



December 6, 2021

José J. Reyes
Puerto Rico National Guard
JFHQ, Fort Buchanan
Guaynabo, PR 00902

Dear Mr. Reyes:

The Centers for Disease Control and Prevention (CDC) is terminating the CDC Provider Agreement with the Puerto Rico National Guard, signed on December 9, 2020, effective immediately. CDC is taking this action based on information provided to the agency by the HHS Office of Inspector General.

In December 2020, CDC began distributing COVID-19 vaccine to providers enrolled in the CDC COVID-19 Vaccination Program for administration of COVID-19 vaccine to those eligible to receive it as determined by the Food and Drug Administration (FDA) and as recommended by CDC or CDC's Advisory Committee on Immunization Practices (ACIP). As a condition of enrollment in the CDC COVID-19 Vaccination Program and receipt of vaccine, eligible providers were required to agree to CDC's Provider Agreement. The general purpose of the Provider Agreement is to ensure compliance with all requirements of the program, including those related to individuals eligible to receive the vaccine. Providers who violate the terms of the Provider Agreement are subject to termination of the Agreement and discontinuation of vaccine receipt.

In December 2020, FDA authorized use of Pfizer-BioNTech COVID-19 vaccine for individuals aged 16 years and older under an Emergency Use Authorization (EUA), and Moderna COVID-19 vaccine for individuals aged 18 years and older under an EUA, followed by ACIP and CDC recommendations regarding the same. On May 10, 2021, FDA further authorized use of Pfizer-BioNTech COVID-19 vaccine for adolescents aged 12 through 15 years, and on May 12, ACIP and CDC recommended use of the same for this age group.

On October 28, 2021, CDC received reports from the HHS Office of the Inspector General indicating that between February and July 2021, the Puerto Rico National Guard administered COVID-19 vaccine to children under the age of 16 prior to authorization of such use by FDA and recommendation from CDC/ACIP. The dose size administered was that authorized by FDA for individuals aged 16 and older (for Pfizer-BioNTech COVID-19 vaccine) and individuals aged 18 years and older (for Moderna COVID-19 vaccine). This activity violates, at a minimum, the following provisions of the CDC Provider Agreement:

- Paragraph 1: Organization must administer COVID-19 Vaccine in accordance with all requirements and recommendations of CDC and CDC's Advisory Committee on Immunization Practices (ACIP).
- Paragraph 12a: Organization must comply with all applicable requirements as set forth by the U.S. Food and Drug Administration, including but not limited to requirements in any EUA that covers COVID-19 Vaccine.

CDC also is terminating the CDC Supplemental COVID-19 Vaccine Redistribution Agreement with the Puerto Rico National Guard, effective immediately.

All CDC Provider Agreement requirements as to COVID-19 Vaccine doses administered up to termination of the CDC Provider Agreement continue to apply. CDC will provide instructions on removal of any remaining doses within the Puerto Rico National Guard's possession.

You may seek review of this decision should you choose to do so by sending a request to the CDC official listed below within 14 days of the date of this letter. If no review request is received, this termination letter will constitute final agency action at that time. Any request for review must explain, in writing, why you believe CDC's termination was made in error. CDC's review will be limited to the written record and limited to disputes of fact. Upon receiving such a request, CDC will review and issue within 30 days a final, written determination. Such a request may be sent to Sam Posner, Acting Director, National Center for Immunization and Respiratory Diseases, CDC at the following email address: shp5@cdc.gov.

Sincerely,



Kristin Pope
Deputy Director for Management and Operations
National Center for Immunization and Respiratory Diseases
Centers for Disease Control and Prevention

cc: Dr. Iris Cardona
Chief Medical Officer
Puerto Rico Department of Health