2021 Long Term Care Provider State and Federal Legal Update

2021 PACAH Spring Conference

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Introduction

- 2020 was a year filled with 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 and regulatory challenges left in the wake of COVID, as well as other important long term care issues from the past year.

COVID 19: An Ongoing Risk

- Numbers as of April 21, 2021:
- To date, Pennsylvania has had 1,122,662 confirmed COVID-19 infections.
- Pennsylvanians have experienced 25,879 deaths to COVID-19.
- COVID-19 cases for Nursing Homes and Personal Care Homes
  - Residents: 70,322
  - Staff: 14,671
  - Deaths: 13,058

Vaccines

- Pennsylvania is currently within Phase 2 of its vaccination rollout. All Pennsylvanians age 16 and older are eligible to receive a COVID-19 vaccine.
- Vaccination Numbers as of April 22, 2021:
  - Partial Vaccinations: 4,602,578
  - Full Vaccinations: 2,969,315
  - Total Vaccinations: 7,571,893

Legal Immunity and Liability Protections

- Pennsylvania Law
  - On May 6, 2020, Governor Wolf issued an executive order which extended immunity from civil liability to individual practitioners who provided care in response to the COVID emergency in a health care facility (SNF, PCH, or Assisted Living). This order remains in effect during the emergency declaration.
- Other States
  - Many states have passed grants issuing immunities for providers that also extend to LTC providers. The immunity extended typically applies to injuries, deaths, and health care decisions but does not protect against civil liability for acts of gross negligence or willful misconduct.
  - There is still considerable variance among state legislatures with some states (such as Alabama and Ohio) implementing new immunities, or expanding existing ones, while other states (such as New York and New Jersey) consider legislation that would remove liability protection from nursing and other such facilities.

Legal Immunity Under PREP Act

- The Public Readiness and Emergency Preparedness Act ("PREP ACT") extended immunity from civil liability for the manufacture, development, testing, distribution, administration, and use of countermeasures against public health emergencies, including pandemics.
  - The PREP Act covers the United States and those that manufacture, distribute, administer, prescribe, or use countermeasures.
  - Thus far the act's protections have only been applied to individual practitioners, nurses and physicians.
- In response to an increase in litigation targeting healthcare facilities, the Department of Health and Human Services issued an advisory opinion regarding the PREP Act on January 8, 2021.

Legal Immunity PREP Act HHS Guidance

- The advisory opinion addresses venue for cases or claims involving the PREP Act and the immunity provisions within the PREP Act.
- In the opinion HHS states that immunity under the PREP Act is intended to extend in situations where the provider has to “prioritize”, allocate, or make decisions on the use of a countermeasure.
  - If such decisions are made in accordance with a directive or guidance from a public authority, then immunity will still attach.
  - If scarcity prevents a provider from successfully delivering countermeasures to its patients, then immunity may still attach.
- Immunity will not attach for wanton or willful conduct resulting in death or serious injury.

Legal Immunity PREP Act HHS Guidance

- The HHS advisory opinion further states their stance that claims or cases involving the PREP Act must be litigated in Federal Court.
- Be aware that HHS's advisory opinion is interpretive guidance, stating their opinion to the manner in which the PREP Act should be interpreted. The advisory opinion does not carry force of law and is subject to change by HHS at anytime.
- Ultimately, this "theory of liability protection" will be evaluated and decided by the courts hearing these cases.

Legal Immunity Ongoing PREP Act Litigation

- In PA, a defendant citing the immunity argument found within the HHS advisory opinion was unable to remove the case from State to Federal Court.
  - Brighton Rehabilitation and Wellness Center was sued with the plaintiff claiming wrongful death resulting from the facilities failure to use countermeasures.
  - The Federal Court issued a ruling that because Brighton failed to provide countermeasures to the decedent, they were not immune from civil liability. The Court elaborated that immunity may not attach from inaction, only from actions taken to prevent the spread of COVID-19.
  - The Federal Court also denied the defense's claim that PREP act cases and claims are preempted by the federal government. Therefore, allowing State Courts to hear claims and cases relating to the PREP Act.
  - This case is currently ongoing in the Court of Common Pleas.
- The same pre-emption claim was raised by the defense team of Knollwood Nursing Home in Alabama in an attempt to get their case removed to Federal Court. The Court has yet to rule on the preemption matter in that case.

Legal Immunity: Liability Insurance

- Without a grant of immunity, LTC providers are subject to private causes of action (personal injury, medical malpractice, and wrongful death/survival, etc.) that may come from the residents of the facilities or their families, and the plaintiff's bar for COVID-related deaths.
- This issue is compounded further by the quickly rising costs and reductions in coverage of liability insurance.
  - Premiums prices in at least 14 states have seen costs increasing in excess of 10%. Premium price increases have been reported as high as 150% - 400% over 2020's rates in Kentucky.
  - Many insurance companies are considering limiting COVID-19 related coverage.
  - The rising costs and reduction of coverages may make it difficult for LTC providers to afford plans, which, may offer them limited protections against today's risks. This may encourage a financial crisis in the provider community.

