In this Industry Update you will discover:

1) *"OSHA Has Your Back – for Now"*
   - MCKNIGHT'S LONG-TERM CARE NEWS, 7/20/2020; pg. 1
2) *"Antigen Testing for Nursing Homes 'Great for Screening' But Can't Be Only Tool for Potential Outbreaks"*
   - SKILLED NURSING NEWS, 7/16/2020; pg. 2
3) *"DOJ Rarely Used Nursing Home Data to Pursue Abuse Claims, COVID-19 Could Change That"*
   - SKILLED NURSING NEWS, 7/17/2020; pg. 4

McKnight's LONG-TERM CARE NEWS

OSHA Has Your Back – for Now

It's no secret that most operators have been struggling lately. The coronavirus has hammered this field in almost every way possible, but skilled nursing facilities have to find new ways to adapt to the challenges that face their operations.

Written by: John O'Connor

7/20/2020

Thousands of residents and staff have perished, with the prospect of more to come. The task of finding adequate protective equipment has ranged from being extremely difficult to being virtually impossible. Costs for almost every budget item have risen, while revenues have bottomed out. And by the way, this sector continues to be maligned and ridiculed by many media outlets, public officials and others who should know better.

So there's that.

At times like these, it's easy to forget that some good things are happening too. Such as the way the Occupational Safety and Health Administration has been doing its job. Or to be more accurate, has not been doing its job.

To say that OSHA has taken a laissez-faire approach to the COVID-19 pandemic would be an extreme understatement. For all practical purposes, the organization has shut down.

So far, more than 6,000 workplace-related complaints have been filed since the pandemic began. Care to guess how many citations OSHA has issued in response? The answer isn't zero, but it's awfully close. In Congressional testimony last month, Labor Secretary Eugene Scalia said the agency has issued one citation so far. Yes, one.

From the perspective of someone running a long-term care organization, that's actually encouraging. In effect, the feds are staying off your back. One might even say OSHA has your back.

But here's the thing: OSHA takes its marching orders from the White House. For the moment, that is a good reality for most operators. It's well known that President Trump is no fan of regulatory oversight.

However, as things now stand, he is looking to lose in November's election. At least, that's what the polls are now telling us. (I know, I know, he was behind in the polls four years ago too. But not by nearly so huge a margin.)

To be sure, a lot can change in the next three-plus months. But if they don't, there is a pretty good chance we will soon have a new commander in chief. And should Joe Biden win, you can be pretty sure OSHA is going to start responding to workplace complaints with far more interest and enthusiasm.

So here's my advice to operators: Stay well and do all you can to weather COVID-19. And as far as OSHA's restful slumber is concerned, enjoy it while it lasts.

Skilled Nursing News

Antigen Testing for Nursing Homes 'Great for Screening' But Can't Be Only Tool for Potential Outbreaks

Skilled nursing operators and infectious disease experts have expressed optimism about the government's push to send point-of-care testing tools and test kits to facilities across the U.S. They also emphasize that it's one only tool among many that SNFs need to be deploying as they try to keep COVID-19 out of their facilities.

Written by: Maggie Flynn

7/16/2020

The testing initiative, announced by Department of Health and Human Services (HHS) assistant health secretary Admiral Brett Giroir on Tuesday, will send the Quidel Sofia and Sofia 2 Instruments and BD Veritor Plus Systems — along with associated test kits — to 2,000 nursing homes in COVID-19 hotspots starting next week, with other SNFs to receive their devices after that point.

The tests themselves have to be matched to their devices; in other words, a BD testing device will only take BD test kits, Giroir said on a call with reporters on Thursday.

However, he emphasized that the BD and Quidel platforms are common for diagnostic purposes in health care settings outside of COVID-19, for illnesses like flu or strep throat. And though production schedules for both companies "are just getting online," Giroir reiterated that the goal is to start shipments to nursing homes in COVID-19 hotspots by next week.

HHS will be sending an initial allotment of tests to cover every nursing home resident and all employees once a week for approximately four weeks, Giroir said. After that, BD and Quidel will prioritize nursing home requests for replacement tests through "a concierge service," he added, noting that the companies have committed to this.

"After we send the first allotment, we want the commercial market to work," Giroir said. "These are not upstart companies. These are very mature companies with distribution networks around the country."

