

Risk Management Bootcamp

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Introduction

- 2020 and 2021 to date have been 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-19, and how providers can address/manage the risks associated 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

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Overview of "Risk Areas" To Address Today

- Industry Immunity and Liability Concerns
- Operational challenges and risks in response to CMS Regulatory and Guidance throughout the COVID-19 pandemic
- Responding to financial challenges during COVID-19 and in the wake of multiple governmental funding programs
- HIPAA and Compliance challenges resulting from COVID-19 and the "re-invigoration" of governmental oversight
- Corporate and transaction challenges impacted by COVID-19

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Immunity and Liability Issues

- Today, the overriding legal question resulting from the governmental and private sector responses to COVID-19 involves the determination of responsibility and liability.
 - Long term care providers serve the population most vulnerable to the effects of COVID-19.
 - The plaintiffs' bar has already begun to initiate suits against providers on behalf of residents who were infected and died as a result of COVID-19.
 - Governmental agencies have also sanctioned providers for their actions, or lack thereof, in fighting COVID-19.
- In these actions, what level of responsibility falls on the facility? How do we accurately and fairly assess liability?

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Immunity and Liability Issues

- Liability must be analyzed by examining what the facility did or did not do in the context of the resources available to it and the government guidance and mandates in effect at the time.
- What actions/inactions of the provider may have affected the ability to respond?
 - Accepting COVID-positive patients without protocols to protect other residents?
 - Failure to have sufficient staff and PPE?
 - Failure to initially "cohort" residents?
 - Failure to follow governmental protocols once those were announced
- What government guidance or mandates were in effect at the time and what resources were available to the provider?
 - Orders to admit COVID-positive patients from the hospital to the LTC facility?
 - Sufficiency of available tests and testing labs?
 - Sufficiency and availability of PPE?
 - Closure, quarantine and social distancing orders
 - Delay in providing industry-specific guidance to providers

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Immunity and Liability Issues

- 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-19 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.
- Federal Law

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Immunity and Liability Issues

- The Public Readiness and Emergency Preparedness Act ("PREP Act") granted liability immunity for the manufacture, development, testing, distribution, administration and use of countermeasures (e.g. vaccines, PPE, etc.) against public health emergencies, including pandemics, and is applicable to the nation's COVID-19 response.
- On its terms, the PREP Act grants immunity to the United States, and those that manufacture, distribute, administer, prescribe or use countermeasures (i.e. "covered persons")
- The LTC industry requested clarification from CMS that facilities were included as "covered persons", and until January 2021, no confirmation was provided.
- 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.

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Immunity and Liability Issues

- HHS Advisory Opinion
 - Signed on January 8, 2021, Advisory Opinion 21-01 addresses the applicability of the PREP Act to lawsuits involving nursing homes and other health care providers.
 - Specifically, the AO was designed to address cases involving allegations that the facilities either failed to provide staff with PPE, failed to teach staff how to properly use such PPE, or failed to ensure that staff used the PPE that it had been given.
 - In response to growing number of cases, filed primarily in state courts, which raise issues relating to health care providers' use of countermeasures (such as the use of PPE) to combat the COVID-19 pandemic.

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Immunity and Liability Issues

- HHS Advisory Opinion
 - The first issue addressed by the AO is a legal one, involving "preemption", a term that refers to situations where federal law controls, and essentially "overrides" any state law claims that could be pursued.
 - HHS concludes that the PREP Act completely preempts all state court jurisdiction, meaning that all cases/claims implicating the PREP Act must be litigated exclusively in federal court.
 - Practically speaking, this means that if a patient files a lawsuit against a health care facility in a state court, the defending provider could move to have the case removed to the applicable federal district court.