Claim Mitigation

- Informed Consents
  - Informed consent is the process by which the provider engages the resident or resident representative to communicate risks and potential outcomes pertaining to rendering services to the resident.
  - Informed consent is intended to provide residents with an understanding of the provider's risk mitigation for their care without taking away their decision-making power.
  - Seeking informed consent from residents can help to mitigate the facilities liability in instances where consent would constitute a defense to the claim.

Continuing Risk Management Issues

- With the advent of the virus came inconsistencies in Federal and State governmental guidelines relating to COVID-19. What follows in 2021 are some of the ongoing challenges from 2020 and new guidance relating to vaccine distribution.
- Providers will need to consider ongoing mitigation efforts in conjunction with vaccinating staff and residents against the risk of contracting COVID-19 or a COVID-19 variant.
- Providers will need to continue to monitor and comply with any State or Federal mandates that may result from the vaccine or the ongoing COVID-19 crisis and should keep detailed records towards that end.

Continuing Risk Management Issues

COVID-19 Vaccine for Residents

- As an initial matter, there is no federal or state law which mandates that residents (at any level of the continuum) must receive the vaccine. Rather, current law is clear that residents have the right to refuse the vaccine.
- 1st Phase of Federal Pharmacy Partnership for Long-Term Care Program
  - CDC partnered with CVS and Walgreens to offer onsite COVID-19 vaccination services for residents of long-term care facilities (i.e., NF, PCH and ALR)
  - LTCF staff could also be vaccinated as part of the program.

Continuing Risk Management Issues

COVID-19 Vaccine for Staff and Residents of LTC Facilities

- On March 16, 2021, the Acting Secretary of the PA DOH issued on Order requiring skilled nursing care facilities to complete the COVID-19 vaccine needs assessment survey by 3/23/21.
  - As of April 1, 2021, the statewide average facility vaccination rate was a follows:
    - Residents – 78.84%
    - Staff – 52.64%
  - DOH will be leveraging federal COVID-19 vaccine allocations through the Federal Pharmacy Partnership for LTC Program to ensure the provision of vaccine to staff and residents of LTC facilities.
- LTC facilities can request COVID-19 vaccine from eligible Pennsylvania long term care pharmacies who in turn order from Federal LTC Pharmacy Partners receiving federal vaccine allocation.

Continuing Risk Management Issues

COVID-19 Vaccine for Staff and Residents of LTC Facilities Cont.

- The Federal LTC Pharmacy Partners consist of three Group Purchasing Organizations (GPOs) and CVS/Omnicare
  - GPOs – GeriMed, Innovatix and Managed Health Care Associates (MHA)
- MHA and CVS/Omnicare - limiting participation to those LTC pharmacies already in their network who became eligible pharmacies through the Federal Pharmacy Partnership and enroll in PA's State Immunization Information System (PA-SIIS).
- GeriMed - has the capacity to bring more LTC Pharmacies into their network.

Continuing Risk Management Issues

COVID-19 Vaccine for Staff and Residents of LTC Facilities Cont.

- Each LTC Pharmacy must sign CDC's COVID-19 Vaccination Program Provider Agreement for Pharmacies Serving LTC Facilities to participate and be deemed eligible and must also be enrolled in PA-SIIS.
- An eligible LTC Pharmacy will administer the vaccine on-site at the LTC facility or may use contractors (including a LTC facility) to perform some or all of the eligible pharmacy's duties under the Provider Agreement.
- NOTE: DOH's vaccine strategy is applicable to LTCFs and LTC Pharmacies in all counties except Philadelphia. Philadelphia's vaccine programs can be accessed via the following link: https://vax.phila.gov/index.php/covid-19/

Continuing Risk Management Issues

COVID-19 Vaccine for Residents – Consent

- Obtaining consent for COVID-19 vaccination
  - Competent resident v. incompetent resident
  - Provide EUA Fact Sheets for the applicable COVID-19 vaccine to resident or legal representative
- Challenges related to obtaining consent
  - Concerns about safety of vaccine
  - Contacting legal representative where resident lacks capacity

Continuing Risk Management Issues

COVID-19 Vaccine for Residents – Refusal

- In the absence of guidance to the contrary from CMS, DOH or DHS, what are the options for providers when a resident refuses the vaccine:
  - Informed Consent and Acknowledgement of Risk Document
  - Does a resident's refusal of the vaccine pose a risk to the resident's or other individual's health and/or safety?
  - Interventions and mitigating efforts to reduce risk of exposure to COVID-19 in the event resident refuses vaccine
- Note that the resident's "place" within the continuum (e.g., NF, PCH or ALR) will impact on a provider's options.

Continuing Risk Management Issues

Testing of Residents and Staff

Nursing facilities must continue to test residents and staff in accordance with QSO-20-38-NH, even after COVID vaccination.

