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COVID-19 VACCINATION

Considerations for Seniors Housing Communities

asha
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COVID-19 VACCINATION

Considerations for Seniors Housing Communities

I. INTRODUCTION

More than nine months after start of the coronavirus pandemic, the beginning of the end finally appears to be within sight. Novel vaccines have shown tremendous promise in clinical trials, and the United States Food and Drug Administration (FDA) has granted Emergency Use Authorizations (EUAs) to the first two COVID-19 vaccines—one developed by a collaboration between Pfizer and BioNTech SE and the other developed by Moderna. The first Americans received initial doses of the Pfizer-BioNTech vaccine on Monday, December 14, 2020—a remarkably quick turnaround from the initial identification of the SARS-CoV-2 virus at the end of 2019 to the delivery of the first doses of a vaccine one year later.

While the efforts to bring vaccines to long-term care communities will not begin in earnest until December 21 or December 28, residents of long-term care communities in a handful of states have begun to receive COVID-19 vaccines. To that end, although companies in the seniors housing industry are likely well on their way to preparing for the upcoming vaccinations in their communities, this Special Issue Brief provides some background on the COVID-19 vaccine approvals and an overview of some of the key issues operators should make sure to consider.

II. STATUS OF COVID-19 VACCINES, ALLOCATION, AND APPROVALS

The fact that the United States will have two vaccines in use via EUAs by the end of 2020 follows an unprecedented international effort to quickly develop vaccines to put an end to the coronavirus pandemic. With a number of promising vaccine candidates still undergoing clinical trials, the Pfizer-BioNTech and Moderna vaccines have both been demonstrated to be safe and nearly 95% effective in preventing illness from COVID-19. Federal officials originally projected that 40 million doses of the two vaccines would likely be available for distribution by the end of 2020. With two doses needed per person, that would be sufficient to vaccinate 20 million of the more than 330 million people living in the United States, although it now appears that fewer than the initially projected 20 million individuals will be vaccinated by the end of 2020.

Nonetheless, December 2020 has proven to be an eventful month in the quest for a COVID-19 vaccine. Since the beginning of December, there have been three critical developments: First, on December 3, 2020, the Centers for Disease Control and Prevention (CDC)'s Advisory Committee on Immunization Practices (ACIP) voted 13-1 to approve initial recommendations for how to allocate the initial doses of COVID-19 vaccines. Second, on December 11, 2020, the FDA issued an EUA for the Pfizer-BioNTech vaccine, thereby permitting its administration to members of the public. Most recently, the FDA issued an EUA for the Moderna vaccine on December 18, 2020, and the first doses of the vaccine are expected to be distributed imminently.

ACIP Recommendations for Initial Allocation of Vaccines

In issuing its Interim Recommendation for Allocating Initial Supplies of COVID-19 Vaccine¹, ACIP took an unusual step by making its recommendations before the FDA issued approval for any COVID-19 vaccines rather than waiting until after approval was issued. ACIP's initial recommendations were the culmination of months of work by national experts who carefully studied and considered the impacts of the pandemic as well as the pros and cons of various options for prioritizing how initial doses of vaccines should be distributed. ACIP concluded that healthcare workers and residents of long-term care communities should be prioritized to receive COVID-19 vaccines as part of the initial "phase 1a" rollout of the vaccines.

ACIP noted that "[h]ealth care settings in general, and long-term care settings in particular, can be high-risk locations for SARS-CoV-2 exposure and transmission" and that "LTCF residents, because of their age, high rates of underlying medical conditions, and congregate living situation, are at high risk for infection and severe illness from COVID-19." Indeed, residents of long-term care communities are highly susceptible to both exposure to and severe outcomes from COVID-19 infections. They have accounted for nearly 6 percent of diagnosed COVID-19 cases since the start of the pandemic and nearly 40 percent of the more than 310,000 U.S. deaths attributed to the virus to date. ACIP is hopeful that reducing the rate of infection among the long-term care population will not only save lives, but will also alleviate some of the current major stresses on the hospitals that care for gravely ill COVID-19 patients.

While ACIP's recommendations provide a framework to help states determine how to allocate initial batches of COVID-19 vaccines, they are not binding on the states, nor do they address all of the details necessary for distributing the vaccines. In particular, even if states adopt the ACIP recommendations, they will still need to determine how to prioritize their healthcare workers and long-term care communities, since the initial availability of vaccines will be insufficient to allow for everyone in these two groups to be vaccinated immediately.