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Immunity and Liability Issues

- HHS then addressed when the immunity provisions of the PREP Act are triggered:
 - "... A covered person shall be immune from suit and liability under Federal and State law with respect to all claims for loss caused by, arising out of, relating to, or resulting from the administration to or the use by an individual of a covered countermeasure, ..."
 - Immunity "applies to any claim for loss that has a causal relationship with the administration to or use by an individual of a covered countermeasure, including a causal relationship with the design, development, clinical testing, or investigation, manufacture, labeling, distribution, formulation, packaging, marketing, promotion, sale, purchase, donation, dispensing, prescribing, administration, licensing or use of such countermeasure"

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Immunity and Liability Issues

- Based on its review of the PREP Act's language, HHS concluded that:
 - The immunity provisions of the PREP Act are intended to cover situations where a provider must "prioritize" or allocate countermeasures (e.g., PPE or vaccines) or make decisions on whether to utilize a particular countermeasure.
 - Such "program planning" is expressly governed by the language of the PREP Act, and if decisions are made in accordance with a public authority's directive or guidance, then the liability protections would attach.
 - Further, to the extent that a scarcity of PPE or other countermeasures exist, and as a result, the provider fails to deliver such countermeasures to its patients, immunity under the PREP Act may still attach.

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Immunity and Liability Issues

- The PREP Act does not provide immunity to all conduct:
 - Significantly, the PREP Act does not provide immunity for "wanton or willful" conduct that results in death or serious injury.
 - For example, if a provider willfully failed to purchase PPE or attempt to purchase such PPE, or its conduct in delivering the PPE or other countermeasures was wanton and caused death or injury, then liability protections would not apply, and the case would proceed in federal court.
- In the opinion, HHS states that immunity under the PREP Act is intended to extend in situations where the provider must "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.

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Immunity and Liability Issues

- Applicability of Advisory Opinion
 - An Advisory Opinion is just that – a document that sets forth the current views of HHS. It does not have the force of law, and is not binding on a court to follow.
 - It is also subject to modification by HHS. We do not yet know what position the Biden Administration will take on this AO, as they have yet to address it.
 - However, given that immunity protections specifically designed for health care facilities and other senior service providers have not been issued by either the federal government or many states to date, this Advisory Opinion does offer guidance to providers and courts in connection with pending COVID-19 litigation matters.

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Immunity and Liability Issues

- While this AO is directed primarily at a facility's use of PPE countermeasure, the concepts here also should apply to the vaccines as countermeasures, and may also provide immunity for the implementation of the vaccine.
- Ultimately, this "theory of liability protection" will be evaluated and decided by the courts hearing these cases.
 - According to Politico, there are currently approximately 200 wrongful death lawsuits pending against nursing homes in the country, with more expected.
 - Most courts in these cases have yet to address this issue, but at least 30 decisions have gone against the providers and PREP Act protection was denied.
 - There are a few cases where the courts have applied PREP Act immunity to long term care providers. These cases have been very "fact specific", and while analogies can be drawn, each case will turn on its own facts.
 - But courts are referencing the Advisory Opinion in these cases.

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Immunity and Liability Issues

- 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.

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Immunity and Liability Issues

- 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 plaintiffs' bar for COVID-19-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.

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Immunity and Liability Issues

- Claim/Mitigation, and What to Do
 - Documentation of compliance efforts:
 - Develop a "timeline" of Guidance issued by Government, and your facility's responses and actions taken as a result;
 - Document how you tried to comply with guidance issued;
 - Document how you assessed need for PPE and what training you provided to staff;
 - Document vaccine roll-out efforts for residents and staff.
- 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 facility's liability in instances where consent would constitute a defense to the claim.

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COVID-19 Vaccine Issues for Residents

- CMS Interim Final Rule – COVID-19 Vaccine Immunization Requirements for Residents and Staff (QSO-21-19-NH); Effective 5-21-21
 - F887: COVID-19 Immunization
 - LTC facilities must develop policies and procedures to educate residents or resident representatives and staff regarding the benefits and risks and potential side effects associated with the COVID-19 vaccine and offer the vaccine unless it is medically contraindicated or the resident or staff member has already been immunized.
 - All residents and/or resident representatives and staff must be educated on the COVID-19 vaccine they are offered, in a manner they can understand, and receive the FDA COVID-19 EUA Fact Sheet before being offered the vaccine.
 - Residents and their representatives have the right to refuse the COVID-19 vaccine in accordance with 42 CFR § 483.10(c)(6) (F578).