- Test all staff and residents with signs or symptoms of COVID-19.
- Test all staff and residents if there is an outbreak.
  - An outbreak is defined as a new COVID-19 infection in any health care personnel or any nursing home-onset COVID-19 infection in a resident.
  - Staff and residents who test negative should be retested every 3 – 7 days until no new cases of COVID-19 infection are identified for at least 14 days since the most recent positive result.
- Routine testing of staff should occur based on the facility's county positivity rate:
  - If less than 5% then staff should be tested once per month
  - If 5% - 10% once per week
  - If greater than 10% twice per week
- Compliance with the testing requirements must be demonstrated through documentation.

Continuing Risk Management Issues

Temporary Suspension of TB Regulatory Requirement Due to COVID Vaccination

- 28 Pa. Code §201.22(j) provides that new employees at LTC facilities must have a 2-step intradermal skin test before employment unless there is documentation of a previous positive skin reaction
- CDC guidance relating to vaccination indicates that the 2-step TB skin test should not be given within 4 weeks after the COVID-19 2-dose vaccination process.
- To avoid any delay in the administration of the COVID-19 vaccine to staff, DOH has granted a temporary suspension of the requirement of 28 Pa. Code §201.22 (j) until the end of the Governor's Disaster Declaration
- Overview of requirements for facilities regarding TB testing during time of suspension

Continuing Risk Management Issues

Visitation

- On March 10, 2021 CMS revised QSO-20-39-NH regarding updated guidance for visitation during COVID-19.
- Outdoor Visitation
  - CMS notes that outdoor visitation is still preferred even when the resident and visitor are fully vaccinated against COVID-19. (NOTE: Fully vaccinated refers to a person who is ≥2 weeks following receipt of the second dose in a 2-dose series, or ≥2 weeks following receipt of one dose of a single-dose vaccine.)

Continuing Risk Management Issues

Visitation Cont.

- Indoor Visitation
  - Facilities should allow indoor visitation at all times and for all residents (regardless of the vaccination status of the resident or the visitor), except under the following scenarios that would limit indoor visitation for:
    - Unvaccinated residents, if the nursing home's COVID-19 county positivity rate is >10% **and** <70% of residents in the facility are fully vaccinated;
    - Residents with confirmed COVID-19 infection, whether vaccinated or unvaccinated, until they have met the criteria to discontinue Transmission-Based Precautions; or
    - Residents in quarantine, whether vaccinated or unvaccinated, until they have met criteria for release from quarantine.

Continuing Risk Management Issues

Visitation Cont.

- Indoor Visitation During an Outbreak
  - CMS provides that when a new case of COVID-19 among residents or staff is identified, a facility should immediately begin outbreak testing and suspend all visitation, until at least one round of facility-wide testing is completed. Visitation can resume based on the following criteria:
    - If the first round of outbreak testing reveals no additional COVID-19 cases in other areas (e.g., units) of the facility, then visitation can resume for residents in areas/units with no COVID-19 cases. However, the facility should suspend visitation on the affected unit until the facility meets the criteria to discontinue outbreak testing. (NOTE: Outbreak testing is discontinued when testing identifies no new cases of COVID-19 infection among staff or residents for at least 14 days since the most recent positive result.)
    - If the first round of outbreak testing reveals one or more additional COVID-19 cases in other areas/units of the facility (e.g., new cases in two or more units), then facilities should suspend visitation for all residents (vaccinated and unvaccinated), until the facility meets the criteria to discontinue outbreak testing.
    - If subsequent rounds of outbreak testing identify one or more additional COVID-19 cases in other areas/units of the facility, then facilities should suspend visitation for all residents (vaccinated and unvaccinated), until the facility meets the criteria to discontinue outbreak testing.

Continuing Risk Management Issues

Visitation Cont.

- Compassionate Care Visits
  - CMS notes that compassionate care visits and visits required under federal disability rights law should be allowed at all times, regardless of a resident's vaccination status, the county's COVID-19 positivity rate or an outbreak.
- Other CMS Visitation Guidance
  - If resident is fully vaccinated, they can choose to have close contact (including touch) with their visitor while wearing a well-fitting face mask and performing hand-hygiene before and after.
  - Visitors should not be required to be tested or vaccinated (or show proof of such) as a condition of visitation.
  - Federal and state surveyors are not required to be vaccinated and must be permitted entry into facilities unless they exhibit signs or symptoms of COVID-19. Surveyors should adhere to the core principles of COVID-19 infection prevention and adhere to any COVID-19 infection prevention requirements set by state law.

Continuing Risk Management Issues

- On 03/16/2021, DOH following revised CDC guidelines issued PA-HAN 559 updating its quarantine guidelines for persons exposed to COVID-19.
  - Guidelines for fully vaccinated residents
    - DOH recommends that fully vaccinated residents should continue to quarantine following prolonged close contact (within 6 feet for a cumulative total of 15 minutes or more over a 24-hour period) with someone with SARS-CoV2 infection.
    - Quarantine is no longer recommended for residents who are being admitted to a post-acute care facility if they are fully vaccinated and have not had prolonged close contact with someone with COVID infection in the prior 14 days.
- DOH summary of COVID-19 PA-HANs can be accessed via the following link:

  https://www.health.pa.gov/topics/Documents/HAN/COVID-19HANsummary.pdf

Impact of COVID-19 on PA DOH Reporting Requirements & Licensure Renewals

- Effective December 24, 2020, skilled nursing facilities are no longer required to report capacity data into the CORVENA software.
- SNFs still need to complete the survey data collection tool (Survey 123) daily.
- DOH has indicated that the extension on licenses that was granted on March 31, 2020 still continues and licenses will be issued as licensure surveys are able to be completed.
  - A renewed license will be in effect from the month that the survey was completed for the next year.