¹ Dooling K, McClung N, Chamberland M, et al., "The Advisory Committee on Immunization Practices' Interim Recommendation for Allocating Initial Supplies of COVID-19 Vaccine – United States, 2020." *Morb Mortal Wkly Rep*, 69(49):1857-1859, Dec. 3, 2020, DOI: <http://dx.doi.org/10.15585/mmwr.mm6949e1>.

FDA Emergency Use Authorization for COVID-19 Vaccines

Under Section 564 of the U.S. Food, Drug and Cosmetic Act (FDCA), the FDA can issue an Emergency Use Approval to allow use of an as-yet-unapproved medical product or a new use of an approved product as a countermeasure to “diagnose, treat, or prevent serious or life-threatening diseases or conditions” during a public health emergency.² Specifically, Section 564 allows for the issuance of an authorization if “the totality of scientific evidence... including data from adequate and well-controlled clinical trials, if available,” demonstrates that the product may be effective at, among other things, preventing a serious or life-threatening disease or condition and the known or potential benefits of the product outweigh the known and potential risks.³

While the EUA process is faster than the process for full approval of a vaccine, it still demands the submission of significant amounts of data and the rigorous review of that data. The clinical trials for the two COVID-19 vaccines quickly enrolled thousands of participants, easily and significantly exceeding the FDA’s floor of 3,000 vaccine recipients required for issuance of an EUA. Specifically, the Pfizer-BioNTech clinical trial enrolled around 44,000 participants, more than 20,000 of whom received the vaccine and the Moderna clinical trial enrolled nearly 30,000 individuals, of whom half received the vaccine. Both vaccines were tested in clinical trial participants from diverse backgrounds and age ranges.

Many people have raised concerns about whether the new COVID-19 vaccines are actually safe, especially considering the rapidity with which they were developed, tested, and authorized. Indeed, as discussed in Section III below, safety concerns are among the major reasons many Americans are currently showing hesitation to get vaccinated. However, as the CDC has explained, the new COVID-19 vaccines are “being held to the **same safety standards** as all vaccines.”⁴ The clinical trials collected safety data for at minimum eight weeks following vaccination, which is the period in which side effects are most likely to appear. Nonetheless, safety concerns will continue to be carefully monitored as the vaccines are distributed more widely through a number of longstanding tools including the Vaccine Adverse Event Reporting System (VAERS) and the Vaccine Safety Datalink (VSD) as well as new tools developed specifically for COVID-19 vaccination efforts.

There are a number of reasons for which the COVID-19 vaccines were able to move through the development and EUA processes faster than most vaccines. First, the new vaccines were developed using technology that has already been under research and development for years. Second, there was a large body of clinical trial volunteers to draw from in short order and sufficient community spread of the virus to ensure that clinical trial participants would be exposed. Third, the FDA has fast tracked its review of

² U.S. Food & Drug Admin., “Emergency Use Authorization for Vaccines Explained,” last updated Nov. 20, 2020, <https://www.fda.gov/vaccines-blood-biologics/vaccines/emergency-use-authorization-vaccines-explained>.

³ 21 U.S.C. § 360bbb-3(c)

⁴ CDC COVID-19 Response Vaccine Task Force, “COVID-19 Vaccine Basics: What Healthcare Personnel Need to Know,” Dec. 2020, https://www.cdc.gov/vaccines/covid-19/downloads/What-HCP-NeedToKnow_508.pdf (emphasis in original); see also Mayo Clinic, “COVID-19 vaccines: Get the facts,” Dec. 17, 2020, <https://www.mayoclinic.org/diseases-conditions/coronavirus/in-depth/coronavirus-vaccine/art-20484859>. It is also worth noting that the vaccines developed by Pfizer-BioNTech and Moderna do not contain any viral material and can neither infect the recipient with COVID-19 nor change the recipient’s DNA. See *id.* and “Fact Sheet for Recipients and Caregivers, Emergency Use Authorization (EUA) of the Pfizer-BioNTech COVID-19 Vaccine to Prevent Coronavirus Disease 2019 (COVID-19) in Individuals 16 Years of Age and Older,” <https://www.fda.gov/media/144414/download>.

the COVID-19 vaccines at each stage of the process, so the usual administrative processes have moved much faster than usual. Finally, because of the serious public health exigencies, both Pfizer and Moderna began manufacturing the vaccines while they were still being studied so that millions of vaccine doses would be ready for distribution as soon as approval was granted.

