PG Briefing
September 2, 2020

COVID-19 Presents Existential Legal and Regulatory Challenges for Long Term Care Facilities

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This Briefing is brought to you by AHLA's Post-Acute and Long Term Services Practice Group.

The novel coronavirus (COVID-19) has devastated—and transformed—nearly all aspects of life, in every community in the country, with no end in sight. While anyone can contract the virus, the elderly population is particularly at risk—especially those with weakened immune systems and other co-morbidities, such as diabetes or heart disease. The pathology of COVID-19, coupled with the fact that the virus is most easily spread in indoor settings where individuals congregate, makes Long Term Care Facilities (LTCFs) highly vulnerable to outbreaks, with devastating results.

As of August 13, more than 68,000 deaths—or 41%—of the nationwide total were linked to LTCFs.[1] Operators of LTCFs have struggled—often unsuccessfully—to keep their facilities equipped with personal protective equipment and to secure adequate testing kits for the safety of residents and staff. Although the scope of outbreaks varied by region, the spring was terrible, the summer in many respects worse, and the fall—when flu season begins—looms ominously on the horizon.

Yet other risks and challenges for LTCFs are increasingly coming into focus: a wave of investigations, litigation, and rapid regulatory changes have begun, and will continue for the foreseeable future. Properly addressing these legal issues will be essential for many LTCFs to remain solvent. This article assesses and addresses these issues, offering perspectives LTCF operators should consider.

Looking Back: Government Investigations and Private Litigation

LTCFs' coronavirus response will be closely scrutinized in the context of both government investigations and discovery in private lawsuits filed against operators. Well aware of this risk, and scrambling to reduce it, the industry has successfully lobbied in several states for liability protections—either via legislative enactment or executive order—that may prove crucial to the continued operation of these facilities. Where enacted, the scope of such protections will certainly be contested, and so LTCF operators in every jurisdiction should understand and prepare for present and future challenges.

Government Investigations

LTCFs, by nature, operate pursuant to dual and overlapping regulatory regimes. Facilities are funded through multiple sources—both public and private—including state and federal governments.[2] The federal government also sets rules regarding eligibility and care standards, while state oversight consists of licensure and health boards. This means that both federal and state regulators and law enforcement can—and have begun to—scrutinize LTCFs' response to the pandemic, and in particular, the care provided to elderly residents.

On March 3, U.S. Attorney General Bill Barr announced the National Nursing Home Initiative, an effort designed to "coordinate and enhance civil and criminal efforts to pursue nursing homes that provide grossly substandard care to their residents."[3] The Department of Justice (DOJ) has initiated investigations into approximately 30 individual nursing facilities in nine states, though the DOJ has not provided detailed updates on the Initiative since its announcement.

Among the issues federal prosecutors may probe are potential violations of the federal False Claims Act (FCA), which prohibits the making of a knowingly false statement to secure federal funds, with violators subject to fines (including treble damages) or prison, depending on the context and nature of the violation. Federal authorities may look particularly closely at instances of grossly "substandard care"—i.e., the impropriety of billing the government for substandard services rendered. Courts have not fully addressed all of the contexts in which FCA liability may arise when the standard of care was not met, but the DOJ has pursued this theory in recent investigations and settlements, including an $18 million settlement with Vanguard Healthcare LLC concerning allegations of "grossly substandard nursing home services."[4] Amidst the crisis, the DOJ reaffirmed its commitment to pursuing health care fraud under the FCA, "especially during this critical time as our nation responds to the outbreak of COVID-19."[5] Moreover, Provider Relief Funds under the Coronavirus Aid, Relief, and Economic Security Act (CARES Act) were conditioned on a facility's attestation that the funds would be used for "permissible purposes" as specified by the Department of Health and Human Services' (HHS') Terms and Conditions.[6] Given widely publicized reports of deficient care in LTCFs, there is significant FCA risk involved in the receipt and use of these Provider Relief Funds by such facilities.

