care based on protections of all Pennsylvania citizens under the Pa Human Relations Act, and section 1557 of the Affordable Care Act, and to nursing home residents under federal resident rights regarding ability to pay
- The facility shall post in a conspicuous place near the entrances and on each floor of the facility

# PA Department of Health Updates to the Long Term Care Regulations

- **Chapter 201**

- **201.29 Resident Rights**

- In addition to the resident rights set forth in 483.10, a resident also has the right to the following under PA licensure rules:
  - If changes in charges occur during the resident's stay the resident shall be advised verbally and in writing reasonably in advance (interpreted to be 30 days prior unless circumstances dictate otherwise). If a facility requires a security deposit, then the written procedure or contract that is given to the resident, or resident representative, shall indicate how the deposit will be used and the terms for return of the deposit. A security deposit is not permitted for a resident receiving Medical Assistance
  - Prior to transfer, the facility shall inform the resident as to whether the facility where the resident is being transferred to is certified to participate in Medicare and Medical Assistance programs



# PA Department of Health Updates to the Long Term Care Regulations

- **Chapter 201**

- **201.29 Resident Rights**

- Experimental research or treatment in a facility may not be carried out without the approval of the Department including the Department's Institutional Review Board, and without the written approval and informed consent of the resident obtained prior to participation and initiation of the experimental research or treatment

# PA Department of Health Updates to the Long Term Care Regulations

- **Chapter 201**

- **201.29 Resident Rights**

- A Resident has the right to care without discrimination based upon race, color, familial status, religious creed, ancestry, age, sex, gender, sexual orientation, gender identity or expression, national origin, **ability to pay**, handicap or disability. Use of guide or support animals because of the blindness, deafness or physical handicap of the resident or because the resident is a handler or trainer of support or guide animals
  - Note the expansion of the list of protected categories
- The Department has created a template of resident's rights, which lists those rights in clear and easy to understand language. This template, which facilities may use as a tool to meet the posting and notice requirements, 201.29 Resident Rights subsections (c.1) and (c.2). This is available on DOH's Nursing Facility website

# PA Department of Health Updates to the Long Term Care Regulations

- **Application of Life Safety Code for Long-Term Care Nursing Facilities**
- **Chapter 204 (for construction, alteration or renovation approved after July 1, 2023)**
  - Shall comply with the 2018 edition of the Facility Guideline Institute Guidelines for Design and Construction of Residential Health Care and Support Facilities
- **Chapter 205 (for Construction, alteration or renovation approved before July 1, 2023)**
  - See Appendix B for physical environment requirements for nursing facility construction, alteration or renovation projects approved before July 1, 2023

# PA Department of Health Updates to the Long Term Care Regulations

- **Chapter 211 Program Standard for Long-Term Care Nursing Facilities**
  - **211.2 Physician services** – The Medical Director will need to complete at least 4 hours annually of CME pertinent to the field of medical direction or post-acute and long-term care medicine.
  - The medical director's duties now include:
    - assisting in the development of educational programs for facility staff and other professionals
    - developing infection surveillance and control policies
    - promoting person centered care
    - identifying performance expectations and providing feedback to physicians and other healthcare professionals
    - intervening when practices do not meet standards of care
    - participating in the development of systems to monitor performance of healthcare practitioners

# PA Department of Health Updates to the Long Term Care Regulations

- **Chapter 211 Program Standard for Long-Term Care Nursing Facilities**
  - **211.3 Verbal and telephone orders**
  - Changes terminology from oral orders to verbal orders
  - Adds consideration for physician's delegee
  - Discusses the permissibility to send secure electronic transmissions (fax or secure electronic transmission) of information such as the physician's signature and an initial order and counter signature
  - Countersignature must be obtained within 72 hours as opposed to 7 days as previously required