Pfizer and Moderna submitted applications for EUAs in November 2020. The FDA's Vaccines and Related Biological Products Advisory Committee (VRBPAC), a group of outside scientific and public health experts who have been screened for conflicts of interest, recommended that the FDA issue an EUA for both vaccines. ACIP also conducted separate reviews of the vaccine safety data on behalf of the CDC. The FDA officially issued an EUA for the Pfizer-BioNTech vaccine on December 11, 2020⁵ and for the Moderna vaccine on December 18, 2020⁶. In its EUA approval letters, the FDA noted that its review of the data "did not identify specific safety concerns that would preclude issuance of an EUA"; that the vaccines were 95% and 94.1% effective, respectively; and that "it is reasonable to conclude... that the known and potential benefits of [the] vaccine outweigh the known and potential risks of the vaccine."

Under the terms of the EUAs, Pfizer and Moderna are required to provide fact sheets about the vaccines to healthcare providers administering the vaccines⁷ and other fact sheets to recipients of the vaccines and their caregivers.⁸ Seniors housing communities should make sure that all residents and staff have received and reviewed the applicable fact sheet and have had the chance to ask any questions they might have.

III. EDUCATION AND MESSAGING

While the vaccine approvals constitute a development critical to bringing about the end of the pandemic, the majority of Americans will have to be vaccinated in order for life to return to normal. Unfortunately, at present, a large portion of the country says that they are unlikely to get vaccinated against COVID-19. According to a survey of 12,648 American adults conducted by the Pew Research Center from November 18 to 29, 2020, only 60% of Americans said that they "would definitely or probably" get vaccinated, whereas 39% said they "definitely or probably would not" get vaccinated.⁹ Indeed, a full 21% of the respondents said that not only were they not planning to get vaccinated, but they did not think additional information would be likely to change their minds. The news is not all bad, however: the current numbers represent a large improvement from September, when only 51% of those surveyed said they would definitely or probably get vaccinated and 49% said they would probably or definitely not get vaccinated. Moreover, among survey respondents who were 65 years of age or older, 75% said they would definitely or probably get vaccinated.

⁵ Letter from RADM Denise M. Hinton, Chief Scientist, U.S. Food & Drug Admin., to Pfizer Inc., Dec. 11, 2020, <https://www.fda.gov/media/144412/download>.

⁶ Letter from RADM Denise M. Hinton, Chief Scientist, U.S. Food & Drug Admin., to ModernaTX, Inc., Dec. 18, 2020, <https://www.fda.gov/media/144636/download>.

⁷ Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers), Emergency Use Authorization (EUA) of the Pfizer-BioNTech COVID-19 Vaccine to Prevent Coronavirus Disease 2019 (COVID-19), <https://www.fda.gov/media/144413/download>; Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers), Emergency Use Authorization (EUA) of the Moderna COVID-19 Vaccine to Prevent Coronavirus Disease 2019 (COVID-19), <https://www.fda.gov/media/144637/download>.

⁸ Fact Sheet for Recipients and Caregivers, Emergency Use Authorization (EUA) of the Pfizer-BioNTech COVID-19 Vaccine to Prevent Coronavirus Disease 2019 (COVID-19) in Individuals 16 Years of Age and Older, <https://www.fda.gov/media/144414/download>; Fact Sheet for Recipients and Caregivers, Emergency Use Authorization (EUA) of the Moderna COVID-19 Vaccine to Prevent Coronavirus Disease 2019 (COVID-19) in Individuals 18 Years of Age and Older, <https://www.fda.gov/media/144638/download>.

⁹ Pew Research Center, "Intent to Get a COVID-19 Vaccine Rises to 60% as Confidence in Research and Development Process Increases," Dec. 3, 2020, https://www.pewresearch.org/science/wp-content/uploads/sites/16/2020/12/PS_2020.12.03_covid19-vaccine-intent_REPORT.pdf.