Senate Bill 1268 – Temporary Nurse Aides

- Requirements for temporary nurse aides to be added to PA Nurse Aide Registry
  - SB 1268 allows individuals who became employed as a temporary nurse aide during the declared federal COVID-19 emergency to enroll on the PA Nurse Aide Registry if they satisfy the following requirements:
    - Complete a training program and competency assessment authorized under the Centers for Medicare and Medicaid Services (CMS) COVID-19 pandemic waiver, including online training and an online examination; and
    - Have a minimum of 80 hours of temporary nurse aide or supervised practical nurse aide training, on-the-job training or 80 hours of regular in-service nurse aide education during the declared COVID-19 emergency under the supervision of a licensed or registered nurse; and
    - Demonstrate their skills competency to perform the duties of a nurse aide.

Senate Bill 1268 – Temporary Nurse Aides

- Requirements for temporary nurse aides to be added to PA Nurse Aide Registry
  - With respect to a temporary nurse aide ("TNA") demonstrating their skills competency, this can be achieved in one of three ways (NOTE: the TNA may choose only one option):
    - Pass the PA nurse aide examination; or
    - Be certified by a site administrator responsible for assessing the individual's competency skills as part of an approved apprenticeship program; or
    - Complete an assessment in all areas of required nurse aide training as provided for in 42 CFR 483.152(b) (relating to requirements for approval of a nurse aide training and competency evaluation program) by the hiring entity.

Senate Bill 1268 – Temporary Nurse Aides

- Requirements for temporary nurse aides to be added to PA Nurse Aide Registry
  - Once the employer and individual have attested (i.e., completed the attestation form) and declared to the Pennsylvania Department of Education ("PDE") that the requisite eligibility requirements have been met, the individual shall be deemed to have completed all nurse aide training and competency evaluation program requirements and shall have their name enrolled on the PA Nurse Aide Registry.
  - The attestation form and FAQs related to temporary nurse aides seeking enrollment on the PA Nurse Aide Registry can be accessed via PDE's website at the following link: https://www.education.pa.gov/K12/Career%20and%20Technical%20Education/Nurse%20Aide%20Training%20Program/TempNurseAide/Pages/default.aspx.

Government Enforcement During the COVID Pandemic

- Thus far in 2021, lapses in infection control measures have prompted considerable fines from CMS.
- Since the start of the COVID pandemic, CMS has issued more than $49 million in fines to nursing homes around the country citing infection control violations putting residents in “immediate jeopardy”.
- Oakmont Center for Nursing & Rehabilitation – CMS imposed a civil money penalty totaling $187,365 for infection control deficiency cited under F880.
- Sena Kean Manor – CMS imposed a civil money penalty totaling $119,020 for infection control deficiency cited under F880.

Updates to Nursing Home Compare & Five Star Quality Rating System Due to COVID-19

QSO 21-06-NH (12/4/20)

- On December 1, 2020 Care Compare replaced Nursing Home Compare and several other sites. All of the information from the old Nursing Home Compare website is available on the new site.
- Effective January 27, 2021, CMS resumed calculating nursing home health inspection ratings. Findings from the focused infection control inspections are used to calculate each nursing home's inspection rating.
- Effective January 27, 2021, CMS updated the quality measure rating by using data based on the data collection period ending June 30, 2020.

CMS Revised Criteria for Focused Infection Control Surveys

QSO-20-31-ALL; Issued 6/1/20; Revised 1/4/21

- CMS guidance issued on 6/1/20 provided that on-site focused infection control (FIC) surveys must be initiated within 3-5 days of identification of any nursing home with 3 or more new COVID-19 confirmed cases since the last NHSN COVID-19 report **or** 1 confirmed resident case in a facility that was previously COVID-free.
- CMS guidance updated on 1/4/21 to include the following additional criteria for triggering a FIC survey:
  - Multiple weeks with new COVID-19 cases;
  - Low staffing;
  - Selection as a Special Focus Facility;
  - Concerns related to conducting outbreak testing per CMS requirements; or
  - Allegations or complaints which pose a risk for harm or immediate jeopardy to the health or safety of residents which are related to certain areas, such as abuse or quality of care (e.g., pressure ulcers, weight loss, depression, decline in functioning).
- Nursing homes will be subject to a FIC survey if one of the original criterion is met (i.e., 3 or more new COVID-19 confirmed cases in the past week **or** 1 confirmed resident case in a facility that was previously COVID-free) **and** at least one of the new criterion noted above is met.

