2022 Long Term Care Provider State and Federal Legal Update

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Introduction

- Since 2020, this country, and the long term care community have faced unusual challenges, with COVID-19 effectively putting lives on hold and providing once-in-a-generation level adversity to health care providers.
- Many of the systemic challenges exposed during the pandemic have continued, and it is important to understand the ongoing issues as we work toward a return to "normal."
- In this session, we will review the legal, regulatory and employment challenges left in the wake of COVID-19, review current and pending laws that must be understood, and will provide recommendations for providers to maintain compliance with those issues.

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 here in Pennsylvania and across the nation.
    - Nonprofit systems with similar missions/goals are seeking affiliation to address issues
    - Lenders report that "per bed" prices are reaching all-time highs, and funding is more available for purchasers
    - This expanding activity has drawn the interest of federal and state regulators, as will be discussed further.
  - Re-thinking the LTC delivery of care model in wake of COVID-19
    - Staffing concerns
    - Size and structure of institutional care facilities
    - Rise of telehealth and HCBS options

Introduction

- Industry Trends
  - Slow return to normal governmental oversight:
    - Surveys/Inspections
    - Governmental Audits
    - Revisions to licensure and certification regulatory requirements in an attempt to gain more "control" and oversight over providers
    - Return of penalties/fines
    - Ending of COVID-19 waivers
  - Staffing continues to be one of, if not the main, operational challenge for the LTC industry, and has been exacerbated by the pandemic
  - Against this backdrop, MedPAC's March 2022 report recommends that Congress reduce FY2022 base payment rates by 5%

PA Department of Health Proposed Updates to Nursing Facility Regulations

- On July 31, 2021, the Pennsylvania Department of Health officially began its efforts to make changes and to update the long-term care nursing facility regulations.
- The Department announced its intention to release the proposed changes in 5 packages
- With the release of the 3rd package on March 19, 2022, the Department announced that intends to combine the 4th and 5th packages into one last package for total of 4 packages

Proposed to Changes to PA Nursing Facility Regs

- Package 1
  - Department is making proposed changes of the state regulations to align the requirements of the state regulations with the federal regulation requirements
  - The main change that the Department is proposing in the Group 1 regulatory package is an increase in direct nursing care hours from the current 2.7 to 4.1

Proposed to Changes to PA Nursing Facility Regs

- Package 2
  - On October 12, 2021, the Department released its 2nd package of proposed changes to the Nursing Facility Regs
    - Focused on standards related to facility construction, alterations, or closure.
    - Primarily eliminate provisions in the current state regulations that duplicative of the federal regulations

Proposed to Changes to PA Nursing Facility Regs

- Package 3
  - The Department expressed concerns regarding the complex nature of the ownership interests in for-profit nursing care facilities
  - DOH is proposing significant changes to the New Licensure/CHOW process that will allow the Department to have a more involved review and vetting process by obtaining much more information from applicants

Proposed to Changes to PA Nursing Facility Regs

- Some of the proposed changes:
  - DOH will require additional contact information for those individuals holding direct or indirect ownership and/or management interests in a facility. Specifically, DOH will require disclosure of the name, address, email address, and phone number of any individual who holds 5% or more ownership interest in the entity, the real property owner, or the facility management company. This information would also be required for all officers and directors of non-profit organizations who operate nursing care facilities
  - DOH will require a list of every licensed facility in any state, DC, or territory in which the person has or had any percentage of ownership interest.
  - DOH requires regulatory history for all individuals

Proposed to Changes to PA Nursing Facility Regs

- Some of the proposed changes cont.:
  - DOH requires individuals to provide a detailed summary of any current or settled civil or criminal actions filed against them, such as wrongful death actions
  - DOH requires individuals to provide information regarding any financial failures (bankruptcy, receivership, mortgage foreclosure, sale or closure of nursing facilities, corporate integrity agreement, debt consolidation or restructuring)
  - DOH will require applicants to provide a proposed staffing and hiring plan, a proposed training plan, a proposed emergency preparedness plan, proposed admissions and discharge agreements, and detailed budget for 3 years of operations. (The Department will create a new unit to assess financial information)
  - Finally, DOH has a catch-all provision

Proposed to Changes to PA Nursing Facility Regs

- Should there be any issue with an application that is submitted, or should DOH require additional information then the Department will permit applicants 30 days to cure any defects in the application
- Traditionally, surveys have not been conducted during a CHOW but in the new proposed regulations state that surveys may be conducted during a CHOW based on circumstances
- The Name and address of the owner will be added to the license itself for transparency purposes
- These proposed changes will not be applied to license renewals

Proposed to Changes to PA Nursing Facility Regs

- Other changes proposed in Package 3
  - DOH is requiring facilities to inform the Department of incidents outlined in 28 Pa. Code §51.3 within 24 hours
  - DOH is going to require at least quarterly facility assessments that meet the requirements of 42 C.F.R. § 483.70(e)
  - DOH is proposing to defer to the federal requirements as it relates to Prevention, Control and Surveillance of Tuberculosis, and the are of Infection Prevention and Control as set forth in 42 C.F.R. § 483.80
  - DOH will permit, subject to its review and approval, a facility to be located in a building that also offers health-related services such as personal care, home health or hospice services, and may share services such as laundry, pharmacy and meal preparations

White House Initiative Announcement

- On February 28, 2022, the White House released a statement that announced sweeping initiatives and reforms in the nursing care facility field
- The White House expressed concern regarding the level of care that residents in nursing care facilities are receiving throughout the country, and the level of oversight and accountability in the industry
- All of these proposals would require the issuance of regulations, and CMS wants to seek input from stakeholders before implementing, so this will be a "process."