# PA Department of Health Updates to the Long Term Care Regulations

- **Chapter 211 Program Standard for Long-Term Care Nursing Facilities**
  - **211.5 Medical Records**
    - Changes the requirement to retain records from 7 years following a resident's discharge or death, deferring to the Federal requirement to retain records for 5 years for an adult and 3 years after a minor reaches the legal age, consistent with federal requirements
    - In the event that a facility closes, a facility must provide the Department within 30 days of providing notice of closure a plan for storage and retrieval of medical records

# PA Department of Health Updates to the Long Term Care Regulations

- **Chapter 211 Program Standard for Long-Term Care Nursing Facilities**
  - **211.6 Dietary services**
    - Requires facilities to post their menu at least 2 weeks in advance
    - Records of foods actually served shall be retained for 30 days
    - When changes in menu are necessary, substitutions shall provide equal nutritional value
    - Facilities will need to review their agreements with their food service vendor, to ensure that these new requirements are imposed on the vendor.

# PA Department of Health Updates to the Long Term Care Regulations

- **Chapter 211 Program Standard for Long-Term Care Nursing Facilities**
  - **211.9 Pharmacy services**
  - Adds a requirement that non-prescription medications be administered under a physician's or physician delegee's order
  - Drafted to be in line with Federal requirements under 483.45
  - New section requires written policies regarding disposition of medication that address at least these five listed topics:
    1. Timely and safe identification and removal of medications for disposition
    2. Identification of storage methods for medications awaiting final disposition
    3. Documentation of actual disposition of medications to include the name of person disposing the medication, name of resident, name of medication, strength of medication, prescription number, quantity disposed, and date of disposal
    4. Control and accountability of medications awaiting final disposition consistent with standards of practice
    5. A method of disposition to prevent diversion or accidental exposure consistent with applicable Federal and State requirements, and local ordinances and standards of practice
  - The emergency kit no longer requires a breakaway lock that is replaced after each use, but the facility must have policies and procedures that address the security of the emergency kits



# PA Department of Health Updates to the Long Term Care Regulations

- **Chapter 211 Program Standard for Long-Term Care Nursing Facilities**
  - **211.9 Pharmacy services**
  - Additionally, Residents shall be permitted to purchase prescribed medications from the pharmacy of their choice. If the resident does not use the pharmacy that usually services the facility, the resident is responsible for securing the medications and for assuring that applicable pharmacy regulations and facility policies are met
    - The facility shall notify the resident at admission and as necessary throughout the Resident's stay in the facility, of the right to purchase medications from a pharmacy of the resident's choice as well as the resident's and pharmacy's responsibility to comply with facility policies and State and Federal laws regarding packaging and labeling requirements

# PA Department of Health Updates to the Long Term Care Regulations

- **Chapter 211 Program Standard for Long-Term Care Nursing Facilities**
  - **211.16 Social Services**
  - Facilities with fewer than 120 beds will be required to employ a qualified social worker on a full-time basis, with some exceptions.
    - Those exceptions are:
      - If the facility has 26-59 beds and the facility assessment indicates a full-time qualified social worker is not needed, and the facility may employ a part-time social worker.
      - Facilities with 25 beds or less may employ a part-time social worker or share their services with another facility

# PA Department of Health Updates to the Long Term Care Regulations

- **Chapter 211 Program Standard for Long-Term Care Nursing Facilities**
  - **211.12 Nursing Services**
  - Increases the Nursing Hours Per Patient Day (NHPPD) from 2.7 currently to 2.87 beginning July 1, 2023
  - Increases the Nursing Hours Per Patient Day to 3.2 beginning July 1, 2024
  - Beginning July 1, 2023:
    - A minimum of 1 nurse aide to 12 residents during the day and evening shifts, 1 nurse aide per 20 residents overnight
    - A minimum of 1 LPN per 25 residents during the day, 30 residents during the evening and 1 LPN per 40 residents overnight
    - A minimum of 1 RN per 250 residents during all shifts
  - Beginning July 1, 2024:
    - A minimum of 1 nurse aide to 10 residents during the day, 1 nurse aide to 11 residents in the evening shifts, 1 nurse aide per 15 residents overnight
    - Facilities may substitute an LPN or RN for a nurse aide or an RN for an LPN