These devices could also be used to test for the flu or other illnesses, he added.

The antigen tests themselves detect fragments of proteins on or within the virus by testing samples collected from the nasal cavity via swab, according to HHS.

This type of test has some perks relative to the molecular polymerase chain reaction (PCR) COVID-19 tests, Morgan Katz, an assistant professor of medicine at Johns Hopkins University School of Medicine, told Skilled Nursing News; while the PCR tests are "pretty reliable," lab backlogs have led to delays in getting the results.

"You can run it very quickly, really, on site and get turnaround time in as little as a few minutes," she told SNN on July 15. "It's rapid, it's less expensive, but it is less reliable because you're not looking exactly for that portion of RNA, and you may not be able to capture that particular protein on the outside of the virus."

But for nursing homes, the turnaround time is of paramount importance, she emphasized. Any turnaround time greater than 24 to 48 hours is a bad option in that setting, especially if there's an active outbreak.

Giroir noted in a call with operators Wednesday that while there is a slightly higher rate of "false negatives" with antigen testing, the positivity results are almost completely reliable with "almost 99-plus-percent specificity."

Katz agreed.

"In general that is true — these antigen tests are more specific, meaning if you get a positive it is a true positive," she told SNN when asked about Giroir's assessment of their accuracy in an e-mail on Thursday. "Where they lack is in sensitivity — meaning they may miss some positive cases."

From her vantage point, antigen tests are "really great for screening purposes," since they're ideal for regular surveillance of staff members, residents and possibly, in due time, visitors.

But this is truer in settings without outbreaks, Katz noted.

"It's not a great option in a setting when your suspicion is higher," she explained. "What I mean by that is, if you know that you have a positive case in your facility, and you know that it is an outbreak, potential outbreak situation, you would really want to confirm any negative with a repeat test to make sure that that is a true negative and not a false negative."

This is a point Giroir made in the Wednesday call, advising SNFs to treat negative results for residents with a suspected case as presumptive until a PCR test can be secured.

There's another consideration for SNFs as they get ready for the test kits to arrive: how they collect and process the samples.

According to Philip Christian, the chief medical officer at the Miramar, Fla.-based clinical laboratory American Health Associates, this is paramount for getting the best results.

"I wholeheartedly agree that antigen test specificity provides invaluable diagnostic information," Christian told SNN via e-mail on Thursday. "However, variables such as specimen collection technique and pre-analytic handling are critical to ensuring the stability and integrity of specimens presented to the molecular laboratory for analysis. An essential component of obtaining the highly touted 99% test specificity, is ensuring that focused

attention is given to the quality of each step in the overall process … from swab in the nose to result on the chart."

But even with those considerations, Katz was unequivocal about the benefits of the testing effort.

"This is a huge win for nursing homes, regardless," she said. "Even though it's a little bit less sensitive, they're still going to have in these hotspots where we have much more concern. They're still going to have the ability to identify if they're starting to have transmission in their facility."

Skilled Nursing News

DOJ Rarely Used Nursing Home Data to Pursue Abuse Claims, COVID-19 Could Change That

Prior to the COVID-19 outbreak, the U.S. Department of Justice (DOJ) has been using data collected by nursing homes to investigate reports of abuse. There will be sweeping changes to the ways in which nursing homes provide that information to the DOJ and what information can be given.

Written by: Maggie Flynn

7/17/2020

When the COVID-19 pandemic started gathering momentum in spring, several states took steps to shield health care providers, including skilled nursing facilities, from liability related to care provided during the national emergency.

But the rules varied widely from state to state, and other issues might be looming beyond the realm of lawsuits. The DOJ announced its National Nursing Home Initiative to investigate operators with a history of abuse and neglect on March 3 — right before the start of the pandemic. And though COVID-19 has been top of mind even when it comes to litigation and investigation, that initiative will likely end up looking at aspects of how SNFs responded to the pandemic.

Jon Ferry, a former assistant U.S. attorney and a current partner at the Birmingham, Ala.-based firm Bradley Arant Boult Cummings, joined SNN's "Rethink" podcast to go over some of the legal issues that could surface from the pandemic — and from the DOJ initiative announced just before it all began.