White House Initiative Announcement

- The announcement launched 4 new initiatives:

  - CMS to establish minimum nursing home staffing
    - Will conduct research to determine level of and type of care needed
    - Will issue proposed new staffing rules with 1 year
  - CMS to explore ways to accelerate the phasing out of rooms with 3 or more residents and will continue to promote single occupancy rooms
  - CMS to strengthen the Skilled Nursing Facility Value-Based Program
    - Strengthening the existing SNF-VBP to award incentives to facilities based on performance
    - CMS intends to propose new payment changes based on staffing adequacy, the resident experience, as well as how well the facility retains staff
  - CMS to reinforce safeguards against unnecessary medications and treatment
    - New efforts to identify problematic diagnoses and refocus efforts to bring down inappropriate use of antipsychotic medications

White House Initiative Announcement

- The White House also called on Congress to:
  - Provide CMS with almost $500 million to be used to fund inspections activities (an increase in almost 25%)
  - Raise the dollar amount limit on per-instance financial penalties from $21,000 to $1,000,000
  - Provide CMS with authority to require minimum corporate competency to participate in Medicare and Medicaid
  - Expand CMS enforcement authority enabling CMS to impose enforcement actions on owners and operators of facilities, even after the facility closes

White House Initiative Announcement

- Additional reforms:
  - Increase scrutiny on poor performing facilities by overhauling the Special Focus Facility Program
  - CMS will create a database that will track and identify owners and operator across states
  - CMS to implement Affordable Care Act requirements regarding transparency in corporate ownership by collecting publicly reporting more robust corporate ownership and operating data
  - CMS to enhance Nursing Home Care Compare
  - CMS to focus on private equity ownership

CMS Blanket 1135 Waivers

- CMS Blanket waivers may remain in place during the duration of the Declaration of Emergency **and** the Public Health Emergency (both must be in place for the CMS Blanket 1135 waivers to remain in effect)
- President Biden announced on February 18, 2022 that he was going to extend the Emergency Declaration
- The Emergency Declaration is now extended, extension will expire March 1, 2023
- The Public Health Emergency was extended in January of 2022 by the Secretary of the Health and Human Services and is set to expire April 15, 2022. Expectation is that the PHE will be extended at least one more time as the administration has advised that it will provide states with at least 60 days advance notice of their decision to not extend the PHE

CMS Blanket 1135 Waivers

- On April 7, 2022, CMS Issued QSO-22-15 NH & NLTC & LSC
  - Terminates many of the Blanket 1135 waivers that were issued related to long term care facilities
  - Waivers terminated by the memo are either terminated in 30 days or 60 days from 4/7/22

CMS Blanket 1135 Waivers

- CMS has not continued all of the Blanket 1135 waivers that he had initially instituted, CMS has terminated several waivers
- Waivers that are currently still in place for Long-Term Care Facilities and Skilled Nursing Facilities:
  - Waiver of 3-Day Prior Hospitalization requirement for coverage of a SNF stay
  - Waive Pre-Admission Screening and Annual Resident Review (PASARR) 42 CFR 483.20(k)
  - Waiver of Physical Environment requirements per 42 CFR 483.90 specifically:
    - Permit a non-SNF building to be temporarily certified and available for use by a SNF in the event there is a need for isolation for COVID-19 positive residents
    - Also permitting rooms not normally used for resident rooms to be used to accommodate beds and residents for residents for resident care in emergencies and in situations needed for surge capacity [Terminates 6/6/22]

CMS Blanket 1135 Waivers

- Waiver of requirements which ensure residents can participate in-person in resident groups, per 42 CFR 483.10(f)(5) [Terminates 5/7/22]
- Certification of Nurse Aides: Waiver of requirements at 42 CFR 483.35(d) which require that a SNF and NF may not employ anyone for longer than 4 month unless they met the training a certification requirements [Terminates 6/6/22]
  - Note: CMS did not waive 42 CFR 483.35(d)(1)(i) which still require facilities to ensure that the individual is competent to provide nursing and nursing related services

In PA, Temporary Nurse Aide to Certified Nurse Aide Pathway

- With the termination of the Nurse Aide waiver, if a TNA does not become certified within 4 months of the termination of the waiver, they must stop working as a CNA in a nursing facility
- DOH has set up a pathway for TNAs who were hired during the pandemic to become certified
- 3 main requirements
  - Must complete an 8-hour online training and online examination program
  - 80 hours of temporary nurse aide or supervised practical nurse aide training, or on the-job training or regular in-service nurse aide education during the declared COVID-19 emergency under the supervision of a licensed or registered nurse in all areas of required nurse aide training as provided for in 42 CFR 483.152(a)(1-4)
  - Successfully pass the state nurse aide exam

In PA, Temporary Nurse Aide to Certified Nurse Aide Pathway

- For a TNA to take advantage of this pathway, they must submit an attestation form that is completed by the TNA, and the facility to attest that the TNA has completed the required 80 hours of on the job training
- This form must be submitted by 4 months from the end of the waiver (**October 4, 2022**)

CMS Blanket 1135 Waivers

- Waiver of requirement for physicians and non-physician practitioners to perform in-person visits for nursing home visits, and to allow as appropriate telehealth visits 42 CFR 483.30 [Terminates 5/7/22]
- Resident Roomates and Grouping CFR 483.10(e)(5)(7)- related to solely for the purpose of grouping or cohorting residents with respiratory illness symptoms and/or confirmed COVID-19
- Resident Transfer and Discharge- CMS is waiving requirements under the following regulations:
  - 42 CFR 483.10(c)(5)
  - 42 CFR 483.15(c)(3), (c)(5)(i) and (iv), (c)(9), and (d)