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COVID-19 Vaccine Issues for Residents

- 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 when a resident lacks capacity
- Risk management strategies to address a resident's refusal of the vaccine:
 - Informed Consent and Acknowledgement of Risk Document subject to State laws
 - Interventions and mitigating efforts to reduce risk of exposure to COVID-19 in the event resident refuses vaccine

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Compliance Issues Related to Visitation

- CMS revised QSO-20-39-NH regarding updated guidance for visitation during COVID-19. (Revised 3-10-2021 and 4-27-21).
- Develop policies and procedures regarding visitation consistent with CMS guidance.
- The core principles of COVID-19 infection prevention should be adhered to at all times.
- Outdoor Visitation
 - CMS notes that outdoor visitation is still preferred even when the resident and visitor are fully vaccinated against COVID-19.

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Compliance Issues Related to Visitation

- 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.
 - How does CMS interpret "at all times" as indicated above?

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Compliance Issues Related to Visitation

- 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.

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Compliance Issues Related to Visitation

- 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 in accordance with CDC guidance.
 - Visitors should not be required to be tested or vaccinated (or show proof of such) as a condition of visitation.
 - Overview of CMS guidance regarding communal activities and dining.
 - 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

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Infection Control Compliance Issues Under F880

- 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.

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Enhanced Enforcement for Infection Control Deficiencies Under F880

Scope of Severity of Deficiency	Non-compliance for infection control deficiency when cited in last year (or on last std. survey)	Non-compliance for infection control deficiency cited again in the last year (or last std. survey)	Non-compliance that has been cited for infection control deficiencies 3 times or more in the last 2 years (or twice since second to last std. survey)	Nursing home cited for current non-compliance with infection control deficiencies at harm level regardless of past history	Nursing home cited for current non-compliance with infection control deficiencies at Li level regardless of past history
D, E	• Directed POC	• Directed POC • Discretionary DPMA w/45 days to demonstrate compliance • \$15,000 Per Instance CMP up to \$5,000	• Directed POC • Discretionary DPMA w/30 days to demonstrate compliance • \$15,000 Per Instance CMP or per day as long as total amount exceeds \$15,000		
F	• Directed POC • Discretionary DPMA w/45 days to demonstrate compliance	• Directed POC • Discretionary DPMA w/45 days to demonstrate compliance • \$10,000 per Instance CMP	• Directed POC • Discretionary DPMA w/30 days to demonstrate compliance • \$20,000 Per Instance CMP or per day CMP as long as the total amount exceeds \$20,000		

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Enhanced Enforcement for Infection Control Deficiencies Under F880

Scope of Severity of Deficiency	Non-compliance for infection control deficiency when none cited in last year (or on last std. survey)	Non-compliance for infection control deficiencies cited once in the last year (or last std. survey)	Non-compliance that has been cited for infection control deficiencies <u>twice</u> or more in the last 2 years (or twice since second to last std. survey)	Nursing home cited for current non-compliance with infection control deficiencies at <u>harm</u> level regardless of past history	Nursing home cited for current non-compliance with infection control deficiencies at <u>L</u> level regardless of past history
G, H, I				<ul style="list-style-type: none"> Directed POC Disciplinary CPNk w/30 days to demonstrate compliance CMP imposed at highest amount option within the appropriate (non-L) range in the CMP Analytic Tool 	
J, K, L					<ul style="list-style-type: none"> Temporary Manager Disciplinary POC Disciplinary CPNk w/15 days to demonstrate compliance CMP imposed at highest amount option within the appropriate (L) range in the CMP Analytic Tool

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 \$56 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.

Nursing Home Infection Control Surveys: Are You Ready?

- Utilization of COVID-19 focused survey tool for nursing homes to conduct self-assessments
- Update infection control policies and procedures
- Staff training
- Documentation of any correspondence with or guidance obtained from local, state or federal agencies
- Challenge infection control deficiencies via the IDR/IIDR process