Ending of Select Emergency Blanket Waivers During COVID-19 Pandemic

QSO-21-17-NH (4/8/21)

- Effective May 10, 2021, CMS will end the following blanket waivers:
  - Waiver of requirements related to the timing of notifying residents prior to transfer and discharge to enable facilities to expeditiously cohort residents to prevent the transmission of COVID-19 to uninfected residents. (42 CFR §483.15(c)(4)(ii))
  - Waiver of requirements related to the timing of notifying residents of changes in rooms or roommates. (42 CFR §483.10(e)(6))
  - Waiver of requirements related to the timing of completing a baseline care plan and comprehensive care plan. (42 CFR §483.21(a)(1)(i), (a)(2)(i), and (b)(2)(i))
  - Waiver of timeframe requirements for completing and transmitting resident assessment information (MDS) in order to allow facilities to focus on resident care. (42 CFR §483.20)
    - NOTE: CMS blanket waiver of 42 CFR §483.20(k) related to the PASARR will remain in effect.

CARES Act

- Provider Relief Fund
  - In September of 2020, HHS announced $2 billion in incentive payments for nursing homes.
  - In October of 2020, HHS announced Phase 3 General Distribution of $24.5 billion.
- Reporting Timelines for General and Targeted Distributions
  - February 15, 2021 was the first reporting deadline for providers on the use of their PRF funds.
  - July 31, 2021 is the final deadline for providers who did not fully spend their PRF funds prior to December 31, 2020

Provider Relief Fund (PRF)

- On January 15, 2021 HHS issued a notice regarding 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.
  - 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

PRF Cont.

- “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

PRF Cont.

- 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.

PRF Cont.

- 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.

PRF Cont.

- An entity that received PRF payments for health care related expenses between $10,001 and $499,999 is required to report:
  - Health care expenses related to Coronavirus
  - Net of other reimbursed sources (payments from insurance, patients, federal, state, local governments, etc.) in general and administrative expenses and other health care related expenses (actual expenses incurred over and above what has been reimbursed by other sources).
    - General and administrative expenses attributable to Coronavirus are:
      - Mortgage / rent
      - Insurance
      - Personnel
      - Fringe benefits
      - Lease payments
      - Utilities / Operations
      - Other

PRF Cont.

- Any reporting entities with unused PRF funds after December 31, 2020 have until July 31, 2021 to submit a second and final report. The report must contain patient care related revenue amounts earned from January 1, 2021 to June 30, 2021.
- Any reporting entity that expended $750,000 or more in aggregated federal financial assistance during their fiscal year (including PRF payments) is subject to single audit requirements found in 45 CFR § 75.501 titled “Audit Requirements”.

The American Rescue Plan Act of 2021

- On March 11, 2021 President Biden signed the American Rescue Plan Act of 2021.
- The ARP has allocated $450 million for assisting SNFs with Covid-19 infections and protocols.
  - Specifically, the bill allocates $200 million to HHS for the development and dissemination of Covid-19 protocols by quality improvement organizations; and
  - $250 million to both states and territories in order to fund and deploy strike teams to SNFs experiencing Covid-19 outbreaks.
- The ARP also provides $100 million to the Occupational Health and Safety Administration (OSHA) with a minimum of $5 million devoted to COVID-19 enforcement activities at high-risk workplaces including health care.
  - This may correlate with a rise in OSHA related enforcement actions later in the year.

American Rescue Plan Act (ARP)

- Funding for Rural Providers
  - The bill further allocates $8.5bn to HHS to pay rural providers for health care related expenses and lost revenue attributable to Covid-19.
  - The above funding will be available through an application process created by HHS. In order to qualify for a payment from HHS a rural provider must:
    - Be enrolled in either Medicare or Medicaid
    - Provide diagnosis, testing, or care for individuals with possible or actual Covid-19 cases; and
    - Be a rural provider or supplier
    - Have eligible health care related expenses related to Covid-19; or
      - Expenses to prevent, prepare for, and respond to Covid-19 including the purchasing of PPE, maintaining staff, building new facilities, etc.
    - Have "Lost Revenue Attributable to Coronavirus"
      - Lost revenue attributable to coronavirus or lost revenue attributable to covid-19 is determined by calculating operating revenue from patient care sources. Shareholder and partnership payments are not included in the calculation
      - If the provider had an established and approved budget prior to March 27 of 2020 then the difference between the budgeted and actual revenue meets with the definition of "lost revenue attributable to Coronavirus"
  - Providers must not have received funding from another source to cover the applicable expenses or loss in revenue

ARP Cont.

- Are you a rural provider or supplier?
  - Rural providers or suppliers are those who:
    - Are located in a rural area; or
    - Are treated as being located in a rural area; or
    - Are located in an area serving rural patients (as defined by HHS) which may include (but isn't required to include), a metropolitan statistics area with less than 500,000 people based on the most recently available population data; or
    - Are rural health clinics; or
    - Provide home health, hospice, or long-term services and supports in an individual's home in a rural area; or
    - Are any other rural provider or supplier as defined by HHS.
- "Rural Area" is loosely defined by HHS as an area outside of a metropolitan statistics area with a population of more than 1 million.