  - Important to review the waivers related to resident transfer and discharge as CMS has terminated some waivers that applied during the beginning of the pandemic
  - Facilities are responsible for ensuring that any transfer is conducted in a safe and orderly manner, and that each resident's health and safety is protected

CMS Blanket 1135 Waivers

- Waiver of the requirement that prevents physician from delegating a task when the regulations specify the physician must perform it personally 42 CFR 483.30(e)(4) [Terminates 5/7/22]
- Waiver the requirement at 483.30(c)(3) that all physician visits not already exempted under 483.30(c)(4) and (f) must be made by a physician personally– allows for a physician to delegate the visit to a nurse practitioner [Terminates 5/7/22]
- CMS is modifying 483.75(b)–(d) to the extent necessary to narrow the scope of QAPI program to focus on adverse events and infection control [Terminates 5/7/22]

CMS Blanket 1135

- Modifying the nurse aide training requirements at 483.95(g)(1). CMS is postponing the deadline for completing the requirement of at 12 hours of in-service training annually until the end of the first full quarter after the declaration of the Public Health Emergency concludes [**Terminates 6/6/22**]
- Waiver of the discharge planning requirement at 483.21(c)(1)(viii) [**Terminates 5/7/22**]
- CMS has modified the requirement at 42 CFR 483.10(g)(2)(ii) which requires LTC facilities to provide a resident a copy of their records within two working days – modified to allow ten working days [**Terminates 5/7/22**]

CMS Blanket 1135 Waivers

- Modifying the requirements at 42 CFR 483.60(h)(1)(i) and 483.160(a) regarding required training of paid feeding assistants. CMS modifying minimum timeframe for training from 8 hours to 1 hour [Terminates 6/6/22]
- Waiver of requirements at 42 CFR 483.60(a)(1) and 483.60(a)(2) that dieticians hired or contracted prior to 11/28/16 to meet specified requirements no later than 5 years after 11/28/16

Recent PA Health Alert Network Guidance

- PA-HAN-624
  - When in the past the term “fully vaccinated” was used in infection prevention guidance, the term “up to date” with all recommended COVID-19 doses will be used
  - Revised guidance for ending Transmission Based Precautions (TBP) for patients with suspected or confirmed COVID-19

Recommended Infection Prevention and Control (IPC) Practices When Caring For Patient Who is COVID-19 Positive or Has Been Exposed to COVID-19

- These IPC recommendations apply to:
  - Patients with symptoms of COVID-19
  - Asymptomatic patients who have had close contact with someone with COVID-19
  - Patients with COVID-19

Recommended Infection Prevention and Control (IPC) Practices When Caring For Patient Who is COVID-19 Positive or Has Been Exposed to COVID-19

- Quarantined patients and those with suspected infection should NOT be cohorted with patients with confirmed COVID-19 infections unless they are confirmed to have COVID-19 through testing

Recommended Infection Prevention and Control (IPC) Practices When Caring For Patient Who is COVID-19 Positive or Has Been Exposed to COVID-19

- Patients placed in TBPs based on close-contact with someone with COVID-19 should maintain TBPs for the following time periods:
  - Patients can be removed from TBPs after day 10 following the exposure (day 0) if they do not develop symptoms
  - Alternatively, although the 10 day period is preferred, patients can be removed from TBPs after day 7 following exposure (day 0) if a viral test is negative for COVID-19 and they do not develop symptoms

Recommended Infection Prevention and Control (IPC) Practices When Caring For Patient Who is COVID-19 Positive or Has Been Exposed to COVID-19

- The following patients who are asymptomatic do not require the use of TBPs following a close contact with some with COVID-19
  - Patients who are up to date with all recommended COVID-19 vaccine doses
  - Patients who have had a COVID-19 infection in the last 90 days

  - These patients should be still be tested per testing protocols

Recommended Infection Prevention and Control (IPC) Practices When Caring For Patient Who is COVID-19 Positive or Has Been Exposed to COVID-19

- Patient Placement
  - Patient with a suspected or confirmed COVID-19 should be placed in a single-room, with a dedicated bathroom
  - Facilities should consider designating entire units within the facility, with dedicated HCP, to care for patients with COVID-19
  - Limit transport and movement of patients with suspected or confirmed COVID-19 infection to medically essential purposes

Recommended Infection Prevention and Control (IPC) Practices When Caring For Patient Who is COVID-19 Positive or Has Been Exposed to COVID-19

- Duration of TBPs for Patients with COVID-19
  - Patients with mild to moderate illness, not immunocompromised
    - At least 10 days since first symptoms
    - At least 24 hours since last fever
    - Symptoms have improved
  - Patients who were asymptomatic, not immunocompromised
    - At least 10 days since first positive viral test

Recommended Infection Prevention and Control (IPC) Practices When Caring For Patient Who is COVID-19 Positive or Has Been Exposed to COVID-19

- Patients with severe to critical illness, not immunocompromised
  - At least 10 and up to 20 days have passed since first symptoms
  - At least 24 hours since last fever
  - Symptoms have improved
  - Test based strategy for moderately to severely immunocompromised patients can be used to inform duration of isolation

Recommended Infection Prevention and Control (IPC) Practices When Caring For Patient Who is COVID-19 Positive or Has Been Exposed to COVID-19

- For patients who are moderately to severely immunocompromised:
  - Use of test based strategy, and if available consultation with an infectious disease specialist to recommend when TBPs can be discontinued
  - Criteria for test based strategy:
  - Patients who are symptomatic:
    - Resolution of fever without use of fever reducing medication
    - Symptoms improved
    - Results are negative from at least 2 consecutive test at least 24 hours apart
  - Patients who are not symptomatic:
    - Results are negative from at least 2 consecutive test at least 24 hours apart