Even though a majority of the Pew Research Center study respondents said they would likely get vaccinated, 62% of those surveyed said that they would feel “uncomfortable” being among the first to receive the vaccine, while only 37% said they would feel “comfortable” being in this group. Similarly, a report issued by the University of Michigan’s National Poll on Healthy Aging¹⁰ in November noted that, while “nearly three in five adults age 50–80 were likely to get a COVID-19 vaccine... almost half said they want to wait until others have received it.”

The sentiments revealed by the two surveys underscore the difficulties seniors housing communities will likely face in convincing residents and staff members to get vaccinated, especially in the first phase of vaccine distribution. While these communities are among those that might benefit the most from early vaccination and their staff and residents are at the front of the line to gain access to the vaccines, they will likely be faced with significant reluctance among both staff and residents to be the first in the country (and world, for that matter) to receive the novel COVID-19 vaccines. In addition, although residents are likely to fall in the age group with a comparatively high interest in getting vaccinated, staff are more likely to be in age groups with lower likelihood of vaccination. It also bears noting that the legal representatives of residents who are unable to give their own consent to receiving the vaccine may also be more likely to be in the age groups more skeptical of COVID-19 vaccination.

The Pew Research Center survey also showed significant disparities in likelihood of getting vaccinated along other demographic lines including race/ethnicity, education, political party, and family income. It will be important to keep these differences in mind while developing plans to educate staff and residents and to target messaging accordingly.

Ultimately, it will be essential for seniors housing operators to educate staff and residents about the vaccines in order to dispel concerns and misconceptions about everything from how the vaccines work, to whether they are safe, to why it is important to continue exercising infection control measures even after being vaccinated. Fortunately, the two reports revealed other important information that seniors housing communities may be able to use to target their messaging. According to the Pew Research Center study, “Public confidence in the vaccine development process also plays a role in people’s intention to be vaccinated.” The National Poll on Health Aging report noted that around 50% of those polled are “worried about the safety of a vaccine that is developed quickly.” To that end, education efforts should include messaging about the safety of the vaccines and how the speed with which the vaccines were developed and approved did not compromise safety.

Staff education may be especially important for two primary reasons. First, education about the vaccines will be critical to increasing buy-in among staff members—individuals who live in the surrounding communities and are therefore the most likely to introduce COVID-19 into seniors housing communities. Second, educating staff will give them the tools to then help educate residents and their families and answer any questions or alleviate concerns they might have. Educating residents’ families will also be critical, especially for residents unable to give consent to being vaccinated, as discussed in further detail in Section V.

¹⁰ National Poll on Healthy Aging, University of Michigan, “Older Adults’ Perspectives on a COVID-19 Vaccine,” Nov. 2020, <https://www.healthyagingpoll.org/report/older-adults-perspectives-covid-19-vaccine>.

IV. LOGISTICAL CONCERNS

Planning for Vaccination

At the most basic level, seniors housing communities need to determine how their residents and staff will receive COVID-19 vaccines. Thousands of companies nationwide signed up to participate in the federal government's Pharmacy Partnership for Long-term Care Program, for which the opt-in deadline was November 6, but others may have exercised the option to obtain vaccines outside the program. Through the Pharmacy Partnership Program, the CDC entered into agreements with CVS, Walgreens, and several multistate long-term care pharmacies under which the pharmacies will receive vaccines, bring them to nursing homes and assisted living facilities, and then handle administration of the vaccines to residents and staff.

As noted above, some communities started receiving vaccines the week of December 14, 2020, but vaccinations through the Pharmacy Partnership Program will start in earnest during the weeks of December 21 and 28, 2020. If they have not done so already, communities need to prepare for the vaccination clinics by planning for such issues as: where and how to set up the clinics; how to maintain infection control procedures given the large number of residents and staff who will be moving through those clinics; and how to quickly and efficiently obtain consent from residents or their legal representatives, where appropriate.

Communities also need to develop plans for ensuring that residents and staff receive a second dose of the vaccine at the appropriate time after receiving the initial dose. Both doses must be of the same vaccine. Finally, communities should consider how to handle staff hired and residents admitted after on-site vaccination clinics and the completion of phase 1a vaccinations.

Planning for and Managing Post-Vaccination Symptoms

Given the known short-term post-vaccination side effects, which can include fever, fatigue, headache, chills, muscle aches, and joint pain, seniors housing communities should be prepared to handle the issues that arise from such symptoms in both staff and residents.

