

Impacts of COVID-19 Compliance Protocols to Post-Acute Care Facilities and Home Based Care

April 21, 2021 – Health Care Compliance Association Annual Conference

**Richard Y. Cheng, Esq., CHC
&
Jack Strother, Esq.**

WEAVER JOHNSTON NELSON

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Richard Y. Cheng Overview

Richard Y. Cheng is a member at Weaver Johnston Nelson, a healthcare and cannabis boutique law firm based out of Dallas, Texas. Richard provides representation and advises on corporate transactions, operations, regulatory issues and compliance matters strictly within the healthcare and cannabis industries. He regularly advises clients on fraud & abuse, privacy & security and licensing concerns associated with healthcare and cannabis transactions, investments and business management. Prior to joining Weaver Johnston Nelson, Richard was an equity partner and a member of the healthcare sector at one of the largest AmLaw 100 global firms. During his tenure, he launched the firm's hemp/hemp products practice group where he led multiple initiatives in building the firm's reputation in cannabis. Richard advises cannabis trade associations, cannabis multi-state operators (MSOs), investors in cannabis, businesses in the entire cannabis supply chain and teaches cannabis law at UNT Dallas College of Law.

Richard was selected by his peers in 2015, 2017 through 2020 as a D Magazine Best Lawyer and as a Thomson Reuters SuperLawyers Rising Star in 2015 through 2017. He has been named a top 250 cannabis legal expert by DataBird Research Journal and listed as a Top 200 Cannabis Lawyer with cannabis Law Report & Cannabis Law Journal

Richard earned his occupational therapy degree from Texas Tech University Health Sciences Center, Juris Doctor degree from Nova Southeastern University, Graduate Certificate in Public Health from the University of Texas Health Sciences Center and earned a M.B.A. at University of Memphis Fogelman College of Business & Economics.

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Jack Strother Overview

Jack Strother is Senior Vice President and General Counsel for Aegis Therapies, Inc., a rehabilitation therapy company providing rehabilitative care, including speech, physical and occupational therapies, to patients residing in nursing facilities, assisted living, outpatient and home health environments. Aegis has been in business for over twenty years and currently provides therapy services in approximately 800 locations in thirty-six (36) states. Jack is a core member of the senior leadership team serving as a strategic and legal business partner to the functional leaders of Aegis. Jack is responsible for handling all legal matters for Aegis, which covers a wide range of legal and business issues including contract drafting and negotiation, litigation matters, corporate governance and regulatory matters, intellectual property, labor and employment, social media/information technology matters, insurance/risk management, and mergers and acquisitions. Jack's other areas of responsibility include helping drive corporate strategy and providing guidance and advice to aid executives in making informed decisions that maximizes company value and mitigates risk.

Jack received his J.D. degree in 2001 from Baylor University School of Law. He received a Bachelor of Science degree in Systems Engineering from the United States Military Academy at West Point in 1993.

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Presentation Overview

- Recollection of COVID-19 and Its Impact
- Shift in Mindset
- Awareness of CMS 1135 Waivers
- Use of Space
- Vaccinations
- Employees / Workforce (occupational health programs)
- Telehealth
- Operational Matters
- Payor Issues

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Recollection of COVID-19 and Its Impact

- Devastating for post-acute care (PAC) providers (SNFs, ALCs, CCRCs, HHAs, etc.).
- System failures for many that was designed to protect the fragile and elderly.
- Confusion and reactive for many.
- Providers seek protection from private lawsuits and governmental enforcement.
- Long term and short term changes for PAC providers (e.g. disease control protocols).

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Recollection of COVID-19 and Its Impact

As of February 2021:

- 624,782 - Total Resident COVID-19 Confirmed Cases.
- 125,008 — Total Resident COVID-19 Deaths
- 536,508 — Total Staff COVID-19 Confirmed Cases
- 1567 — Total Staff COVID-19 Deaths
- 40% - Percent of COVID-19 Fatalities Attributed to Patients & Staff to PAC Providers.
- 86% - Percent of PAC Providers That Did NOT Have a One-Week Supply of PPEs.

*Source- CMS, COVID-19 Nursing Home Data & AARP, AARP Nursing Home COVID-19 Dashboard.

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COVID Related Challenges

- Staffing Shortages
- Schools Closings — more staffing challenges
- PPE Shortages
- Controlling Infections Rates
- Family Members and Visitors
- Testing
- Unlike Other Emergency Preparedness Issues
- Impacting Multiple Parties (e.g. staff, patients, family members, insurance)

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Why Such Challenges and What Went Wrong?

- System Failure — governmental action arguably responded too little, too late.
 - 2/6/20 — CMS acted to prepare the nation's healthcare facilities for the COVID-19 threat.
 - 3/4/20 — CMS issued new guidance related to the screening of entrants into nursing homes.
 - 3/19/20 - CMS imposed ban on non-essential visitors in PAC provider facilities.
 - Before 2/6/20, there were multiple examples of MD diagnosis that should have signaled signs of irregularities and potential COVID.
- Forced Separation — lost connectivity and pain of isolation for patients & residents.
- Ineffective lockdowns and inconsistent orders.
- Lack of appropriate testing and PPEs.
- Decreased Oversight - **Example:** on October 7, 2020, a Kansas nursing home had 1 resident test positive. Within two weeks, 62 residents and 12 staff members tested positive, with 10 residents dying during that time.

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Why Such Challenges and What Went Wrong?