Recommended Infection Prevention and Control (IPC) Practices When Caring For Patient Who is COVID-19 Positive or Has Been Exposed to COVID-19

- Important note regarding visitation:
  - For the safety of visitors and residents, patients should be encouraged to limit-in-person visitation while they are in TBPs, however, facilities must adhere to all local, state, and federal regulations. Nursing Facilities must permit visitation, even during an outbreak For Nursing Care Facilities, CMS has issued guidance regarding visitation, QSO-20-39-NH-Revised, in this guidance CMS states:
    - While it is safer for visitors not to enter the facility during an outbreak investigation, visitors must still be allowed in the facility. Visitors should be made aware of the potential risk of visiting during an outbreak investigation and adhere to the core principles of infection prevention. If residents or their representative would like to have a visit during an outbreak investigation, they should wear face coverings or masks during visits, regardless of vaccination status, and visits should ideally occur in the resident's room. Facilities may contact their local health authorities for guidance or direction on how to structure their visitation to reduce the risk of COVID-19 transmission during an outbreak investigation.

Recent PA Health Alert Network Guidance

- PA-HAN-626 (replaces PA-HAN-609)
  - Provides guidance on core infection prevention and control measures for long-term care facilities and incorporates updates made by CDC
    - For instances where "fully vaccinated" was previously used to guide infection prevention and control measures, a person must be "up to date" with all recommended COVID-19 vaccine doses
    - Even if they have met community criteria to discontinue isolation or quarantine per PA-HAN-619, visitors should not visit if they have not met the same criteria used to discontinue isolation and quarantine for residents (typically 10 days)
    - Health care professionals should not work while acutely ill, even if COVID-19 testing is negative, in order to minimize the risk of transmission of other infectious pathogens, including respiratory pathogens such as influenza

Recent PA Health Alert Network Guidance

- PA-HAN-627 (Replaces PA-HAN-610)
  - Provides guidance on response to exposure and outbreaks of COVID-19 for long-term care facilities, incorporates changes made by the CDC. Major additions and edits include:
    - For instances where the term “fully vaccinated” was previously used- now a person must be “up to date” with all recommended COVID-19 doses
    - Residents in quarantine can be removed from TBPs after day 10 after exposure if they do not develop symptoms
    - Although10 day quarantine period is preferred, residents can be removed from TBPs after day 7 following exposure if viral test is negative for COVID-19, and they do not develop symptoms
    - Newly admitted residents and residents who have left the facility for greater than 24 hours, regardless of vaccination status should have a series of two viral test for COVID-19, and if negative another test 5-7 days after admission
    - In general testing is not necessary for asymptomatic people who have recovered from COVId-19 in the prior 90 days

Facility Response to a COVID-19 Outbreak Per Recent DOH Guidance

- An outbreak is defined as an occurrence of one or more cases of COVID-19 in any resident or HCP that meets the following criteria:
  - New nursing home onset of COVID-19 in a resident; or
  - New onset of COVID-19 in an HCP who working in the facility while infectious (during the 2 days prior to the symptom onset or positive test if asymptomatic)

Facility Response to a COVID-19 Outbreak Per Recent DOH Guidance

- Choose an outbreak response method:
  - Use of contact tracing to identify exposed residents, staff, and visitors; or
  - Use of unit-based approach to identify exposed residents, staff, and visitors; or
  - Use of facility-wide approach to identify exposed residents, staff, and visitors

  - Outbreak response method should take into consideration whether the facility has the experience and resources to perform individual contact tracing, the vaccination acceptance rates of staff and residents, whether the index case is a resident or HCP, and the extent of possible exposures

Facility Response to a COVID-19 Outbreak Per Recent DOH Guidance

- Response measures for all 3 response methods:
  - Increase monitoring of all residents to every shift to rapidly detect those with new symptoms
  - If there is a suspected case, and the test results for the suspect case are anticipated to take longer than 2-3 days, begin planning and implementing the outbreak response

Changes to COVID-19 Survey Activities and Increased Oversight in Nursing Homes, CMS Memo dated, November 12, 2021, QSO-22-02-ALL

- CMS expressed concern that due to COVID-19 there has not been enough focus by surveyors on quality of life and quality of care nursing
- CMS advises surveyors to focus on few key areas:
  - Resident Health and Safety
    - Unplanned weight loss
    - Pressure Ulcers
    - Abuse or neglect
    - Loss of function/mobility
    - Depression
  - Nurse Competency
  - Inappropriate Use of Antipsychotic Medication

January 7, 2022, QSO-22-08-NH

- CMS Memorandum, Nursing Home Staff Turnover and Weekend Staffing Levels
  - CMS will begin posting the following information for each nursing home on the Medicare.gov Care Compare website:
    - Weekend Staffing: The level of total nurse and registered nurse staffing on weekends provided by each nursing home over a quarter
    - Staff Turnover: The percent of nursing staff and number of administrators that stopped working at the nursing home over a 12-month period
      - Will be posting:The percent of RN staff that left the facility over the last year
      - The percent of total nurse staff that have left the facility over the last year
      - The number of administrators that left the facility over the last year
    - This information will be added to the Care Compare website in January 2022 and used in the Nursing Home Five Star Quality Rating System in July 2022

QSO-22-08-NH, cont.