# PA Department of Health Updates to the Long Term Care Regulations

- **Chapter 211 Program Standard for Long-Term Care Nursing Facilities**
  - **211.12 Nursing Services**
  - Increases the Nursing Hours Per Patient Day (NHPPD) are calculated per 8 hour shift. If a facility utilizes a 12-hour shift, they must do the appropriate calculations
  - If a staff member is attending to a resident during an appointment - this time can count to PPD calculations
  - Management (NHAs) who due to staffing shortages provide direct resident care may be counted for PPD hours. These individuals need to keep a log of direct resident care work performed.

# Federal Initiatives and Reforms

# Federal Staffing Proposals

- ▶ Federally mandated minimum staffing requirements are on the horizon
- ▶ The staffing study has been completed, and we are awaiting the federal recommendations for minimum staffing
- ▶ It is expected that CMS will announce the minimum staffing requirement sometime this spring and then have the minimum staffing finalized over the summer
- ▶ With that said, the White House Budget that was released on March 9, 2023, does not include any strategies to increase SNF staffing or designate any funding to pay for additional staff
  - But it DOES include \$100 million to be used for enhanced enforcement and survey activity with special focus on nursing facilities

# White House Nursing Home Reform Plan

- ▶ 1st announced in March of 2022; Areas of focus:
  - Minimum Staffing
  - Cracking down on the unnecessary prescription of medications to residents
  - Funding for enforcement activities
  - Increase in scrutiny of poor performing facilities
  - Increase in accountability for chain owners of substandard facilities
  - Improve transparency of facility ownership
  - Provide technical assistance to nursing homes to help them improve
  - Enhance nursing home care compare
  - Ensure nurse aide training is affordable
  - Support state efforts to improve staffing and workforce sustainability
  - Continued COVID 19 testing, vaccinations and boosters in LTC facilities

# CMS- QSO-23-05-NH- January 18, 2023

- ▶ Updates to the Nursing Home Care Compare Website and Five Star Quality Rating System: Adjusting Quality Measure Ratings Based on Erroneous Schizophrenia Coding, and Posting Citations Under Dispute
  - Adjusting Quality Measure Ratings: CMS will be conducting audits of schizophrenia coding in the Minimum Data Set data and based upon the results, adjust the Nursing Home Care Compare quality measure star ratings for facilities whose audits reveal inaccurate coding.
  - Posting Citations Under Dispute: To be more transparent, CMS will now display citations under informal dispute on the Nursing Home Care Compare website
    - Disputed deficiencies will not factor into star rating until confirmed



# Omnibus COVID 19 Health Care Staff Vaccination Rule

- ▶ The CMS Final Rule initially issued in November of 2021 is still in effect. CMS has indicated that without further action, the Rule will remain in effect until November 2024
- ▶ The Biden administration continues cite the importance of COVID 19 vaccination and booster for healthcare staff
- ▶ November 2022, 22 states petitioned CMS to rescind the vaccination mandate and related guidance; Action is pending, but we do not expect CMS to lift the mandate at this point.
- ▶ The House passed a bill Jan. 31 that would invalidate the Biden administration's rule that requires employees to be vaccinated against COVID-19 if they work in healthcare facilities that receive Medicare or Medicaid funding.
  - President Biden has indicated he would veto the bill if it passes the full Congress
- ▶ In short, facilities should prepare for the vaccine mandate to continue until November 2024

# Public Health Emergency Expires May 11, 2023

- ▶ Remaining waivers associated with PHE will end without further action by CMS/DOH

# Survey Enforcement Trends and Issues

# October 24, 2022 Update to State Operations Manual

- ▶ The Centers for Medicare & Medicaid Services (CMS) has revised Appendix PP to the CMS State Operations Manual to reflect regulatory changes that were effective October 24, 2022
- ▶ CMS reported that the updates were designed to enhance nursing home quality and oversight, and to clarify CMS expectations of facilities.
- ▶ Surveyors have been using this revised guidance to identify noncompliance with the Requirements of Participation. As such, it is important to understand how the new standards might affect nursing home operations.