Compliance Issues Related to Reporting Requirements Under F884

- On May 6, 2020, CMS' interim final rule establishing new nursing home requirements for reporting COVID-19 data was published in the Federal Register (D50-20-29-NH).
- Interim final rule added a new subsection at 42 CFR §483.80(g)(1)-(2) (F884) which requires nursing homes to report the following data, at least weekly to the Centers for Disease Control and Prevention ("CDC") through the National Healthcare Safety Network (NHSN) system:
 - Suspected and confirmed COVID-19 infections among residents and staff, including residents previously treated for COVID-19
 - Total deaths and COVID-19 deaths among residents and staff
 - Personal protective equipment and hand hygiene supplies in the facility
 - Ventilator capacity and supplies available in the facility
 - Resident beds and census
 - Access to COVID-19 testing while the resident is in the facility
 - Staffing shortages
 - Other information specified by the Secretary

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Compliance Issues Related to Reporting Requirements Under F884

- CMS Interim Final Rule – COVID-19 Vaccine Immunization Requirements for Residents and Staff (QSO-21-19-NH); Effective 5/21/21
- F884 - LTC facilities must report, on a weekly basis, through NHSN's LTCF COVID-19 Module the following:
 - (a) COVID-19 vaccine status of residents and staff, including the total numbers of residents and staff,
 - (b) the numbers of residents and staff vaccinated,
 - (c) the numbers of each dose of COVID-19 vaccine received,
 - (d) any COVID-19 vaccination adverse events; and
 - (e) therapeutics administered to residents for treatment of COVID-19

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Compliance Issues Related to Reporting Requirements Under F884

- New vaccination reporting requirements under F884:
 - Facilities were to begin including vaccination and therapeutic data reporting in facility NHSN submissions by 11:59p.m. Sunday, June 13, 2021.
 - CMS began reviewing for compliance with the new vaccination reporting requirements effective Monday, June 14, 2021.
- Failure to meet the reporting requirements under F884, which now includes the new vaccination reporting requirements, will result in a single deficiency at F884 (scope and severity Level F) for that reporting week and the imposition of a civil money penalty ("CMP").

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Compliance Issues Related to Reporting Requirements Under F884

- Best Practices/Strategies to avoid deficient practice under F884
 - Develop policies/procedures to ensure compliance
 - Ensure that COVID-19 data and vaccination data are reported timely
 - Ensure CMS Certification Number is correct
 - Have an alternate staff member at all times that can access NHCN system and enter data
- Responding to an adverse survey that results in a deficient practice under F884
 - Challenging fines imposed by CMS via the Federal IDR process
 - IDR to be submitted within 10 calendar days of receipt of offer
 - IDR request to include the following:
 - A written request for an IDR
 - The deficiency being disputed (include copy of CMS Form 2567)
 - An explanation of why you are disputing deficiency
 - Supporting documentation (e.g., screenshots, email correspondence, etc.)
 - Option to request an appeal no later than 60 days from date of receipt of CMS notice re: fine.

NOTE: Failure to request a hearing within 60 days will be considered a waiver of facility's right to a hearing and amount of CMP will be automatically reduced by 35%.

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Financial Compliance Issues

- COVID-19 Financial Assistance
 - CARES Act
 - Paycheck Protection Program
 - Medicare Advances
 - Provider Relief Fund (PRF)
 - American Rescue Plan
 - Allocated \$450 Million to assist 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
 - But, importantly, no new PRF funding for LTC providers
 - States have taken federal funding and passed down to providers, and some have developed their own funding measures

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Financial Compliance Issues

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

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Financial Compliance Issues

- First time (first draw) PPP loan borrowers were eligible if:
 - They 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's) 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 were 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

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Financial Compliance Issues

- These eligibility criteria were further expanded by the American Rescue Plan Act (ARP) enacted on 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 became 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 fewer 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.

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Financial Compliance Issues

- ARP expanded eligibility for second draw applicants as follows:
 - An entity became 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.
- 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 Section 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 Section 6423 of the Internal Revenue Code.

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Financial Compliance Issues

- PPP – What to do now
 - A borrower can apply for forgiveness once all loan proceeds for which the borrower is requesting forgiveness have been used. Borrowers can apply for forgiveness any time up to the maturity date of the loan. If borrowers do not apply for forgiveness within 10 months after the last day of the covered period, then PPP loan payments are no longer deferred, and borrowers will begin making loan payments to their PPP lender.
 - Work with your lender
 - Review the Terms and Conditions and Agreement signed as a condition of accepting the PPP funds
 - Document use of the funds, as permitted within the T/C Agreement
 - Bank account statements and payroll reports documenting compensation paid to employees
 - Health insurance premiums
 - Mortgage interest, lease or rent payments (agreements, canceled checks)
 - Utilities (invoices)

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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.