- Posting Detailed Staffing Data: CMS will begin posting the submitted employee-level staffing data for all nursing homes
- Reminder for nursing homes to link employee identifiers when they are changed due to the changes in the facility's staffing data systems
  - It is critical that facilities use the methodology to link old and new employee identifiers together when these identifier change. If a facility does not do this, it will artificially increase its staff turnover rates

Top Cited Federal Tags Complaint and Annual Surveys

- F880 Infection Prevention and Control
  - Make sure to review in-service trainings for staff
  - Ensure proper documentation of in-service training attendance
  - Ensure that staff can recite to surveyors, facility infection prevention and control practice
- F689 Free of Accident Hazards/Supervision/Devices
  - Use systems approach to identify hazards, implement resident-centered approaches

Top Cited Federal Tags Complaint and Annual Surveys

- F684 Quality of Care
  - Review care plans and documentation to ensure that they are resident-centered
- F686 Treatment Services to Prevent/Heal Pressure Ulcers
  - Again, documentation is important, ensure proper in-service trainings on wound staging
- F609 Reporting of Alleged Violations of Abuse and Neglect
  - Ensure that staff is knowledgeable for reporting alleged violations? Does that staff know who to report to? Does staff know the reporting requirements, and process? Does staff know required time frames?

CMS Memo Issued December 28, 2021

- On December 28, 2021, CMS issued a memorandum, QSO-22-07-ALL, titled Guidance for Interim Final Rule– Medicare and Medicaid Programs; Omnibus COVID-19 Health Staff Vaccination
  - The Memorandum laid out the revised deadlines for compliance with the CMS vaccine mandate, and how the mandate would be enforced by CMS and the state licensing agencies.

Vaccine Requirements for Providers

- By January 27, 2022, facilities were required to:

- Have policies and procedures developed and implemented for ensuring all facility staff are vaccinated against COVID-19; and
- Ensure that 100% of staff have received at least one dose of a COVID-19 vaccine, have a pending request for an exemption, or have been identified as appropriate for a temporary delay per CDC guidance.

- If a facility meets these requirements, it will be considered to be compliant with the mandate.
- If less than 100% of staff who are not exempted or delayed have not received at least one dose of the COVID-19 vaccine, the facility will be considered to be non-compliant with the mandate.
- The facility will receive notice of its non-compliance with the 100% standard.
- A facility that is above 80% and has a plan to achieve 100% staff vaccination within 60 days will not be subject to enforcement action(s).
- Facilities that do not meet these benchmarks could be subject to enforcement action

Vaccine Requirements for Providers

- By February 26, 2022, facilities must:

- Have policies and procedures developed and implemented for ensuring all facility staff are vaccinated against COVID-19 and 100% of all staff have received at least one dose of a single-dose vaccine or all doses of a multi dose vaccine series (fully vaccinated), have been granted an exemption, or have been identified as appropriate for a temporary delay per CDC guidance.

- If a facility meets these requirements, it would be considered compliant under the mandate.
- If the facility is deemed non-compliant with the mandate, it will receive notice of its non-compliance.
- A facility that is above a 90% vaccination rate and has a plan to achieve 100% staff vaccination within 30 days would not be subject to additional enforcement action(s).
- Facilities that do not meet these benchmarks could be subject to enforcement action.

Vaccine Requirements for Providers

- By March 27, 2022, and thereafter, facilities failing to maintain compliance with the 100% standard could be subject to enforcement action.

When Will DOH Begin Surveying For Compliance With The Mandate?

- Beginning January 27, 2022, CMS has advised that it will begin surveying for compliance with the CMS standard as part of the following surveys:
  - Initial Certification
  - Standard Recertification or Reaccreditation
  - Complaint Surveys

Survey Process Updates for Tag F888

- To determine compliance with §483.80(i) surveyors will request from facility's:
  - Their COVID-19 vaccination policies and procedures,
  - The number of resident and staff COVID-19 cases over the last 4 weeks,
  - A list of all staff and their vaccination status
    - The staff list must include the percentage of vaccinated staff, and the position or role of each staff member (including individuals who are likely to be in contact with residents or other staff, regardless of frequency
    - Surveyors will be verifying facility's reporting of vaccine data to NHSN as part of their offsite preparation prior to going onsite for their surveys. Vaccination information reported to NHSN and vaccination information provided onsite to surveyors should be reasonably consistent (within 10% of each other)

Possible Enforcement Actions

- CMS has a variety of established enforcement remedies available. These include: civil monetary penalties, denial of payments, and—as a final measure—termination of participation from the Medicare and Medicaid programs.

Citing Non-Compliance – Scope and Severity

- Facility staff vaccination rates under 100% constitute non-compliance under the rule.
- The level of severity will be cited based on the level of harm, or likelihood of harm for residents.
  - Ex. Facilities with a high percentage of unvaccinated staff, several COVID-19 infections, and gaps in their policy and procedures, represent a higher risk of harm to residents, therefore, they would be cited at a higher level of severity compared to facilities with few unvaccinated staff, no COVID-19 infections, and compliant policies and procedures.

Severity Assessment

- Severity will be based on the following criteria:
  - Level 4- Immediate Jeopardy (IJ)
    - Noncompliance resulting in serious harm or death:
      - Did not meet the requirement of staff vaccinated or has no policies and procedures developed or implemented; and
      - 3 or more resident infections in the last 4 weeks resulting in at least one resident experiencing hospitalization (i.e., serious harm) or death. OR,
    - Noncompliance resulting in likelihood for serious harm or death:
      - Did not meet the requirement of staff vaccinated; and
      - 3 or more resident infections in the last 4 weeks and did not result in serious harm or death; and
      - One of the following:
        - Any observations of noncompliant infection control practices by staff; or
        - 1 or more components of the policies and procedures to ensure staff vaccination sere not developed or implemented.
      - OR,
      - More than 40% of staff are unvaccinated and there is evidence of a lack of effort to increase staff vaccination rates.
  - Level 3- Actual Harm that is not an IJ
    - Did not meet the requirement of staff vaccinated; and
    - 3 or more resident infections in the last 4 weeks which did not result in hospitalization (i.e., serious harm) or death, or the likelihood for IJ for one or more residents; and
    - 1 or more components of the policies and procedures were not developed