# Survey and Enforcement

- ▶ Surveys have been impacted by work force issues at survey agencies
  - This has led to overdue surveys
    - Late CMP notices
    - Time of revisits and complaint surveys have been affected
    - If there is undue delay in notifying the facility of the civil money penalty, it is possible that the effective date of the penalty could be moved to a date later than the date of the noncompliance. (See §7306 regarding timing of civil money penalties.)
    - What can a facility do?
      - Quickly submit POC and push DOH for revisit ASAP
      - Use IDR/IIDR to challenge underlying deficiencies and delay issues
      - Be survey ready – remember that penalty continues if additional deficiencies found during revisit, or subsequent complaint or annual survey prior to the revisit

# Survey and Enforcement

- ▶ In 2022 in Pennsylvania, the average number of deficiencies cited per nursing facility was 6.9
- ▶ Frequently cited deficiencies and recommendations to avoid a deficiency:
  - F 884 Reporting – NHSN
    - Establish routine reporting days, signed off on a calendar
    - More than 1 staff person trained as backup on the reporting process
    - Print/screen shot and save reports before and after submission
    - Review process to monitor compliance

# Survey and Enforcement

- ▶ Frequently cited deficiencies cont:
  - Quality of Care F 684
    - Concerns which have caused or have a potential to cause a negative outcome to a resident's physical, mental, or psychosocial health or well-being that is not specifically addressed by any other tag at 483.5
    - Guidance for end of life and hospice care. Care and services provided need to meet professional standards of practice as well as meet each resident's physical, mental and psychosocial needs
    - Review resident assessments and care plans to ensure resident needs are being properly met

# Survey and Enforcement

- ▶ Frequently cited deficiencies cont:
  - Food Procurement, Store/Prepare/Serve Sanitary F 812
    - Staff education on proper food handling requirements
    - Hand hygiene and cleaning schedules
  - Infection control F880
    - Effective screening for symptoms
    - Testing/Isolating/Quarantine
    - Staff training (correct use of PPE, etc)
    - Tracking and trending
    - Continuous review process to monitor for compliance



# Survey and Enforcement

- ▶ Frequently cited deficiencies cont:
  - F 689 Free of Accident Hazards/Supervision/Devices
    - Determination of “Avoidable” v. “Unavoidable”
    - “Unavoidable accident” means that an accident occurred despite sufficient and comprehensive facility systems designed and implemented to:
      - Identify risks
      - Evaluate/analyze risks
      - Implement interventions
      - Monitor the effectiveness

# Survey and Enforcement

- ▶ Frequently cited deficiencies cont:
  - F 689 Free of Accident Hazards/Supervision/Devices
    - A fall is an unintentionally coming to rest on the ground, floor, or other lower level
    - Not the result of an overwhelming external force
    - A fall without injury is still a fall

# Survey and Enforcement

- ▶ Frequently cited deficiencies cont:
  - F 689 Free of Accident Hazards/Supervision/Devices
    - Fall response
      - Evaluate and monitor the resident for 72 hours after the fall
      - Investigate fall circumstances
      - Record circumstances, resident outcome and staff response
      - Notify primary care provider
      - Implement immediate intervention within 24 hours
      - Complete falls assessment
      - Develop a plan of care
      - Monitor staff compliance and resident response

# Survey and Enforcement

- ▶ Survey Readiness 365 days a year:
  - Staff Education
    - Survey process
    - New DOH regulations
  - Mock Surveys
    - Internal or work with a related or affiliated facility
    - Utilize consultants as necessary/appropriate
    - Make part of compliance plan/efforts

# Survey and Enforcement

- ▶ Survey Readiness 365 days a year:
  - QAPI Process
    - Utilize CMS Critical Element Pathways
    - Use Audit tools
  - Review Documentation
    - Make sure training attendance rolls are complete and documented
    - Personnel files up to date and complete
    - Resident assessments are accurate and up to date