Paycheck Protection Program (PPP)

- Under the Biden administration the PPP has been modified to reflect the following:
  - Sole proprietors, independent contractors, and self-employed individuals are eligible for additional funding based on revised funding formulas for these applicants
  - Small business owners with prior non-fraud felony convictions are now eligible for PPP loans
  - Small business owners with student loan debt delinquency are now eligible for PPP loans
  - Lawful U.S. residents who are non-citizens and small business owners can apply for PPP utilizing their Individual Taxpayer Identification Number (ITIN)
  - The PPP application deadline has been extended to May 31, 2021
  - PPP authorizations have been extended through June 30, 2021

PPP Cont.

- First time (first draw) PPP loan borrowers are eligible if:
  - The are a sole-proprietor, independent contractor, or self-employed person
  - They are a small business with a small business concern that meets the Small Business Administration's (SBA) size standards (either industry size or alternative size standard).
  - The industry size standard for SNFs is $30 million
  - They are a business or non-profit with:
    - 500 or less employees, or
    - That meets the SBA industry size standard if more than 500 employees
- Second draw PPP loan borrowers are eligible if:
  - They previously received a first draw PPP loan and will or has used the full amount for authorized uses
  - Has no more than 300 employees; and
  - Can demonstrate at least a 25% reduction in gross receipts between comparable quarters in 2019 and 2020

PPP Cont.

- These eligibility criteria have been further expanded by the American Rescue Plan Act (ARP) enacted March 11, 2021 as follows:
  - First Draw:
    - Tax exempt non-profits pursuant to 501(c)(3) of the Internal revenue Code that employ not more than 500 employees per physical location are eligible
    - Tax exempt non-profits described in any section of 501(c) of the Internal Revenue Code other than those outlined in paragraphs (3), (4), (6), or (19) that employs 300 or less employees per physical location and the organization does not receive more than 15% of its receipts from lobbying activities, the lobbying activities of the organization do not comprise more than 15% of the total activities of the organization, the cost of lobbying activities of the organization does not exceed $1 million during the most recent tax year that ended prior to February 15, 2020.

PPP Cont.

- The ARP expanded eligibility for second draw applicants as follows:
  - An entity is eligible for a second draw PPP loan if it is a 501(c)(3) non-profit organization, an additional covered non-profit entity, or an eligible 501(c)(6) organization, and employs not more than 300 employees per physical location of the entity.
- The ARP further amended PPP Loan Forgiveness with the following restrictions:
  - Payroll costs not eligible for forgiveness include:
    - Qualified wages taken into account in determining the employee retention credit under 2301 of the CARES Act
    - The employee retention credit under 3134 of the Internal Revenue Code; or
    - The disaster credit under 303 of the Relief Act; and
    - Premiums for COBRA continuation coverage considered in determining the credit under 6423 of the Internal Revenue Code.

Patient Driven Payment Model (PDPM) Changes

- CMS issued a final rule for fiscal year 2021 on July 31st, 2020.
- The rule increases aggregate Medicare program payments to SNFs by $750 million in total (a 2.2% increase from FY 2020).
- The rule made changes to geographic delineations provided by OMB that identify a provider as either “urban” or “rural” in addition to a 5% cap on decreases in a provider’s wage index from FY 2020 to FY 2021.
- The rule made changes to the SNF Value Based Purchasing (VBP) Program adjusting the federal per diem rate applicable to each SNF by 2% and then redistributing 50 – 70% of said reduction as incentive payments for SNF performance
- The estimated economic impact on SNFs of the VBP change is a reduction of $199.54 million in aggregate payments to SNFs in 2021.

Patient-Driven Payment Model (PDPM) Implementation

- PDPM went into effect on October 1st, 2019.
- In 2019 PDPM increased the average per diem reimbursement rate from $562.89 to $614.96.
- In April 2021, CMS determined that the PDPM actually increased payments to nursing homes by about 5% in fiscal 2020, for a total gain of $1.7 billion.
- CMS is considering changes, given that the “goal” of the PDPM was to achieve budget neutrality.
  - What impact did COVID have here? Will CMS propose reductions?

OIG/Fraud and Abuse

- U.S. ex rel. Jackson v. DePaul Health Sys., 454 F. Supp. 3d 481 (E.D. Pa. 2020).
  - In a qui tam relator suit (or whistleblower action as it may be more commonly known) following allegations that the facility was understaffed, provided substandard care, and must have submitted fraudulent federal compliance forms; the Court found that:
  - “a nursing home that does not care for its residents in a way that promotes their quality of life may be liable under a worthless service theory.” However, liability under this theory requires that noncompliance must be so great “that effectively no services were provided”.
  - Non-compliance based on the written regulations isn’t sufficient to meet this standard for liability.