Severity Assessment

- Severity criteria cont.
  - Level 2- No actual harm w/ potential for more than minimal harm that is not IJ
    - Did not meet the requirement for staff vaccinated; and
    - No resident outbreaks
    - OR,
    - Did not meet the requirement of staff vaccinated; and
    - 1 or more components of the policies and procedures to ensure staff vaccination were not developed and implemented
  - Level 1
    - Met the requirement of staff vaccinated; and
    - 1 or more components of the policies and procedures to ensure staff vaccination were not developed and implemented

Scope Assessment

- Scope is based on the percent of staff vaccinated. CMS will base scope on the following criteria:
  - Isolated: 1% or more, but less than 25% of staff are unvaccinated (76%-99% are vaccinated)
  - Pattern: 25% or more, but less than 40% of staff are unvaccinated (61%-75% of staff are vaccinated)
  - Widespread: 40% or more of staff are unvaccinated (0%-60% of staff are vaccinated), OR 1 or more components of the policies and procedures listed above were not developed and implemented.

Scope and Severity Grid

How surveyors rank deficiencies

Severity	Scope: Isolated	Scope: Pattern	Scope: Widespread
Immediate jeopardy to resident health or safety	J	K	L
Actual harm that is not immediate jeopardy	G	H	I
Potential for more than minimal harm	D	E	F
Potential for minimal harm, substantial compliance exists	A	B	C

Nursing home surveyors use this matrix to rank deficiencies. The "severity" of the deficiency refers to the degree of harm, while the "scope" of the deficiency refers to the number of affected residents. These factors are combined to rank deficiencies on a scale from A through L. The ranking is then used to define specific levels of compliance and to select appropriate remedies.

Source: U.S. Department of Health and Human Services

CMS Vaccine Mandate -- Exemptions

- Medical Exemption
  - Available for recognized clinical contraindications to COVID-19 vaccines.
  - Temporary delay in vaccination may also be available for individuals due to "clinical precautions and considerations," which may include acute illness secondary to COVID-19, and individuals who received monoclonal antibodies or convalescent plasma for COVID-19 treatment.
- Medical Exemption Form should include:
  - Information specifying which of the available vaccines are contraindicated and the recognized clinical reasons for the contraindication;
  - A statement that the employee be exempted from vaccination due to recognized contraindications;
  - Licensed practitioner's signature and date;
  - Information indicating the practitioner is acting within the scope of her/his practice; and
  - Information indicating that the licensed practitioner is not the employee seeking exemption.

CMS Vaccine Mandate -- Exemptions

- Religious Exemption
  - Available to employees whose sincerely held religious belief, observance, or practice prevents them from being vaccinated against COVID-19.
  - EEOC guidance states: "an employer should assume that a request for religious accommodation is based on sincerely held religious beliefs. However, if an employer has an objective basis for questioning either the religious nature or the sincerity of a particular belief, the employer would be justified in making a limited factual inquiry and seeking additional supporting information."
- Religious Exemption Forms and Options
  - Simple Form
    - Explains the basis and sincerity of the religious belief, observance or practice AND why it prevents employee from being vaccinated; and,
    - OPTIONAL for employee to submit religious texts, statements from clergy, etc.
  - Complex Form
    - Asks a longer, more detailed series of questions that elicit more detailed information about the employee's religious belief, observance, or practice, when they came to believe that way, how it compares to their other beliefs, information about the religion itself, etc.

Exemption Considerations/Analysis

- Medical Exemption
  - Exemption is complete, signed, and dated by licensed practitioner.
  - LP is practicing within the scope of practice.
  - LP is not the employee requesting exemptions.
  - Clearly indicates employee’s contraindications.
  - Contraindications are recognized and clinically appropriate.

Exemption Considerations/Analysis con't.

- Religious Exemption
  - Employee clearly identifies religious belief and it does not appear to be merely philosophical, moral, or political.
  - Employee demonstrates the sincerity of the belief by explaining WHY the religious belief prevents vaccination.
  - There is no objective information that casts doubt on sincerity of belief or its religious nature. (e.g. first requested a medical exemption but submitted a religious exemption upon denial).

CMS Vaccine Mandate

- What policies and plans must providers develop?

  - The regulations (42 CFR § 483.80 and §483.430) require the following at a minimum:
    - Documentation that staff were provided education regarding the benefits and risks and potential side effects associated with the COVID-19 vaccine
    - Documentation that staff were offered the COVID-19 vaccine or information on obtaining the COVID-19 vaccine.

CMS Vaccine Mandate

- Documentation that vaccines were offered, and whether accepted or declined.
- A process for ensuring all staff (unless exempted) have received the first vaccine prior to providing care.
- A process for ensuring all staff (unless exempted) are fully vaccinated by the deadline.
- A process for ensuring implementing precautions to mitigate transmission by all staff not vaccinated.
- A process for tracking and securely documenting staff vaccination status.
- A process for tracking which staff have received booster(s).
- A process by which staff may request an exemption.

CMS Vaccine Mandate

- A process for tracking and documenting information from staff regarding exemption requests.
- A process for ensuring all appropriate documentation respecting a medical exemption is collected.
- A process for ensuring and tracking the vaccination status of all staff for whom the vaccination must be delayed.
- Contingency plans for staff who are not fully vaccinated.