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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

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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

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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.

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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.

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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

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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

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HIPAA/IT Compliance Issues

- The Office of Civil Rights (OCR) issued a number of bulletins and guidance documents during the COVID-19 pandemic:
 - Expanded telehealth communications
 - Expanded guidance to first responders to receive information about individuals exposed to COVID-19
 - Reminder guidance that individuals exposed to COVID-19 still have protections under HIPAA and anti-discrimination laws
 - Guidance to business associates to allow them to share information with governmental oversight agencies, as necessary
 - Media guidance to providers on what can/can't be disclosed even during the pandemic

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HIPAA/IT Compliance Issues

- Despite the guidance and several flexibilities provided, it is clear that even during the pandemic, covered entities must comply with HIPAA, and limit their disclosures of information regarding individuals with COVID-19
 - For example, covered entities are not permitted to disclose resident names/information in connection with COVID-19 diagnosis absent either (a) an applicable exception or (b) the resident/POA's Authorization
 - Governmental oversight exception
 - Persons at risk of contracting disease
 - To prevent serious/imminent threat
 - Remember minimum necessary standard
 - Over the course of the pandemic, this has proven to be a challenge, especially given the need to advise residents of "close contacts" with others with a COVID-19 diagnosis
- COVID-19 forced more remote/teleworking than ever before, and the IT/ privacy issues that accompany remote working have also been challenging
 - Access and security issues are paramount, when employees working remotely have access to resident PHI

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HIPAA/IT Compliance Issues

- 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.

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HIPAA/IT Compliance Issues

- 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.

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HIPAA/IT Compliance Issues

- 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.

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HIPAA/IT Compliance Issues

- 21st Century Cures Act
 - 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.

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HIPAA/IT Compliance Issues

- 21st Century Cures Act
 - 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.

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HIPAA/IT Compliance Issues

- 21st Century Cures Act
 - 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/courses/resources/information-blocking-faqs>

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HIPAA/IT Compliance Issues

- Ransomware Issues
 - Cybercrime continues to be an ever-growing problem, not just in the healthcare industry, but across the nation and all business types
 - Criminals attack a business' IT system, and demand money for "safe return" of data
 - Tips to address and work with your IT provider:
 - Train staff so basic "phishing" emails can be recognized, deleted and ignored;
 - Keep all hardware, software and security systems/firewalls updated;
 - Impose appropriate password requirements (address for Zoom and other platforms also)
 - Review mobile device policy, and inter-connection with organization's email and EHR systems
 - Assign IT professional to constantly monitor this issue and the types of attacks being reported on health care providers
 - Conduct an audit of IT system to determine potential for successful ransomware attacks

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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.

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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

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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

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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?

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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

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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)

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COVID Impact on Transaction and Corporate Issues

- Transactions
 - Infection rates and vaccination status of residents and staff impact on purchase price and timing of the closing of a transaction
 - 2020 was an "outlier" year for purposes of valuation of assets, so cash-flow and other asset determinations may be difficult
 - Appropriate use and reporting of PRF and other CARES Act funds impacts on a transaction
 - Federal: Equity vs. Asset Deal
 - State: More flexibility, and may allow parties to allocate funds
 - SBA Guidance on CHOW Transactions effective October 2, 2020
 - If the transaction is determined to be a CHOW under the guidance, and if the PPP note is not repaid in full or the loan forgiveness process is not completed, prior notice to the PPP lender, and the approval of the PPP lender, is required.
 - Furthermore, SBA approval and an escrow of funds in the amount of the outstanding balance of the PPP loan may be necessary in order to close.
 - Increase in Insurance Requirements
 - Tail Insurance for "Claims Made" policies (e.g. Professional, D/O and Employee Liability)
 - Representations and Warranties Insurance (RWI) to provide indemnification funding for breach of reps/warranties (e.g. health care reps). Note, however, that such insurance won't cover fraud
 - May require expansion of due diligence process to secure coverage

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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 how it is paid.
- 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.