Excerpts from the conversation, condensed and edited for clarity, are below; the podcast was recorded on June 24 and reflects the COVID-19 situation at the time.

You can listen to the podcast on iTunes, Google Play or Soundcloud, and if you like what you hear, be sure to subscribe.

Several states passed variations of immunity laws for health care providers as a result of the pandemic, but they could be quite different in terms of what was protected. Are these liability protections new in the health care space, or are they normal in a time of disaster like COVID-19?

I don't think it's completely novel. Some states actually have immunity provisions that kick in automatically when an emergency is declared. So it's not unprecedented, and pretty standard, for governors and other state legislators to think about how those that are on the front line of responding to crisis need some protections from after-the-fact second-guessing that can come when everybody is acting in real time to deal with something new, unknown, and where everyone pretty much agrees they're not exactly sure what all the parameters are around the problem.

In these particular immunity provisions, some of them are by executive order; others have been passed by the legislature and then signed by the governor, so they're statutory. And what we're seeing in these is really a change to the level of culpability that facilities could be held to, in the case of a liability for COVID-related matters.

So if someone were to bring a lawsuit for a standard of care at a nursing facility in the normal world, they would need to prove a negligence type of standard and show that the actions of the facility — or more likely the lack of actions by the facility — were negligent in the context of what was going on there.

What these immunity provisions have done is basically ratcheted up that standard. In fact, what they basically said is facilities and individuals working in the facilities won't be responsible for what might be negligence. Instead, they've said that gross negligence or willfulness or reckless disregard are going to be the standard by which the facilities will be judged.

They haven't done that by explicitly using those terms. Instead, what they generally do is they simply state: Hey, the facilities and the individuals in them won't be subject to civil liability for their actions in responding to COVID-19 situations or patients or people who fall ill. But then they carve out situations in which there might be gross negligence and willfulness or criminal activity — and those are all kind of loaded legal that we can get into a little bit more if you'd like.

Yeah, let's dive into those a little bit. In the pandemic situation, what does that mean for those terms and how they're understood?

Sure, so let's take a quick step back. The negligence standard itself is richly developed in the case law. What that really means is that somebody acted reasonably under the circumstances. And so even in an emergency situation, there would be a good argument that that standard is different than it would be in a non-emergency situation.

But a gross negligence type of situation, it's another legal term and it's developed in the case law. As the term kind of implies, it's not negligence, it's something more. It's something may involve willfulness — something that, to use a legal term, looks really bad.

What it means is for lawyers that might be looking at these cases: If you have somebody who is understandably distraught because a loved one may have succumbed to coronavirus while in a facility, they go to a lawyer and they say, "Hey, I'd like to look into this."

What those lawyers then have to do is look at what they've got to show for a case. And when they see negligence — very familiar with that, that's how it's always been. But then they see: Well, wait a minute, under these new statutes, it's going to require gross negligence. That's a different analysis of whether that case might be viable.

To take an example, you'd have a case that maybe somebody could argue negligence if a facility did not have sufficient personal protective equipment (PPE), because that's considered what somebody reasonable would have in the case of an infectious disease.

But if that PPE is not available, or if at the time the facility is making these decisions, it's not quite clear just how contagious the virus is, that probably won't rise to the level of gross negligence, and a facility would not necessarily have a liability for that type of situation. Whereas under the old rules, a lawyer looking at this might consider that case more viable.

I think one of the things facilities can look at in the few states that have passed these immunity laws is the fact that the people that are looking at bringing these cases are still going going to do a fact-specific analysis. We're not going to see the end of cases being brought just because these laws are out there. Instead what we may see is fewer, perhaps greater cases being brought, or facilities having a greater opportunity to dispose of the case early on in the proceedings.

What are some aspects of responding to COVID-19 are likely to come up in litigation against nursing homes? Will it be issues like equipment, staffing, testing?

You've hit on a few right there, and I'll dive into those in a little bit more detail. What we've seen in nursing home litigation in the past — I'm talking mainly from the private angle right now, so private litigants who are trying to hold the nursing home liable for some bad consequences to their loved ones.

Perhaps there's a whole separate part of this that also involves government enforcement, but from the perspective of private litigation, I think it's still going to be revolving around the same thing, particularly in states that don't have these various statutes and executive orders.