Recommendations:

- Ensure Vaccination Policy is in place.
- Ensure a procedure is in place to evaluate and grant/deny requests for religious and/or medical exemptions.
- Communicate new deadlines within the organization.
- Have documentation of the above available for surveyors.
- If found non-compliant, implement a plan to bring within compliance.

Quality Measure Recalibration

- CMS recently announced the quality measure thresholds by which the 5 Star Quality Ratings are calculated will be recalibrated beginning in April of 2022
- Thresholds will increase at a rate of 50% of the previous rate of improvements and will recalibrate every 6 months. (For example, if there is an average rate of improvement of two percent, the QM rating thresholds would be raised one percent.)
  - The recalibration strategy was initially announced in October 2019, but with the onset of the COVID-19 pandemic the implementation was delayed

Fraud and Abuse/Compliance Issues

- During the pandemic, CMS and its contractors, as well as state agencies "paused" their routine audits and inspections of health care providers, both from a licensure and payment perspectives.
  - On the licensure side, many states instituted a "hold" on licensure activities and an extension of actual licenses beyond their effective dates. For providers in these states, it will be important to ensure that timely renewals are submitted, so that once these "holds" are released, updated licenses can be issued. It also may be important to advise any lenders, etc. of how the state has treated licenses during the pandemic.
  - It will also be important to be in contact with your local licensing agency, so that you can understand when the "inspection cycle" will begin again.

Fraud and Abuse/Compliance Issues

- From a payor perspective, we can expect the MACs, RACs, ZPICs, UPICs, and state agencies (and attorneys general) to increase their reviews over the coming year. Potential "issues" to address:
  - 3-Day Stay and "two midnight" rule;
  - Staffing issues, leading to "worthless service" allegations
  - Therapy and outpatient billing issues
  - Traditional "documentation" reviews (e.g. certs/recerts)
- "Worthless Service" theory:
  - Service so lacking in quality (e.g. deficiencies identified) or non-existent, that it is worthless, and not eligible for payment
  - Case law holds that a regulatory violation, alone, is not sufficient to trigger a "worthless service" claim

Fraud and Abuse/Compliance Issues

- Anti-Kickback Statute Safe Harbor Changes
  - Personal Services/Management Safe Harbor
    - No longer requires compensation to be set forth "in the aggregate, in total over the course of the contract"
    - So long as the methodology of payment is set forth in advance, and is consistent with FMV and not indexed to volume/value of referrals, this will be sufficient
    - As a practical matter, this will enable the vast majority of ancillary provider agreements to be structured to fit within the Safe Harbor
  - As always, it is important to review contractual arrangements not just from a business perspective, but also from a compliance perspective
    - Therapy Agreements and Medical Director Agreements are the "highest risk" ancillary provider agreements executed by long term care providers

Fraud and Abuse/Compliance Issues

- Compliance Plan Effectiveness
  - OIG Guidance to Health Care Boards
    - In 2012 and 2015, OIG released a Toolkit and Guidance for Health Care Boards
    - Coupled with the regulatory requirements now under Part 483, these documents provide a roadmap for review
  - In June 2020, DOJ Criminal Division again updated its guidance document, "Evaluation of Corporate Compliance Programs" discussing what, in its mind, constitutes an effective compliance plan. Three "fundamental questions":
    - Is the corporation's compliance program well designed?
    - Is the program being applied earnestly and in good faith? In other words, is the program adequately resourced and empowered to function effectively?
    - Does the corporation's compliance program work in practice?

Fraud and Abuse/Compliance Issues

- Compliance Plan Effectiveness
  - DOJ provides a "checklist" of features they consider important in a plan:
    - Risk Assessment
    - Development of Policies/Procedures
    - Training and Communication
    - Reporting and Investigation
    - Third Party Management
    - Mergers/Acquisitions
    - Adequate Funding and HR Resources
    - Incentives/Disciplinary Measures
    - Auditing/Monitoring/Testing
    - Remediation/Correction of Identified Misconduct

Fraud and Abuse/Compliance Issues

- To do list:
  - Review your Compliance Plan against OIG and DOJ guidance, and make revisions as necessary
  - Re-institute a compliance calendar, to ensure that Plan is implemented as designed
  - Identify "risk areas" of potential audit, and ensure that you have documentation systems in place to review
  - Consider re-institution of regular survey and billing self-audits (which are likely required under your Compliance Plan)
  - Conduct a review of recent ancillary provider agreements to ensure compliance with AKS and Stark Law (for Medical Director agreements)

Fraud and Abuse/Compliance Issues

- United States v. Walgreens Co
- The 60-day Repayment Rule imposes False Claims Act liability on providers that fail to refund overpayments received from Medicaid managed care plans
- In US v. Walgreens the government is alleging that Walgreens, acting through store manager and pharmacist Amber Reilly, knowingly submitted materially false information to TennCare for dozens of enrollees who lacked eligibility for Medicaid reimbursement. Walgreens did not return the over payment after it discovered the fraud. The government is alleging liability via the FCA
- Walgreens argued that it can not be vicariously liable under the FCA because it did not know about the fraudulent actions while they were taking place, and therefore had filed a motion to dismiss
- The Court held that a corporation can be held vicariously liable when it benefits from the fraud of a managerial agent who is acting within the scope if his or her employment
- The Court further found Walgreens should have known about it had an obligation to return the over payment to the government
- The Court denied Walgreen's motion to dismiss

Financial Compliance Issues

- Provider Relief Fund Distributions and Reporting Deadlines
  - Sept. 30, 2021: Deadline for reporting use of PRF funds received between April 10, 2020 and June 30, 2020 via Reporting Portal (deadline to spend these funds was June 30, 2021)
    - Note, there is a 60 day "grace period" ending Nov. 30, 2021, where recoupments will be stayed
  - Funds received between July 1, 2020 and Dec. 31, 2020 must be used by December 31, 2021, and reporting begins January 1, 2022 and ends March 31, 2022
  - Funds received between January 1, 2021 and June 30, 2021 must be used by June 30, 2022, and reporting begins July 1, 2022 and ends Sept. 30, 2022
  - Funds received between July 1, 2021 and Dec. 31, 2021 must be used by Dec. 31, 2022, and reporting begins Jan. 1, 2023 and ends March 31, 2023.
  - Funds received between January 1, 2022 and June 30, 2022 must be used by June 30, 2023 and reporting begins July 1, 2023– and ends September 30, 2023.