In its "Interim Considerations for COVID-19 Vaccination of Healthcare Personnel and Long-Term Care Facility Residents," the CDC addresses potential post-vaccination symptoms and notes that "strategies are needed to mitigate possible [healthcare personnel] absenteeism and resulting personnel shortages due to the occurrence of these symptoms."¹¹ Communities need to prepare for the possibility that some staff members will need to call out sick following vaccination; this is even more likely following the second shot. They also should determine whether staff will be required to take sick leave or vacation days if they suffer from post-vaccination symptoms and how they will handle staff who have already used up their annual sick leave or vacation time.

¹¹ "Interim Considerations for COVID-19 Vaccination of Healthcare Personnel and Long-Term Care Facility Residents," last reviewed Dec. 3, 2020, <https://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/covid-19/clinical-considerations.html>.

Communities should assess the potential impact of vaccination on staffing levels and consider staggering vaccination of staff. Companies that choose to stagger the vaccination of their staff should also engage in dialogue with local and state health officials and the pharmacies that will be providing on-site vaccination clinics to determine how they can best stagger vaccination while ensuring that staff members who do not get vaccinated during the first on-site clinic can still receive the vaccine in short order.

With respect to residents, seniors housing communities should pay careful attention to symptoms and their duration to assess whether a resident is simply suffering from temporary post-vaccination side effects or if they might be infected with COVID-19. Communities will need to exercise extra caution until it is clear whether a resident's symptoms are consistent with receiving the vaccine or with an active COVID-19 infection. The CDC has issued guidance on how long-term care communities should treat symptoms in the days following vaccination, including how long to take extra precautions and when and how to test residents for COVID-19.¹²

The CDC is also recommending that infection control measures such as mask wearing and social distancing remain in place until more is known about the protection the vaccines provide and until most Americans have been vaccinated. While the clinical studies for the two vaccines provided significant evidence that the vaccines strongly protect against COVID-19 illnesses, the studies have not yet shown whether they protect against asymptomatic infections or silent transmission of the SARS-CoV-2 virus. Furthermore, the vaccines are not 100% effective and they do not confer immunity immediately after injection; instead, it takes a period of time after receiving the second dose of the vaccine before a recipient has fully developed the immunity conferred by the vaccine. Thus, vaccine recipients could still be infected with COVID-19 even after vaccination, and especially after only a single dose and in the days following the second dose.

V. CONSENT ISSUES

Before mass vaccination efforts begin, communities will need to obtain informed consent from or on behalf of their residents. CVS and Walgreens have both developed vaccine intake questionnaire and consent forms, and communities should add copies of the completed forms to each resident's record. Communities might also consider developing their own, simple informed consent forms, especially if they want to be able to show that they discussed the risks and benefits of vaccination with the resident. Alternatively, they might consider memorializing conversations about the vaccine in a patient's medical record to document the information they provided about the vaccine. Conversely, communities might consider having staff and residents who decline to get vaccinated sign an informed consent form that lays out the risks of not getting vaccinated as well as the impact that choice will have on the individual in terms of ongoing restrictions on activity and additional precautions they might be required to take.

Obtaining consent goes hand-in-hand with the education and messaging efforts discussed above, and providers should anticipate more questions than they would ordinarily receive prior to administering a routine vaccine. Communities may need to convince staff members, residents, and residents' families and legal representatives

¹² CDC, "Post Vaccine Considerations for Residents," last updated Dec. 13, 2020, <https://www.cdc.gov/coronavirus/2019-ncov/hcp/post-vaccine-considerations-residents.html>.

that they should receive the vaccine. As discussed at length in a recent *New York Times* article¹³, obtaining consent may be especially tricky for residents who can no longer provide their own consent, as communities will need to get in touch with and obtain consent from such residents' legal representatives. Successfully contacting a resident's legal representative may take time and those representatives may need to be convinced that vaccination is appropriate. And with more widespread vaccination expected to begin imminently, time is of the essence.

Documenting a resident's consent to vaccination may be important so as to allow a community to demonstrate that an individual was not vaccinated against their wishes. Signed informed consent forms also provide evidence that an individual received information about the potential risks and benefits of vaccination, had the opportunity to ask and obtain answers to any questions they had, and still chose to receive the vaccine. Such evidence can be important in the event that a resident (or the resident's legal representative) reacts badly to a vaccine or later regrets the decision to get vaccinated and then accuses the community of failing to properly inform the resident about the vaccine and obtain proper consent.