# Liability and Immunity Issues

# Prep Act Litigation Update

- ▶ The extent and reliability of the PREP Act's immunity protections have been called into question as federal courts throughout the country consider whether the PREP Act preempts certain or all state law claims
- ▶ On November 21, 2022, the U.S. Supreme Court denied certiorari of the Ninth Circuit Court of Appeals opinion issued in [Saldana v. Glenhaven Healthcare LLC](#), which found that there was no federal jurisdiction over state-law claims in which the defendant nursing home raised an immunity defense under the PREP Act.
- ▶ The denial of certiorari means that the interpretation, application, and scope of the immunity provided by the PREP Act will continue to vary by state.

# Prep Act Litigation Update

- ▶ Testa v. Broomall Operating Company, L.P., et al Civil Action No. 21-5148 [United States District Court, Eastern District of Pennsylvania]
  - On November 2, 2021, Plaintiff initiated an action against the facility
  - In filings the Plaintiff clarified that she is not bringing claims of willful misconduct
  - The facility filed a Motion to Dismiss arguing that it was immune from suit under the PREP Act, and alternatively under the Order of the Governor of the Commonwealth of Pennsylvania to Enhance Protections of Health Care Professionals dated May 6, 2020
  - On August 18, 2022, the Court denied the Facility's Motion to Dismiss
    - The Court ruled:
      - The PREP Act does not completely preempt state law claims, only those that fall within the narrow cause of action for “willful misconduct”
      - The PREP Act only provides the immunity for the use of countermeasures- not the non-use
      - The May 6, 2020, order of the Governor only provides protections to individuals, not to entities



# Fraud/Abuse/Compliance Issues

# Fraud/Abuse/Compliance Issues

- ▶ **December 27, 2022**, CMS published a Proposed Rule titled: Medicare Program; Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, Medicare Parts A, B, C, and D Overpayment Provisions of the Affordable Care Act and Programs of All-Inclusive Care for the Elderly; Health Information Technology Standards and Implementation Specifications

# Fraud/Abuse/Compliance Issues

- ▶ This proposed rule addresses and would revise:
  - Medicare Advantage (Part C)
  - Medicare Prescription Drug Benefit (Part D)
  - Medicare cost plan
  - Programs of All-Inclusive Care for the Elderly (PACE) regulations to implement changes related to Star Ratings
  - Medication therapy management
  - Marketing and communications
  - Health equity
  - Provider directories, coverage criteria, prior authorization, passive enrollment, network adequacy, identification of overpayments, formulary changes, and other programmatic areas.

# Fraud/Abuse/Compliance Issues

- ▶ This proposed rule addresses and would revise:
  - Coverage criteria
  - Prior authorization
  - Passive enrollment
  - Network adequacy
  - Identification of overpayments
  - Formulary changes
  - Other programmatic areas

# Fraud/Abuse/Compliance Issues

- ▶ Note: One of the proposed changes would require the reporting and returning of overpayments to CMS within 60 days of identification
  - If finalized, the rule change would revise the meaning of "identification" to remove the "reasonable diligence" standard and replace it with the False Claims Act's (FCA's) "knowing" standard. Under the proposed rule, providers, suppliers, Medicare Advantage Organizations (MAOs), and Part D sponsors will be deemed to have identified an overpayment if they have "actual knowledge of the existence of the overpayment or act in reckless disregard or deliberate ignorance of the overpayment."
  - the proposal goes further by eliminating the current regulatory language that an overpayment has to be quantified before the 60-day reporting requirement is triggered—that is, before the overpayment has been “identified.”

# Fraud/Abuse/Compliance Issues

- ▶ Settlements and judgments under the False Claims Act exceeded \$2.2 billion in 2022. The government and whistleblowers were party to 351 settlements and judgments, the second highest number of settlements and judgments in a single year.