Financial Compliance Issues

- On June 11, 2021 HHS issued an updated notice regarding Provider Relief Fund (PRF) reporting requirements
  - Recipients who received one or more payments exceeding $10,000 total need to report their use of PRF payments by submitting the following information:
    - Health care related expenses attributable to Coronavirus that another source has not reimbursed and is not obligated to reimburse.
    - PRF payment amounts that were not fully expended on health care related expenses attributable to Coronavirus are then applied to patient care lost revenues.
  - Order of reporting:
    - Interest earned on PRF payments;
    - Other assistance received;
    - Use of SNF and Nursing Home Infection Control Distribution Payments(if applicable)
    - Use of General and Other Targeted Distribution Payments
    - Net Unreimbursed Expenses Attributable to Coronavirus
    - Lost Revenues Reimbursement

Financial Compliance Issues

- "Health care related expenses attributable to Coronavirus" are the actual expenses incurred over and above what has been reimbursed by other sources in the following categories:
  - Supplies
  - Equipment
  - Information Technology (IT)
  - Facilities
  - Other Health care related expenses

Financial Compliance Issues

- On June 11, 2021 HHS issued an updated notice regarding Provider Relief Fund (PRF) reporting requirements
  - Recipients of PRF payments can apply the payments towards lost revenue using one of the following options, up to the amount of their payment:
    - The difference between 2019 and 2020 actual patient care revenue;
    - The difference between 2020 budgeted and 2020 actual care revenue provided that the budget was established and approved prior to March 27, 2020; or
    - A revenue calculation based on any reasonable method of estimating revenue

Financial Compliance Issues

- Entities reporting a use of PRF funds for "Lost Revenue Attributable to Coronavirus" need to provide the information used to calculate the loss in revenue attributable to Coronavirus.
- Specifically, entities must report revenue/net changes from patient care (prior to netting with expenses) from 2020 by calendar year (quarterly) and by payer mix. Examples include:
  - Actual revenues/net charges received from Medicare Part A or B for patient care for the calendar year.
  - Actual revenues/net charges received from Medicare Part C for patient care for the calendar year
  - Actual revenues/net charges received from Medicaid / Children's Health Insurance Program (CHIP) for patient care for the calendar year
  - Actual revenues/net charges received commercial insurance for patient care for the calendar year
  - Actual revenues/net charges received from Self-Pay for patient care for the calendar year. (this includes uninsured individuals who pay for their health care
  - Actual gross revenues/net charges from other sources received for patient care services and not included in the list above for the calendar year.

Financial Compliance Issues

- Additionally, depending on the lost revenue calculation option selected, the following information must be included:
  - If you calculated lost revenue based on the difference between 2019 and 2020 actual patient care revenue, then you must submit Revenue from Patient Care Payer Mix for the 2019 calendar year (by quarter)
  - If you calculated lost revenue based on the difference between the 2020 budgeted revenue and 2020 actual patient care revenue then you must submit the 2020 budgeted amount of patient care revenue, a copy of the 2020 budget (which again, must have been approved prior to March 27, 2020), and an attestation from the CEO, CFO, or similarly responsible individual attesting that the exact budget being submitted was established and approved prior to March 27, 2020. (This attestation is made under 18 U.S.C. § 1001).
  - If you calculated lost revenue based on an alternative methodology you must submit a description of the methodology, a calculation of revenues lost attributable to coronavirus using the methodology, an explanation of why the methodology is reasonable, and a description establishing how lost revenue was attributable to Coronavirus and not another source.

Financial Compliance Issues

- What to do now for PRF
  - Develop "grid" for all funds received (federal and state)
  - Calendar the deadlines as currently in place (and assign appropriate facility representative to continually check HHS and state websites for updates)
  - Document the use of PRF funds received, within the allowable categories as noted above
  - Note that in September, the Biden Administration advised that it will soon be releasing another $25 Billion in "leftover" PRF funds to providers. The cycle begins again, so:
    - Look for emails/notifications from CMS on amounts to be distributed;
    - Review the new Terms and Conditions, to see what, if anything, has changed;
    - Plan for the use/documentation of the new funding to be received
- CMS will enforce the use/reporting requirements through the provisions of the CARES Act itself and through its anti-fraud statutory authorities, so it is critical to timely and accurately report and document use of PRF funds

Financial Issues Update

- Pennsylvania Distributions of ARPA Funds
  - NFs to see payments appear as a gross adjustment transaction/lump sum payment on the PROMISe remittance advice dated September 6, 2021, with payment occurring September 15, 2021.
  - PCHs and ALRs must complete the Facility Acceptance Form and return it, by October 15, 2021, to DHS at covidpayments@pa.gov.
- CHOW Issues
  - Medicare currently prohibits the "distribution" of PRF funds from Seller to Buyer during a CHOW
  - PA does not address in guidance, but conversations with counsel would indicate that such transfers are possible, per agreement of parties.

Questions and Conclusions

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