Finally, some states have specific requirements with respect to informed consent, and communities should make sure they are aware of and comply with any such requirements.

VI. VACCINE MANDATES

A major question facing seniors housing communities is whether to mandate that residents and staff receive a COVID-19 vaccine. As a practical matter, a vaccination mandate at the initial stages of the vaccine distribution efforts might be difficult to enforce while ensuring sufficient staffing at a community. While current staff members may be able to obtain a vaccine through a community's vaccination clinics, it is unclear if, how, and when any staff hired after those clinics and not otherwise vaccinated as part of the phase 1a vaccination efforts would be able to obtain the vaccine prior to its becoming widely available.

There has been some confusion and debate over the permissibility of making vaccination mandatory for a vaccine that has only obtained an EUA as opposed to full approval. The debate arises from language in Section 564 of the FDCA which provides that individuals to whom a product authorized under an EUA is administered must be informed "of the option to accept or refuse administration of the product, of the consequences, if any, of refusing administration of the product, and of the alternatives to the product that are available and of their benefits and risks."¹⁴ That said, this language could also be interpreted to give an individual the ability to refuse to be vaccinated, but not to prohibit an employer from imposing a mandate as a condition of employment or the operator of a seniors housing community from mandating vaccination as a condition of admission. Nonetheless, some federal agencies appear to be interpreting the language to preclude vaccination mandates while the vaccines are being administered pursuant to an EUA.

¹³ Rebecca Robbins and Jessica Silver-Greenberg, "Vaccination Campaign at Nursing Homes Faces Obstacles and Confusion," *N.Y. Times*, Dec. 16, 2020, <https://www.nytimes.com/2020/12/16/business/covid-coronavirus-vaccine-nursing-homes.html>.

¹⁴ 21 U.S.C. § 360bbb-3(e)(1)(A)(ii)(III).

A potential vaccine mandate raises a number of potential issues related to employment law. The Equal Employment Opportunity Commission (EEOC) updated its COVID-19 guidance on December 16, 2020, to address employment law-related concerns for employers seeking to have their employees vaccinated for COVID-19.¹⁵

First, if employers are administering the vaccine or have contracted for somebody to administer on their behalf, they should be careful about pre-vaccination screening questions that could be considered a disability-related inquiry under the Americans with Disabilities Act (ADA). Second, companies that choose to impose a vaccination mandate must be prepared to handle any requests for exemptions for medical or religious reasons. Employees with medical conditions preventing them from being vaccinated may request accommodations under the ADA. In its recent guidance, the EEOC recommended use of a four-factor test to evaluate a request for an exemption in the event that an employer determines “that an unvaccinated employee would pose a direct threat due to a ‘significant risk of substantial harm to the health or safety of the individual or others that cannot be eliminated or reduced by reasonable accommodation.’” With respect to requests for an exemption from a mandatory vaccination policy because of an employee’s “sincerely held religious practice or belief” pursuant to Title VII of the Civil Rights Act of 1964, the EEOC reminds employers that they must provide a reasonable accommodation unless doing so would pose an “undue hardship,” defined as imposing more than a de minimis cost or burden on the employer. Third, the EEOC advised employers to be aware of whether any screening questions could implicate Title II of the Genetic Information Nondiscrimination Act of 2008.¹⁶

Companies should be careful to ensure that they apply any vaccination mandates and exemptions to such mandates fairly, consistently, and in a non-discriminatory manner. In the event that a community has a unionized workforce, the employer may need to bargain with the union in accordance with existing collective bargaining agreements. Finally, as always, state laws may also have further anti-discrimination restrictions, and communities should ensure any vaccination mandate complies with the relevant state laws. On the other side of the coin, it is possible that some states or localities may institute vaccination mandates either broadly or within certain industries, such as the healthcare industry.

VII. LIABILITY CONCERNS

In addition to potential employment discrimination lawsuits related to enforcement of a vaccine mandate, seniors housing companies should be aware of other litigation that could arise in connection with vaccination efforts. As discussed in greater detail above, a resident who regretted a decision to get vaccinated could attempt to assert that the community did not properly obtain their informed consent, perhaps by failing to adequately apprise the resident of the potential risks. A resident’s representative could assert that a resident who was vaccinated and provided his or her own consent lacked capacity to provide that consent. And in the unlikely event a resident suffers a serious

¹⁵ EEOC, “What You Should Know About COVID 19 and the ADA, the Rehabilitation Act, and Other EEO Laws,” last updated Dec. 16, 2020, <https://www.eeoc.gov/wysk/what-you-should-know-about-covid-19-and-ada-rehabilitation-act-and-other-eeo-laws>.