- CMS Surveys — on 03/20/20, CMS suspended routine surveys, but kept infection control surveys. Added more to lack of oversight.
- Decreased Governmental Staffing — in multiple states, state officials responsible for the inspection process lost their jobs (e.g. Illinois).
- Direct correlation between rate of infection at a facility and the immediate community.
- Federal Enforcement Delay — failed to rollback CoPs before COVID.
- Strong virus and unprepared

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Governmental Enforcement

- The Dept. of Justice (DOJ) already had PAC providers in its sight, particularly nursing facilities.
- On March 3, 2020, the DOJ launched a "National Nursing Home Initiative" to coordinate and enhance civil and criminal penalties for nursing homes providing "grossly substandard" care.
- OIG Chief Counsel Gregory Demske — "The HHS Office of Inspector General (OIG) continues to pursue nursing home operators who provide potentially harmful care to residents who are often unable to protect themselves. . . . Creating this Initiative sends a message to those in charge of caring for these beneficiaries that **grossly substandard care will not be tolerated.**"

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Other Type of COVID Related Liabilities

- Regulatory Citations — from multiple agencies
- Wrongful death lawsuits
- Police Investigations
- Employments Lawsuits

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Initial Examples

- PAC Provider #1 - One Outbreak – 4 Actions to Defend Simultaneously – Immediate Jeopardy, Local Police, Wrongful Death.
- PAC Provider #2 - early April 2020 - rural nursing facility faces COVID-19 outbreak, losing about a dozen residents.
- Individual accountability announced by governors.

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Operational and Resident / Patient Challenges

- **Staffing** – fear of infection; asymptomatic infected individuals a concern; there were already staffing shortages for many PAC providers pre-COVID.
- **Many governmental agencies at issue** – CDC, CMS, state and local bodies; often regulations change quickly and need to stay informed; sometimes there are contradictions.
- **PPE application** – takes longer to address patient issues, less time for person-centered care and more stressful on staff.
- **Impact on residents** – isolation and mobility through less visitations and suspended congregant activities (e.g. no meals together and only in rooms); dementia patients who are more used to routines result in behavior issues which impacts staff.

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Solutions Used Due to COVID

- Different units or floors used to separate infected residents.
- Temperature monitoring for staff and residents/patients.
- Smaller units or pods – still subject to infection due to staff.
- Home Health Care – no issue until staff is sent to the patient's home.
- Monitor local county COVID-19 infection rates.

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Governmental Enforcements

Varying degrees of perspective. Some see it this way:

- Minor Infractions – some major enforcement actions, but many have not been impactful.
- Surveys suspended & reserved for later – states will catch up and a surge may arise.
- Medicaid – like surveys, Medicaid will realign and expected surge by MFCUs.
- FCA Enforcement remains strong despite pandemic.
- DOJ Reticence – substandard care cases take time to develop and career prosecutors may be reticent to put in time.
- Unpredictable new US Attorney General.

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Regulation Waivers During COVID

- Some increased flexibility for PAC providers – patient/resident focus over paperwork - <https://www.cms.gov/files/document/covid-long-term-care-facilities.pdf>
- Waivers provided – impacted physical building requirements and relaxed minimum data set and staffing data submissions.
- Waivers also provided – resident admission and discharge planning requirements to be waived & QAPI requirements focused on adverse events and infection control.
- CNA certifications and annual in-service training requirements waived.
- Telehealth waivers - billable physician visits can be conducted via telehealth, including telephone visits.

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Remedies and Compliance Programs

- Fines
- Suspensions
- Revocations
- Deny payments
- *Talevski vs. Health and Hospital Corporation of Marion County*, No. 20-1664 (7th Circuit 2020) - would expand to certain nursing home consumers a private right of action for violations of resident rights.
- SNFs participating in CMS programs have been mandated to have compliance plans in place as a result of the ACA.
- Post-pandemic compliance plans will need to include enhanced infection control and disaster preparedness procedures.

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Investigation and Other Considerations

- Policies and procedures used to address COVID-19 – does it need to be updated?
- Assessment of PAC provider implementation of infection control practices and identify risk areas.
- Confidentiality – we live in a technology world
- Identify any conflicts of interest issues
- Qui Tam / Whistleblower issues

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Investigation and Other Considerations, Cont.

- Documentation – dates of investigations, who, what, where, how, to what extent.
- Litigation Hold Letters.
- Understanding and be aware of the regulatory timeline.
- Coordinate facts with documentation and regulation – tells an accurate and ethical story.
- Measuring risk level – assessments to show compliance.

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Investigation and Other Considerations, Cont.

- Work with outside counsel to preserve evidence.
- Subsequent remedial measures
- Insurance Concerns and Coverage
- Risk Mitigation
 - Waivers — should be very specific and use “negligence” with it; some states may not allow.
 - Informed Consents — shows effort to communicate inherent risks with services.
 - Attestations — verify the truthfulness of information (e.g. staff will abide by screening protocols).
 - Track Immunity Develops

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Are Post-Acute Care Providers Willing to Change?

- Unknown how much change in operations is needed post-COVID, but it is inevitable.
- Need more innovative ways on how post-acute care providers approach safety.
- Will technology impact how we monitor safety and infection control?

Challenges to Change:

“This is how we have always done it.”

COVID-19 was once in a lifetime event . . . it’ll never happen again.

Infection control was already a challenge.

Small margins which limit investment to innovative solutions.

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THANK YOU FOR THE OPPORTUNITY

Richard Y. Cheng — rcheng@weaverjohnston.com
<http://weaverjohnston.com/attorneys/richard-cheng/>
<https://www.linkedin.com/in/richardchengesquire/>