The FCA is not the only source of potential federal claims, and the DOJ is not the only federal authority. The HHS Office of Inspector General announced it would undertake "Nursing Home Life Safety and Emergency Preparedness Reviews" to understand the vulnerability of nursing homes to disease outbreaks, particularly COVID-19.[7] In addition, the Centers for Medicare & Medicaid Services' (CMS') rules[8] established quality of care standards for LTCFs, including Infection Control regulations requiring LTCFs to "establish and maintain an infection prevention and control program designed to provide a safe, sanitary, and comfortable environment and to help prevent the development and transmission of communicable diseases and infections."[9] On April 30, CMS announced the creation of an independent commission to "conduct a comprehensive assessment of

the nursing home response to the 2019 Novel Coronavirus (COVID-19) pandemic."[10] A month later, CMS announced it would pursue "enforcement actions on lower level infection control deficiencies to ensure they are addressed with increased gravity."[11] Finally, in late August, CMS issued an interim final rule with comment period revising infection-control regulations for LTCs participating in Medicare and Medicaid to require nursing homes to routinely test staff for COVID-19, including individuals providing services under arrangement and volunteers, and to test residents when there is an outbreak or when a resident shows symptoms subject to civil monetary penalties for noncompliance.[12]

Broadly speaking, CMS issued these rules hoping the penalties—or the threat thereof—boost accountability, prevent backsliding, and improve care. While compliance data has not been made public in its entirety to determine the penalties' impact, it must be said that by mid-August, CMS reported that it issued more than $15 million in penalties to approximately 3,400 nursing homes for noncompliance with infection control requirements and failure to report necessary coronavirus data.[13]

States have their own tools to regulate LTCFs—in fact, more than the federal government. They also have a history of examining LTCFs' responses to natural disasters, in which residents in their care have died. In Louisiana, for example, the state charged the owners of a nursing home for failing to evacuate the facility during Hurricane Katrina; 35 residents died. Attorney General Charles Foti prosecuted the owners for negligent homicide; they were acquitted at trial. The State Attorney's Office of Broward County, Florida, similarly charged four nursing home employees (currently awaiting trial) when 12 residents died during Hurricane Irma after the air conditioning system failed.

States can utilize an established, robust infrastructure to investigate LTCFs' responses to the coronavirus through their federally funded Medicaid Fraud Control Units (MFCUs),[14] which are most often located within state attorneys general offices. To date, the attorneys general of Massachusetts, New Mexico, New York, New Jersey, and Pennsylvania have all announced investigations into the response of nursing homes in their states.[15] MFCUs in many states can bring state FCA claims, as 30 states and the District of Columbia have FCA statutes modeled after the federal statute. What's more, state law enforcement can also utilize elder abuse and neglect statutes, which prohibit individual and institutional caregivers alike from harming vulnerable elderly persons.

Private Litigation

LTCF operators also can expect to face large numbers of suits filed by private plaintiffs, whether elderly residents and their families or other private parties filing their own FCA cases. Indeed, this wave of litigation has already begun.

As can the federal government and many state regulators, *any* private person in many states may also bring FCA suits, acting on the government's behalf. Once a private plaintiff—termed a "relator" in FCA parlance—files a lawsuit, the government has the

statutory right to intervene and litigate the case; however, should the government decline to do so, the relator may still proceed with the litigation. The FCA is designed to incentivize such "whistleblowers"—in this context, LTCF staff, contractors, volunteers, residents or family members—who bring claims regarding potential wrongdoing based on non-public information. Indeed, LTCFs have long been targets of FCA actions, pre-dating the coronavirus pandemic, and thus are likely targets of FCA claims now. Private plaintiffs can also make other claims, including state tort law claims. Wrongful death and negligence suits have already been filed against LTCFs by survivors seeking damages for lost wages, lost companionship, and funeral expenses.[16]

Against this backdrop of substantial operational challenges and enormous legal risk, the LTCF industry has sought protection by lobbying policymakers at the state and federal level. In response, state legislatures and governors in at least 20 state have amended their laws to varying degrees to protect the industry from civil liability, including Utah,[17] Wisconsin,[18] Arizona,[19] Connecticut,[20] and Vermont.[21]

New York has taken the most sweeping action. In March, Governor Andrew Cuomo issued an Executive Order barring civil liability for medical care providers. Shortly thereafter, the Emergency Disaster Treatment Protection Act immunized nursing homes against civil liability absent "willful or intentional criminal misconduct, gross negligence, reckless misconduct, or intentional infliction of harm by the health care facility," whether or not the action in question was undertaken as a result of the COVID-19 crisis.[22] Following political backlash against this policy,[23] New York State rolled back some of these legal protections; medical facilities "will no longer have immunity for care not related to COVID-19 provided from now until the state's COVID-19 emergency declaration ends," though such facilities will remain protected against legal liability for care "impacted" by efforts to respond to the pandemic.[24]