¹⁶ 42 U.S.C. §§ 2000ff et seq.

adverse event following vaccination, the resident could attempt to hold the community liable for his or her injury. On the other hand, if a community does not do enough to encourage vaccination or take appropriate precautions and an outbreak occurs, infected residents and staff could assert a claim for negligence.

It is possible that a seniors housing community could seek protection from certain state law-based lawsuits through the federal Public Readiness and Preparedness Act (PREP Act), 42 U.S.C. 247d-6d. The PREP Act provides “covered persons” immunity from liability for certain claims related to the administration or use of covered countermeasures. Immunity offered by the PREP Act comes into play only upon a declaration issued by the Secretary of Health and Human Services (HHS), declaring the existence of a public health emergency and outlining the parameters of the PREP Act’s coverage in relation to the particular emergency. The Secretary issued such a declaration pertaining to the coronavirus pandemic on March 17, 2020¹⁷ (the “Declaration”) and has subsequently amended the declaration several times; HHS has also issued several opinion letters and guidance documents interpreting the Declaration and amendments thereto.¹⁸

Per the Declaration, covered countermeasures include any vaccines used to prevent COVID-19 and the “Administration of Covered Countermeasure” is defined as the “physical provision of the countermeasures to recipients, or activities and decisions directly relating to public and private delivery, distribution and dispensing of the countermeasures to recipients, management and operation of countermeasure programs, or management and operation of locations for purpose of distributing and dispensing countermeasures.”¹⁹ Many of a long-term care community’s activities related to vaccination could conceivably fall under this definition of administration of covered countermeasures. The key question is whether and to what extent such communities and their staff would qualify as “covered persons” under the PREP Act and the Declaration in connection with vaccine administration efforts. In order to maximize the chances of immunity under the PREP Act, and in accordance with an Advisory Opinion issued on May 19, 2020, communities should be careful to “take, and document, reasonable precautions under the current emergency circumstances to facilitate the safe use or administration of covered countermeasures and [] make those documents publicly and easily available.”²⁰

Finally, seniors housing communities should also keep abreast of the issuance and/or expiration of any liability waivers provided under state law.

¹⁷ HHS, “Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19,” 85 Fed. Reg. 15198 (March 17, 2020).

¹⁸ See Office of the Assistant Secretary for Preparedness and Response, HHS, “Public Readiness and Emergency Preparedness Act,” last reviewed Dec. 9, 2020, <https://www.phe.gov/Preparedness/legal/prepact/Pages/default.aspx>.

¹⁹ 85 Fed Reg. 15202.

²⁰ Robert P. Charrow, General Counsel, HHS, Advisory Opinion on the Public Readiness and Emergency Preparedness Act and the March 10, 2020 Declaration Under the Act, May 19, 2020.

VIII. INDEPENDENT LIVING

Although the vaccination of nursing home and assisted living facility residents and staff has been prioritized by the federal government, it remains unclear where residents of independent living units fit in and whether they will be able to obtain vaccines in this initial phase of vaccination. Indeed, in its Interim Recommendation issued in early December, the ACIP referenced the “3 million adults resid[ing] in LTCFs, which include skilled nursing facilities, nursing homes, and assisted living facilities,” but said nothing about seniors living in independent living communities. Organizations including ASHA are engaging in advocacy efforts to ensure that independent living residents are not only not forgotten, but are prioritized along with assisted living residents. In the meantime, however, it is important that communities that include both assisted and independent living residents consider what changes they may need to make in the event that only assisted living residents are vaccinated while independent living residents remain unvaccinated.

IX. CONCLUSION

As a tumultuous 2020 draws to an end, much remains unclear as to precisely how U.S. vaccination efforts will ultimately unfold. As with all matters pandemic-related, stakeholders in the seniors housing arena must continue to follow the constantly changing information, plans, requirements, and recommendations from federal, state, and local authorities.

Disclaimer: This Special Issue Brief has been prepared and published for informational purposes only and is not offered, nor should be construed, as legal advice.

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