



DATE: April 6, 2021

TO: Josh Brammer, OMB Desk Officer

FROM: Lisa Wright-Solomon, HRSA Information Collection Clearance Officer

Request: The Health Resources and Services Administration (HRSA) Bureau of Primary Health Care Division requests approval for non-substantive changes to the “Application for Deemed Health Center Program Award Recipients to Sponsor Volunteer Health Professionals (VHPs) for Deemed PHS Employee Status under the Federal Tort Claims Act” (0906-0032, expiration date 12/31/2023) to support federal government COVID-19 response efforts.

Purpose: The purpose of this request is to modify the “Application for Deemed Health Center Program Award Recipients to Sponsor Volunteer Health Professionals (VHPs) for Deemed PHS Employee Status under the Federal Tort Claims Act” to enable qualified health centers to obtain FTCA coverage for volunteers providing only COVID-19 vaccine-related services that are now eligible under the Acting HHS Secretary’s fifth amendment pursuant to section 319F–3 of the PHS Act. This amendment added additional categories of Qualified Persons authorized to prescribe, dispense, and administer COVID–19 vaccines that are covered countermeasures under section VI of this Declaration with an effective date of January 28, 2021.

The Federally Supported Health Centers Assistance Act of 1992 and 1995 (FSHCAA) granted medical malpractice liability protection through the Federal Tort Claims Act (FTCA) to HRSA-supported health centers. Volunteer health professionals were initially not eligible for such liability protections granted under FSHCAA. Section 9025 of the 21st Century Act added section 224(q) to the Public Health Service (PHS) Act making certain qualified volunteer health care professionals eligible for the coverage extended under FSHCAA. Under section 224(q), volunteers are not automatically covered, but are required to individually apply for coverage under a process distinct from a Health Centers deeming application. Health Center volunteers in the VHP program are not covered

by the liability protections established under FSHCCA until their sponsoring application is approved and the name of the individual included on a deeming letter. As part of that application, documentation must be provided that demonstrate that they have a license or certificate that authorizes them to provide health care services as required by the law of the state in which they practice.

This request seeks the change of existing questions so as to enable health centers to identify volunteers eligible under the new category of eligible volunteers created by the Acting Secretary's 5th Amendment. Furthermore, these changes to the form will also address other state legislative changes in response to COVID-19 that may impact the applicable requirements for administering COVID-19 vaccines and who may qualify as a volunteer health professional to administer vaccines. This memo explains the proposed changes and supporting rationale.

The overall proposed change of application form is minimal and represents an update of existing content so as to permit Health Center volunteers with their services limited to healthcare services related to the COVID-19 vaccine. Applications will require no additional information than sought in the current application. Given the unprecedented nature of the pandemic, the increased need for VHPs, and the amendment creating a new category of eligibility, these changes are required.

Time Sensitivity: The COVID-19 data collection changes must be completed in an expedited manner to permit the expanded use of VHPs at health centers and fulfill the intent of the amendment to expand availability of health care providers addressing the nation's vaccination needs. Immediate approval is needed due to new VHP applications having been set to be release in production within the 2nd or 3rd week of April.

Burden: This data collection is not expected to increase the burden upon health centers. The application provides the required information to enable HRSA to approve FTCA coverage for volunteers. These changes do not increase the burden on health centers with the current application and only allow identification and approval of a newly eligible category of providers. The overall burden calculation may increase to the extent that Health Centers utilize this newly eligible category of providers to meet the increased demand for COVID-19 vaccination and related services. Health Centers are not required to obtain coverage or submit these applications. The proposed changes will allow health centers to obtain coverage for the

category of providers now eligible for coverage under the FTCA in the midst of the global pandemic.

PROPOSED CLARIFICATIONS AND NON-SUBSTANTIVE CHANGES

Health Center VHP Application Form

a. Heading, page 1 (page referenced are to tracked changes version) – Clarification

Clarified title: Replaced “Employment” with “Employee Status under the Federal Tort Claims Act. Title as modified:

“Application for Deemed Health Center Program Award Recipients to Sponsor Volunteer Health Professionals (VHPs) for Deemed PHS Employee Status under the Federal Tort Claims Act”

Rationale: The application title as modified fully reflects the outcome of submitting a successful application.

b. Section I, question 1, page 1 – Clarification

Replaced the word “a title” with “honorific.” Clarified question:

CONTACT INFORMATION (Include an honorific (Ms., Mrs., Mr., Dr., etc.) before the name) All fields marked with an * are required.

Rationale: Term more applicable.

c. Section II, question 1, page 4 – Clarification

Clarified question: Removed the word “deemed” to accurately reflect that this application may be submitted as part of a deeming application. Resulting question:

“The services provided by the VHP occur at the sponsoring deemed health center’s facilities (i.e., at its approved service sites) or through offsite programs or events carried out by the sponsoring deemed health center (section 224(q)(2) (A)).”

Rationale: Increases accuracy and decreases potential for confusion.

d. Section III, page 8 – Modification

Modified application to permit identification of VHP’s for which coverage is sought only for administration of COVID-19 vaccinations. Resulting question:

Is this volunteer a COVID-19 vaccination volunteer who will be volunteering solely to administer COVID-19 vaccinations?

Yes

No

Rationale: This will enable Health Centers to apply for coverage of the new category of providers and identify those providers so as to allow application of appropriate coverage requirements.

e. Section III, page 8 – Modification

Modified question to include VHP requirements for vaccination only volunteers.
Resulting question.

Note: For volunteers that are solely administering COVID-19 vaccines, the volunteer agreement should clearly include that information and should also include any other state or federal requirements that must be met for the individual to volunteer as a COVID-19 vaccinator.

Rationale: Modified statement applicable to VHPs generally that includes requirements of agreement for all VHPs.

f. Section III, page 8 – Modification

Inserted question to request number of hours worked by volunteers. Resulting question.

“Please estimate, how many hours on average will the volunteers work per month?”

Rationale: Need to evaluate impact of change in eligibility related to COVID-19 and overall impact of VHP program. Moreover, this information will be used for data requests from legislative bodies and submissions to White House staff who are working with HRSA on the Health Center vaccine program.

g. Section III, p. 9 – Modified Question

Modification: Modified questions regarding Licensure and/or Certification to include choice applicable to VHPs for Covid-19 Vaccination only volunteers. Modified questions are as follows:

Or

For VHPs that are solely administering COVID-19 Vaccines, the individual is operating under a state or federal legislation, declaration, or exemption that permits the VHP to administer COVID-19 vaccinations under a special grant of authority due to the ongoing COVID-19 pandemic.

Yes No

Rationale, the two questions above permit applicant to specify whether they are utilizing criteria based upon existing State regulation or pursuant to the new category.

h. Section III, page 9-10 – Modification

Modification: added “Please upload one of the following:” numbered the existing direction to upload primary source verification, and added option 2 for VHP vaccination only volunteers. Resulting question:

Please upload one of the following:

- 1) **Upload primary source verification of current licensure and/or certification, or**
- 2) **Upload all applicable documentation that demonstrates the VHP is allowed to provide services under a state or federal legislation, declaration, or exemption that permits the VHP to administer COVID-19 vaccinations under a special grant of authority due to the ongoing COVID-19 pandemic.**

Rationale: This question provides different methods of demonstrating and providing method of compliance with statutory requirements for VHP Vaccine Only volunteers.

Attachments:

1. Tracked Changes from previously approved version.