# Fraud/Abuse/Compliance Issues

- ▶ United States v. Am. Health Found., No. 2:22-cv-02344 (E.D. Pa.)
  - Government alleges that Provider failed to maintain adequate staffing, provide necessary services, and housed residents in unlivable conditions.
  - Government alleges that Provider repeatedly gave its residents unnecessary medications, including antibiotic, antipsychotic, antianxiety and hypnotic drugs, while also failing to ensure that its residents had the prescriptions they actually needed.
  - It is still early in the litigation. On October 6, 2022 briefing for the Provider's motion to dismiss concluded.
  - Currently awaiting decision from the District Court

# Fraud/Abuse/Compliance Issues

- ▶ United States ex. Rel. Polansky v. Executive Health Resources, Inc.
  - A former consultant for EHR (a company that submits claims to Medicare on behalf of healthcare providers) filed an FCA case alleging that EHR was falsely certifying inpatient hospital admissions as medically necessary leading to overbilling
  - DOJ investigated the claims for 2 years before declining to intervene. Polansky proceeded with the lawsuit, after 5 years of litigation the DOJ sought to dismiss the case
  - District Court granted the DOJ's Motion to Dismiss and the 3rd Circuit Court of Appeals Affirmed



# Fraud/Abuse/Compliance Issues

- ▶ United States ex. Rel. Polansky v. Executive Health Resources, Inc.
  - Appeal to the SCOTUS
  - Argument of Polansky: Because the DOJ initially declined to intervene, and then chose to intervene at a later date, then the DOJ must show good cause in order to limit the “the status and rights” of the person who initiated the claim
  - Argument of DOJ: The statute does not constrain dismissals as long as the person who initiated the action is provided notice of the Motion to Dismiss and was provided an opportunity for a hearing, then the Dismissal is proper

# Fraud/Abuse/Compliance Issues

- ▶ United States ex. Rel. Polansky v. Executive Health Resources, Inc.
  - Given the unclear and different interpretations of the dismissal standard employed by the trial court, the SCOTUS decision should provide a uniform standard for consistency across the circuits
  - Should bring more predictable outcomes within the health care industry when faced by qui tam litigation

# New Department of Justice Initiatives

- ▶ March 2023 DOJ Updated its Evaluation of Corporate Compliance Programs guidance
- ▶ In the guidance Boards are encouraged to evaluate and respond to a series of important new corporate compliance initiatives recently announced by the DOJ.
- ▶ These initiatives, and corresponding changes to DOJ's Evaluation of Corporate Compliance Programs (ECCP) guidelines, are an important leadership reminder that the presence (or absence) of a functioning compliance program is an important element of DOJ's decision making in corporate fraud matters.

# New Department of Justice Initiatives

## ▶ Executive Compensation

- DOJ encourages providers to develop compensation structures that:
- Clearly and effectively impose financial penalties for misconduct can deter risky behavior and foster a culture of compliance.
- Provide positive incentives, such as promotions, rewards, and bonuses for improving and developing a compliance program or demonstrating ethical leadership, can drive compliance.

# New Department of Justice Initiatives

## ▶ Executive Compensation

- Intended to incentivize compliance by promoting behavior through innovative approaches to executive compensation and the use of claw backs
- DOJ's goal is to ensure that the company uses compliance-related criteria to reward ethical behavior and punish and deter misconduct.
- Intended to shift the burden of corporate malfeasance away from uninvolved shareholders onto those more directly responsible

# New Department of Justice Initiatives

## ▶ **Messaging Applications**

- A new focus on corporate policies and procedures governing the use of personal devices, communications platforms, and messaging applications including ephemeral messaging applications
  - If the company has a policy regarding whether employees should transfer messages, data, and information from private phones or messaging applications onto company record-keeping systems in order to preserve and retain them, is it being followed in practice, and how is it enforced?

