



April 3, 2020

The Honorable Alex M. Azar
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, DC 20201

Dear Secretary Azar:

Argentum and the American Seniors Housing Association (ASHA) are writing to seek confirmation that senior living communities and their employees will be among those afforded critical legal protections under the “Declaration Under the Public Readiness and Emergency Preparedness Act (the PREP Act) for Medical Countermeasures Against COVID-19” (the Declaration)¹ published by the Department of Health and Human Services (HHS) on March 17, 2020 in response to the ongoing COVID-19 public health emergency.

Argentum and ASHA are the leading national associations exclusively dedicated to supporting companies operating professionally managed, resident-centered senior living communities and the older adults and families they serve. Our member senior living communities offer assisted living, independent living, continuing care, and memory care services, representing approximately 75 percent of the professionally managed senior living industry. Many seniors and their families turn to senior living communities, often during a time of crisis, to provide the services and supports needed to care for their loved ones.

I. Senior Living Communities Should Be Protected from Liability Under the PREP Act

The COVID-19 public health emergency is a challenging time for the thousands of senior living communities serving our nation’s seniors around the United States. The Centers for Disease Control and Prevention (CDC) has clearly indicated that people aged 65 years and older and people who live in congregate settings are at a higher risk for severe illness.² Through these

¹ Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 85 Fed. Reg. 15198 (March 17, 2020) (hereinafter, “Declaration”).

² CDC, Coronavirus Disease 2019 (COVID-19), People who are at higher risk for severe illness, https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-at-higher-risk.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fcoronavirus%2F2019-ncov%2Fspecific-groups%2Fhigh-risk-complications.html, last updated March 26, 2020.

statements, CDC and other public health officials have made it clear that caretakers of elderly adults must take aggressive actions to protect the health of elderly adults and further the greater public health interest by helping to stop the spread of COVID-19. Senior living communities are at the front lines of providing this protection to elderly adults. For senior living communities to respond to COVID-19 in a way that best serves the interests of the elderly adults residing in their communities, the protection from liability provided to Covered Persons by the PREP Act should apply to senior living communities and their employees. We urge the Secretary to confirm this interpretation in an expedited manner to remove current and anticipated barriers to care for the nation's elderly adults.

II. Legal Authority to Clarify that Senior Living Communities Are Afforded Protections Under the PREP Act

Under the PREP Act, a “covered person” is “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” if a declaration is published in the Federal Register.³ As described below, senior living communities meet the definition of a “covered person” and also engage in the activities protected by the PREP Act, and therefore should be protected from liability for all claims for loss caused by, arising out of, relating to, or resulting from the administration to an individual of a covered countermeasure.

a. Senior Living Communities are a “Covered Person”

Based on the plain language of the PREP Act and the Declaration, senior living communities should be considered a “covered person.” Under the PREP Act and Declaration, a “covered person” is, among others, a “qualified person who prescribed, administered, or dispensed such countermeasure”⁴ and a “program planner of such countermeasure.”⁵

“Qualified person” means, in relevant part:

“any person authorized to administer, or dispense the Covered Countermeasures.”⁶

Specifically, senior living communities meet this definition because employees of senior living communities are licensed, registered, certified, or authorized to assist with and administer medications to community residents who are not capable of self-administration. These employees, working under the delegation of a nurse, administer daily medications to residents of senior living communities. These employees are available to administer countermeasures to the residents, as prescribed/ordered by a physician.

“Program planner” means:

“a State or local government, including an Indian tribe, a person employed by the State or local government, or other person who supervised or administered a program with respect to the administration, dispensing, distribution, provision, or use of a security

³ 42 USC 247d-6d(a)(1); (b)(1).

⁴ 42 USC 247d-6d(i)(2)(B)(iv); Declaration, Section V.

⁵ 42 USC 247d-6d(i)(2)(B)(iii); Declaration, Section V.

⁶ 42 USC 247d-6d(i)(2)(B)(iv); Declaration, Section V.

countermeasure or a qualified pandemic or epidemic product, including a person who has established requirements, provided policy guidance, or supplied technical or scientific advice or assistance or provides a facility to administer or use a covered countermeasure in accordance with a declaration.”⁷

Senior living communities clearly meet the definition of “program planner.” Specifically, many of the senior living communities in the U.S. provide a facility that ensures the elderly are able to have access to covered countermeasures, such as a drug, biological, or device that could diagnose, mitigate, prevent, treat, cure, or limit the harm of COVID-19. The communities provide the space for community employees to assist with and administer medication, including covered countermeasures as needed, to community residents.

For the reasons described above, senior living communities and their employees meet the definition of a covered person for purposes of the PREP Act. Therefore, HHS should clarify that senior living communities and their employees will be afforded every protection from liability provide by the PREP Act and the Declaration.

b. Senior Living Communities Engage in the Activities Protected From Liability Under the PREP Act

In the Declaration, the Secretary extended the protections afforded by the PREP Act to “the manufacture, testing, development, distribution, administration, and use of the Covered Countermeasures.”⁸ Senior living communities engage in “Administration of a Covered Countermeasure” as defined in the Declaration, and therefore should be protected from liability under the PREP Act.

The Declaration specifically defines “Administration of Covered Countermeasure” to mean:

“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.”⁹

Senior living communities manage and operate locations that are used to distribute and administer certain drugs, biologicals, and devices, including those used to diagnose, mitigate, prevent, treat, or cure COVID-19, and assist with and administer countermeasures to the residents of their senior living communities. As described above, qualified and trained community employees assist with and administer medications to residents of senior living communities, including countermeasures as appropriate. They also use and apply masks, gowns, gloves, disinfectants and other devices and products designed to mitigate and prevent the spread of COVID-19. The senior living communities provide the physical locations for the administration of such countermeasure dispensing. Therefore, the senior living communities and their employees should be considered to manage and operate locations that, in part, distribute and dispense countermeasures. For these reasons, HHS should clarify that senior living communities

⁷ 42 USC 247d-6d(i)(6).

⁸ Declaration, Section III.

⁹ Declaration, Section IX.

and their employees engage in the “Administration of Covered Countermeasures” through the “management and operation of locations for purposes of distributing and dispensing countermeasures” and are therefore immune from suit or liability for their activities related to such “Administration of Covered Countermeasures.”

III. Authority to Amend the Secretary’s Declaration

If HHS determines, despite the above, that senior living communities and their employees do not fall under the definition of a “covered person,” Argentum and ASHA strongly recommend that HHS amend the Declaration to specifically include senior living communities and their employees in the Declaration. Under the PREP Act, “the Secretary may through publication in the Federal Register amend any portion of a declaration.”¹⁰ HHS should exercise its authority to make such a change to help bolster the critical activities of senior living communities and their employees to protect our elderly during the COVID-19 public health emergency.

IV. Conclusion

Given the urgency of the COVID-19 public health emergency, Argentum and ASHA thank you for your attention to the elderly population living in senior living communities. We recommend HHS promptly clarify that senior living communities and their employees are considered to be protected from liability under the PREP Act, or, in the alternative, that HHS amend the Declaration to include senior living communities. If it would be helpful to discuss these issues further, please do not hesitate to reach out to James Balda at JBalda@argentum.org or David Schless at DSchless@seniorshousing.org.



Sincerely,

James Balda
President and CEO
Argentum



David Schless
President and CEO
American Seniors Housing
Association

¹⁰ 42 USC 247d-6d(b)(4).