OIG/Fraud and Abuse

- In 2020:
  - On September 30 the DOJ released an update relating to ongoing efforts to combat health care fraud and abuse having focused on enforcement pertaining to issues in telehealth, opioids, durable medical equipment, and genetic/other diagnostic testing.
  - DOJ enforcement in 2020 accounted for $4.5 billion in alleged fraud loss relating to telemedicine fraud and abuse alone
  - OCR continued pursuit of its Rights of Access Initiative targeting non-compliance with HIPAA
- Areas to watch in 2021:
  - The federal government has devoted large amounts of funding to responding to Covid-19 and will seek to recoup said funding from facilities that use money in a non-compliant or fraudulent manner
  - Expiration of Covid-19 agreements and flexibilities will open the door to liability for facilities that were operating under special parameters
  - As telehealth expands and is clarified by regulation DOJ will continue to heavily scrutinize telehealth
  - HHS has specifically indicated that HRSA will view loss of revenue determinations based on alternative revenue methodology with heightened scrutiny.

HIPAA

- In December 2020, OCR proposed a number of changes to the HIPAA Privacy Rule. In March 2021, OCR extended the comment period for the proposed regulations to May 2021. The proposed changes include:
  - Allowing patients to inspect their PHI in person and take notes or photographs of their PHI.
  - Changing the maximum time to provide access to PHI from 30 days to 15 days.
  - Requests by individuals to transfer ePHI to a third party will be limited to the ePHI maintained in an EHR.
  - Individuals will be permitted to request their PHI be transferred to a personal health application.
  - States when individuals should be provided with ePHI at no cost.
  - Covered entities will be required to inform individuals that they have the right to obtain or direct copies of their PHI to a third party when a summary of PHI is offered instead of a copy.
  - HIPAA-covered entities will be required to post estimated fee schedules on their websites for PHI access and disclosures.

HIPAA

- Proposed Privacy Rule Changes (continued)
  - HIPAA-covered entities will be required to provide individualized estimates of the fees for providing an individual with a copy of their own PHI.
  - Pathway created for individuals to direct the sharing of PHI maintained in an EHR among covered entities.
  - Healthcare providers and health plans will be required to respond to certain records requests from other covered health care providers and health plans, in cases when an individual directs those entities to do so under the HIPAA Right of Access.
  - The requirement for HIPAA covered entities to obtain written confirmation that a Notice of Privacy practices has been provided has been dropped.

HIPAA

- Proposed Privacy Rule Changes (continued)
  - Covered entities will be allowed to disclose PHI to avert a threat to health or safety when harm is “seriously and reasonably foreseeable.” The current definition is when harm is “serious and imminent.”
  - Covered entities will be permitted to make certain uses and disclosures of PHI based on their good faith belief that it is in the best interest of the individual.
  - The addition of a minimum necessary standard exception for individual-level care coordination and case management uses and disclosures, regardless of whether the activities constitute treatment or health care operations.
  - The definition of healthcare operations has been broadened to cover care coordination and case management.
  - The Armed Forces permission to use or disclose PHI to all uniformed services has been expanded.
  - A definition has been added for electronic health record.

21st Century Cures Act of 2020

- Pursuant to the Cures Act, health care providers, which is defined under the Act as including skilled nursing facilities and nursing facilities, are subject to the information blocking provisions as of April 5, 2021.
- In general, information blocking is a practice by a health care provider, health information technology (IT) developer of certified health IT, health information network, or health information exchange that, except as required by law or specified by the Secretary of Health and Human Services (HHS) as a reasonable and necessary activity, is likely to interfere with access, exchange, or use of electronic health information (EHI); and, if conducted by a health care provider, such provider knows that such practice is unreasonable and is likely to interfere with, prevent or materially discourage access, exchange, or use of EHI.

21st Century Cures Act of 2020

- The following are some examples of practices that could constitute information blocking:
  - Practices that restrict authorized access, exchange, or use under applicable state or federal law of such information for treatment and other permitted purposes under such applicable law, including transitions between certified health information technologies (health IT);
  - Implementing health IT in nonstandard ways that are likely to substantially increase the complexity or burden of accessing, exchanging, or using EHI;
  - Implementing health IT in ways that are likely to:
    - Restrict the access, exchange, or use of EHI with respect to exporting complete information sets or in transitioning between health IT systems; or
    - Lead to fraud, waste, or abuse, or impede innovations and advancements in health information access, exchange, and use, including care delivery enabled by health IT.

21st Century Cures Act of 2020

- Two “categories” of exceptions:
  - Exceptions that Involve Not Fulfilling Requests to Access, Exchange or Use EHI
    - Preventing Harm Exception
    - Privacy Exception
    - Security Exception
    - Infeasibility Exception
    - Health IT Performance Exception
  - Exceptions that Involve Procedures for Fulfilling Requests to Access, Exchange, or Use EHI
    - Content and Manner Exception
    - Fees Exception
    - Licensing Exception
- The Office of the National Coordinator for Health Information Technology (ONC) has provided several FAQs related to the information blocking provisions that you may find helpful, which can be accessed via the following link: https://www.healthit.gov/curesrule/resources/information-blocking-faqs.

Telehealth

- Telehealth or Telemedicine (used here interchangeably, be mindful that different statutes or regulations may make distinctions between telehealth and telemedicine) is employing secure two-way, real-time, interactive communication between patient and practitioner.
- In light of the COVID-19 Pandemic, telehealth has found its way into the majority of health care services that do not require provider to patient face to face interaction.
- Staffing shortages continue to plague LTC Providers.
  - Telehealth may be able to provide an incentive to attract practitioners and specialized providers.