Staffing is always an issue, the allegation that there is insufficient staffing to handle the case load and the census that's in the nursing home. The reason that that is always at issue is because litigants are looking to get at the company and the management of the nursing home. That's where, frankly, the deep pockets are. So staffing questions and staffing decisions are the things that happen at the management level. When they look at these cases, they say, what are the staffing levels — and that's publicly available information.

Also things that are going to be at issue: publicly available metrics, because these are things that are reported to the government. [These] would be protocols, and whether there have been violations of the protocols for infection control. That's going to be a big issue. We're already seeing that being analyzed by Congressional oversight. Recently, Congress sent letters out to five various large nursing home companies asking about a lot of these things to include infection protocols. Interestingly, Congress is focused also on staffing. So they're looking into that as well.

I do think that a lot of the action is going to be in the staffing at the nursing homes, the allegations that there was insufficient staffing to handle the situation; there's going to be allegations that the nursing homes did not have sufficient infection protocols, or that they violated their own infection protocols that led to the spread. Also, there's going to be allegations that the nursing homes, even after it was clear that this was necessary, did not properly put the PPE in the hands of its staff.

You mentioned the government enforcement, and one of the things that has fallen off the radar with COVID-19 was the announcement about the DOJ's National Nursing Home Initiative. What are some things about how SNFs are dealing with the pandemic that could come up in the government investigation?

I do think there's going to be some important effects here. I'm actually a former government enforcement lawyer; I was at the United States Attorney's office here in Charlotte for seven years, and I saw how government enforcement priorities would move around.

This was the all part of the Elder Justice Initiative that the DOJ had been working on for a significant time before March 3, and they announced that they were going to move into nursing homes and look at substandard care in nursing homes.

Which is interesting, because a lot of the enforcement action [around] nursing homes from the government before, at least at the DOJ level and from the civil liability level, had actually been focused on things like overcharging for therapy — RUG [Resource Utilization Group] scores and the level of therapy that was being provided and deep analysis of that, which are easily quantifiable.

What [the March 3 announcement] signaled was a shift, that DOJ was going to be looking more at the idea that people were just not being properly taken care of, and which would lead then to problems of substandard care that we're familiar with. Those have traditionally been very difficult cases for the DOJ to bring. With focus in that area, what you get is when Attorney General Barr comes out and makes that announcement on March 3, there's going to be resources directed in that direction.

You're going to have U.S. Attorney's offices that will probably have elder coordinators that are responsible for keeping their eye on those types of issues; you're going to have portions of the DOJ that are tasked with looking at those issues and developing cases. When you get that type of focus, things that perhaps in the past hadn't gotten looked at as carefully start getting looked at more carefully. That can include the state survey reports, that report on certain violations that are happening in nursing homes; those are all reported and tracked.

And as we're seeing now, that data has all been out there but hasn't necessarily been crunched in a way that DOJ prosecutors or federal investigators have looked at very carefully. I think with the initiative that was announced on March 3, they were about to start doing that. They were probably going to start putting targets together that they wanted to take a deeper dive into based on the metrics that they were seeing.

Then all of a sudden, COVID comes along, and COVID basically is the perfect storm. Now we have harm — patients in skilled nursing facilities falling sick, in many cases, and in some cases, dying — that can possibly be tracked, or at least associated with some of the metrics that the DOJ would have been looking at.

The obvious example is the infection protocols. That is a metric that is tracked. When state survey organizations go into nursing homes and do their surveys, they will track whether there is an infraction or a violation of the requirements for infection control. Those metrics are then tracked over time.

If there are nursing homes out there that perhaps have multiple of those infractions over a period of time, multiple years in a row, and now we see spread of COVID within some of those facilities, that's a pretty natural progression for the U.S. government to decide: Well, let's take a deep dive into what was happening there.

I think what we're going to see then is the government is starting to put the dots together. They're starting to connect the dots. They have all this data from the nursing homes over the period of years, based on the state surveys and the data that gets collected. Now they have problems with COVID.

As you know, they have requested data, the Centers for Medicare & Medicaid Services requested data from all the nursing homes about their COVID-related deaths, or COVID cases. I think we're going to start seeing perhaps enforcement actions based on the accumulation of that data.