## ▶ **Voluntary Self Disclosure (VSD)**

- VSD policy offers new significant and concrete incentives for companies to self-disclose identified corporate misconduct to the government

# New Department of Justice Initiatives

\*\*Totality of these new compliance policies and initiatives is intended to send corporate leadership a clear signal concerning the DOJ's commitment to corporate fraud enforcement, individual accountability and establishing the right incentives to promote and support a culture of corporate compliance\*\*

# HIPAA Updates



# HIPAA Updates

- ▶ December 2020 HHS Announced Its Proposed Modifications to the HIPAA Privacy Rule to Empower Patients, Improve Coordinated Care, and Reduce Regulatory Burdens
- ▶ The HIPAA Journal reports that the Changes to the HIPAA Privacy Rule are expected in 2023

# HIPAA Updates

- ▶ Some of the proposed updates:
  - Allowing patients to inspect their PHI in person and to take notes or photograph their PHI
  - Change the max time to provide access to PHI from 30 days to 15 days
  - Restrict the rights of individuals to transfer ePHI to a 3rd party to only ePHI that is maintained in an EHR
  - Stating when individuals should be provided with ePHI without charge
  - Requiring covered entities to inform individuals that they have the right to obtain direct copies of the PHI to a 3rd party when a summary of the PHI is offered instead of a copy

# HIPAA Updates

- ▶ Some of the proposed changes cont...
  - Added a definition of HER
  - Covered entities are not required to obtain a written acknowledgment from an individual that they have received a Notice of Privacy Practices
  - Covered entities will be required to post estimates fee schedules on their websites for PHI access and disclosures
  
- **\*\*\*Updates will be necessary to policies and procedures and to Notices of Privacy Practices when the Final Rule is released**

# Miscellaneous/Potpourri

# Temporary Nurse Aide to Certified Nurse Aide

- ▶ **The TNA-CNA program was set to expire April 5, 2023**
- ▶ PA Department of Health announced on March 16, 2023 that they have received notice from CMS that the TNA waiver has been extended to **May 11, 2023**
- ▶ TNS who do not complete the required testing by May 11, 2023 may still become a Nurse Aide Candidate by enrolling in an approved Nurse Aide Training Program. **From May 11, 2023 Nurse Aide Candidates will have 4 months (September 8, 2023) to complete the required testing as long as they are enrolled in an approved Nurse Aide Training Program.** Nurse Aide Candidates may continue working in facilities while completing the program

# New Pennsylvania Staffing Agency Regulations

- ▶ PA Health Care Facilities Act Chapter 8-A: Temporary Health Care Services Agencies.
- ▶ Sets forth regulations for Staffing Agencies
  - Staffing agencies that were operating through Nov. 3, 2022 have 180 days to register with the state's department of health, whereas those who were created Nov. 4, 2022 and beyond have 90 days to register
  - Additionally, the law requires that staffing agencies validate the health care credentials of contracted employees as well as the creation of policies and procedures for agencies to abide by, such as carrying medical malpractice insurance.

# New Pennsylvania Staffing Agency Regulations

- ▶ “ A temporary health care services agency . . . may not restrict in any manner the employment opportunities of Health Care Personnel. This requirement shall also apply to a health care facility.”
- ▶ Grandfather provision?
- ▶ What does this mean for “placement fees?”

# Joint Effort by CFPB and CMS

- ▶ September 2022 CFPB (Consumer Financial Protection Bureau) and CMS issued a joint letter
- ▶ Nursing Facilities that participate in Medicare or Medicaid are subject to the Nursing Home Reform Act's prohibitions on requesting or requiring a caregiver guarantee payment as a condition of admission, expedited admission, or continued stay in the facility
  - Also, a prohibition under new PA nursing facility licensure regulations
- ▶ CFPB confirmed that debt collectors can violate the Fair Debt Collection Practices Act and the Fair Credit Reporting Act when they attempt to collect a nursing facility debt from a care giver based on contract terms that are invalid under the Nursing Home Reform Act



# Questions

**David C. Marshall**

dmmarshall@ldylaw.com

**Jennifer Russell Spence**

jrussell@ldylaw.com

**Latsha Davis & Marshall, P.C.**

717-620-2424

ldylaw.com