Telehealth (PA Law)

- In 2020, Governor Wolf issued guidance to indicate that Licensed Health Care Practitioners are able to provide telehealth services to Pennsylvanians.
- In order to provide telehealth services to a patient in PA
  - Local practitioners need to be licensed under the Department of State's Bureau of Professional and Occupational Affairs (BPOA) in order to engage in Telehealth.
  - Out of state providers can see in state patients but to do so they must:
    - Be licensed and in good standing in their home state, territory, or country.
    - Provide the PA board they would seek a license from with their full name, home or work address, telephone number, email address; and
    - Their license type, license number, or other identifying information that is unique to the practitioner's license, and the state or government body that issued the license.

Telehealth

- Practitioners may rely on various services that allow for direct video chats, Zoom, Skype, Microsoft Teams, FaceTime, and others.
  - There is no penalty for using a non-public audio or video communication product if the provider acted in good faith in the provision of services using telehealth.
- Providers should inform patients about potential information and privacy risk from the use of third-party applications.
  - Providers should enable all encryption and privacy mode options for telehealth visits.

Telehealth (Federal Law)

- As long as the COVID-19 PHE lingers, Medicare will make payments for professional services provided to Medicare beneficiaries country-wide and in all settings.
- The final rule from CMS regarding fiscal year 2021 that was published on December 1, 2020 also contained provisions which expanded Medicare coverage of telehealth services (effective January 1, 2021).
  - Some services were permanently added to the Medicare telehealth services list as Medicare covered services.
  - Some services will be covered by CMS until December of 2021
  - The remaining telehealth services are covered by Medicare only until the expiration of the PHE.

Telehealth Liability

- The use of telehealth services may invoke provider liability through violations of HIPAA.
  - Thought the nature of the appointment and the meeting may be different the provider still has a responsibility to protect the patient's health information.
  - This means being cognizant of the settings in which appointments are conducted and ensuring the use of appropriate privacy protection measures for telehealth visits.
- The False Claims Act
  - Providers may expose themselves to False Claims Act liability if they certify a payment to CMS but failed to comply with the conditions CMS outlines for that service. As an example, a provider who certifies to CMS that they conducted an appointment using two-way video technology, who in fact did not utilize two-way video technology, would be submitting a false claim to CMS for that service.

Medical Marijuana

- Marijuana is defined as “all parts of the plant *Cannabis sativa L.,* whether growing or not, the seeds thereof; the resin extracted from any part of such plant; and every compound, manufacture, salt, derivative, mixture, or preparation of such plant, its seeds or resin.” 21 U.S.C. § 802(16)(1971).
- Marijuana contains excess of .3% tetrahydrocannabinol (THC). Substances below .3% THC are typically not considered to be intoxicating substances.
- Marijuana has been demonstrated to have wide ranging application as a medicinal tool for mental and physical ailments.
- Federal law has Marijuana classed as a Schedule 1 Drug under the Controlled Substances Act. 21 U.S.C. § 1308.11 1971. In spite of this, many states including PA have passed laws making Medical Marijuana legal.

Medical Marijuana Conflicts and Liability

- 42 C.F.R. § 483.10 regarding resident's rights provides that residents have a right to the accommodation of their needs, freedom of choice, and self administration of medications.
  - Can Medical Marijuana be considered a resident need?
  - Does the facility prevent the resident from using Medical Marijuana?
- Marijuana related liability can come from wide ranging sources
  - An individual or entity convicted of a felony relating to the unlawful manufacture, distribution, prescription, or dispensing of a controlled substance can be excluded from federal health care programs.
  - CMS accreditation opens the door for CMS to impose penalties, restrict federal funding, or exclude a provider for allowing patients to engage in medical marijuana use.

Miscellaneous Updates

- *California v. Texas* is still pending before the Supreme Court presenting challenges to the Affordable Care Act (ACA).
  - The Court will need to determine if the plaintiffs have standing to sue, and
  - If the ACA can be severed from the individual mandate.
  - The Court is expected to hear the case before the end of its current term (October 2021).

Miscellaneous Updates

- In 2019 HHS announced proposed changes to the Anti-Kickback Statute (AKS) and the Stark Law.
- The Biden administration however on January 20, 2021 paused final rules from the Trump administration from going into effect.
- The changes would, if implemented at a later date, align the AKS Personal Services Safe Harbor with the personal service arrangements exception to the Stark Law. This would alleviate difficulties with establishing the safe harbor under the AKS.
- Pending changes to DOH licensure regulations – by the end of the Wolf Administration?

Conclusions

- The COVID pandemic continues to be the overriding “issue” affecting the health care industry as a whole and is causing a re-evaluation of the way that care is delivered and paid for.
- We will continue to see the effects of the pandemic in changes to payment systems and licensure/certification requirements, as well as the expected mergers, sales and consolidation of health care providers.
- As always, providers need to pay close attention to the changes proposed and implemented by government oversight agencies.

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