By contrast, Pennsylvania Governor Tom Wolf's Executive Order provides civil immunity for only individual health care personnel, except in cases of "the most egregious lapses in care involving intentional misconduct or extreme negligence," but does not immunize individuals from criminal liability nor corporations from civil or criminal liability.[25] Congress is also considering analogous federal protections, though as of this writing has not passed any.[26]

Looking Forward: Regulatory Changes

As the nationwide threat from the coronavirus grows, rather than recedes, LTCFs must also adapt to new regulatory requirements, promulgated by federal and state regulators based upon the rapidly evolving understanding of the virus and the steps that must be taken to combat it, and quickly implement best practices into daily operations.

Out of overwhelming concern about the lack of information from operators regarding outbreaks in LTCFs, a number of these changes seek to improve communication with residents, families, and local governments. For example, in April, CMS published a new rule mandating that LTCFs notify state or local health authorities, residents, and

residents' representatives if three or more residents develop respiratory symptoms within 72 hours of each other, with a further requirement to inform residents and their representatives within 12 hours of a confirmed infection.[27]

In some cases, regulations may be modified with the aim of easing LTCFs' administrative burdens in weathering the COVID-19 crisis. For example, in October 2016, CMS issued a final rule that significantly revised the requirements LTCFs must meet to participate in Medicare and Medicaid.[28] After some delay, the third and final phase of implementation was to take effect in November 2019. However, CMS has not commented further on this third phase of regulatory requirements, which mainly impacts whether a LTCF's compliance and ethics program fulfills the requirement of participation. At this time, CMS has not finalized this delayed implementation, and the requirements are still pending. Should the government follow through with this final phase on schedule, LTCFs would need to ensure they are in full compliance within months.

State governments, too, are modifying their regulations, based on experience from the first several months of the pandemic. For example, early in the pandemic, New York's Department of Health issued an advisory barring LTCFs from "den[ying] re-admission or admission [of a resident] solely based on a confirmed or suspected diagnosis of COVID-19" and prohibiting "[LTCFs] from requiring a hospitalized resident who is determined medically stable to be tested for COVID-19 prior to admission or readmission."[29] Following public criticism that the rule contributed to the virus' spread within LTCFs, the state issued a new Executive Order barring hospitals from discharging patients to LTCFs unless the patient tested negative for the coronavirus.[30] The same order also required LTCFs to test personnel for the coronavirus twice per week.

What's more, states will have additional incentive to inspect facilities and determine whether they comply with relevant regulations, as CMS recently announced it will withhold CARES Act funding in the event a state fails to survey nursing homes for regulatory compliance.[31] Under the policy, states failing to inspect all nursing homes by July 31 must submit a corrective action plan. If a state still fails to execute its plan and survey all such facilities after the initial 30-day period, it could receive an up to 10% cut in CARES Act funding. According to published reports, as of early June, only half of all facilities nationwide have been inspected, so the pace of inspection will likely accelerate significantly.[32]

These regulatory changes, both individually and collectively, will significantly impact LTCFs' operations and costs. Given the importance of keeping residents and staff safe, and the legal risks that come from non-compliance, it's important that LTCFs keep abreast of regulatory changes.

Conclusion

The intent of these investigations, litigation, and regulatory changes is to hold providers accountable, while encouraging them to implement best practices to meet a higher

standard of care. These goals, while objectively laudable, come in the wake of extraordinary operational and fiscal challenges, as well as unprecedented media and community scrutiny. LTCFs' capacities to successfully respond to these challenges are dependent upon their abilities to thoroughly understand the legal environment, including areas of regulatory focus, and how LTCFs can demonstrate their past (or future) compliance with applicable legal requirements. Most important, LTCFs should address these issues proactively, before receiving a subpoena or an inspection visit. LTCFs' proactive actions—conducting privileged reviews of their initial response, building an improved compliance function, identifying and addressing potential risks—could determine whether they will weather both the crisis caused by COVID-19 and the investigative storm that follows in its wake.

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