



March 25, 2020

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

Dear Secretary Azar:

We write on behalf of LeadingAge to request clarification regarding the legal immunity afforded to health care facilities, most notably skilled nursing facilities (SNFs) and assisted living facilities (ALFs), under the Public Readiness and Emergency Preparedness Act (the “PREP Act”) and your March 17, 2020 Notice of Declaration under the PREP Act for medical countermeasures against COVID-19 (“the Declaration”).

LeadingAge represents more than 5,000 aging-focused organizations that touch millions of lives every day. Alongside our members and 38 state partners, we address critical issues by blending applied research, advocacy, education, and community-building. We bring together the most inventive minds in our field to support older adults as they age wherever they call home. We make America a better place to grow old. For more information: www.leadingage.org

As you are surely aware, SNFs and ALFs are and will continue to be on the front lines of the country’s battle against COVID-19. They provide the invaluable public service of caring for the country’s most frail and at-risk individuals and preventing the further spread of COVID-19 to that vulnerable population. Given the indispensable public-health role of SNFs and ALFs in tackling this pandemic, it is essential that they are afforded the fullest extent of legal immunity available under the law in connection with their efforts in responding to COVID-19, including the immunity provided under the PREP Act. This immunity will give SNFs and ALFs the confidence to take all necessary measures under these extraordinary conditions to care for elderly and at-risk individuals afflicted by COVID-19 and to prevent the further spread of COVID-19 without fear of liability.

There are two clarifications regarding the PREP Act and the Declaration that would be particularly helpful in ensuring that SNFs and ALFs are afforded the legal immunity needed to respond to this pandemic effectively. The first is an express confirmation that SNFs and ALFs qualify as “covered persons” under the PREP Act and under the Declaration.

We believe that SNFs and ALFs do currently qualify under both the PREP Act itself and the Declaration as written. The PREP Act defines “covered persons” to include, *inter alia*, “qualified

persons” and “program planners.”¹ “Program planner” is defined to include persons or entities “who provide a facility to administer or use a ‘covered countermeasure’ in accordance with a declaration.”² To the extent SNFs and ALFs are administering or using “covered countermeasures” such as covered personal protective equipment (PPE) and covered drugs to prevent and treat COVID-19, they should qualify as “program planners” and thus as “covered persons.”

In addition, the Declaration defines “qualified persons” to include:

Any person authorized in accordance with the public health and medical emergency response of the Authority Having Jurisdiction, as described in Section VII below, to prescribe, administer, deliver, distribute or dispense the Covered Countermeasures, and their officials, agents, employees, contractors and volunteers, following a Declaration of an emergency; (b) any person authorized to prescribe, administer, or dispense the Covered Countermeasures or who is otherwise authorized to perform an activity under an Emergency Use Authorization in accordance with Section 564 of the FD&C Act; and (c) any person authorized to prescribe, administer, or dispense Covered Countermeasures in accordance with Section 564A of the FD&C Act.³

We believe that SNFs and ALFs are included under this definition of “qualified persons” to the extent they are authorized to administer or dispense “covered countermeasures,” such as covered personal protective equipment (PPE) and covered drugs to prevent and treat COVID-19. However, in order to avoid any doubt and potential litigation over whether SNFs and ALFs qualify under these definitions, we request that you issue an express confirmation that health care facilities, including SNFs and ALFs, qualify as “covered persons” under the PREP Act and the Declaration to the extent they administer, use, or dispense covered countermeasures.

Second, we request a clarification that immunity under the PREP Act and the Declaration extends to situations in which covered countermeasures are either scarce or unavailable. As you are surely aware, one of the challenges contributing to this pandemic is the shortage of tests, PPE, respirators, ventilators, and, potentially, drugs needed to prevent and treat COVID-19 in the face of rapidly increasing demand. The PREP Act and the Declaration broadly provide for immunity “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.”⁴ We believe this includes claims alleging the failure to use a covered countermeasure, the shortage of a covered countermeasure, or the insufficient use of a covered countermeasure. However, again to avoid any doubt or litigation and in light of the known scarcity of many of the covered countermeasures

¹ 42 U.S.C. 247d-6d(i)(2).

² 42 U.S.C. 247d-6d(i)(6).

³ Notice of Declaration, 85 Fed. Reg. 15198, 15201-15202 (March 17, 2020).

⁴ 42 U.S.C. 247d-6d(a)(1).

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needed to combat COVID-19, we request that you issue an express confirmation that the legal immunity afforded under the PREP Act extends to claims alleging the failure to use a covered countermeasure, the shortage of a covered countermeasure, or the insufficient use of a covered countermeasure. In order to support SNFs and ALFs providing treatment to elderly and at-risk individuals afflicted by COVID-19, it is essential that they be shielded from liability and costly litigation due to shortages beyond their control.

We thank you for your leadership and support of health care providers during this national health crisis, and we look forward to hearing from you regarding these important issues for our country's SNFs and ALFs that are on the front lines of the fight against COVID-19.

Sincerely,

A handwritten signature in black ink that reads "Katie Smith Sloan". The signature is written in a cursive, flowing style.

Katie Smith Sloan
President and CEO