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**DATE:** May 13, 2021

**TO:** Josh Brammer, OMB Desk Officer

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

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**Request:** The Health Resources and Services Administration (HRSA) Bureau of Primary Health Care Division requests approval for non-substantive changes to the “Federal Tort Claims Act (FTCA) Program Deeming Sponsorship Applications for Free Clinics” (0915-0293, expiration date 1/31/2024) to support federal government COVID-19 response efforts.

**Purpose:** The purpose of this request is to modify the “Federal Tort Claims Act (FTCA) Program Deeming Sponsorship Applications for Free Clinics” to enable qualified free clinics to obtain FTCA coverage for health care volunteers providing only COVID-19 vaccine-related services that are now eligible under the Acting Health and Human Services (HHS) Secretary’s fifth amendment pursuant to section 319F–3 of the Public Health Service (PHS) Act. This amendment added an additional category 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.

Section 224(a) of the PHS Act ([42 U.S.C. 233\(a\)](#)) provides that the remedy against the United States under the (FTCA resulting from the performance of medical, surgical, dental or related functions by any commissioned officer or employee of the PHS while acting within the scope of his office or employment, shall be exclusive of any other civil action or proceeding. Section 224(o) of the Act (added by Section 194 of the Health Insurance Portability and Accountability Act (HIPAA) provides that under certain conditions, free clinic health care professionals shall be deemed to be employees of the PHS within the exclusive remedy provision of section 224(a). Free Clinic volunteers 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 5<sup>th</sup> 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 Free Clinic 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 volunteers to administer vaccines, 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 volunteers at free clinics 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 Free Clinic applications having been set to be release shortly.

**Burden:** This data collection is not expected to increase the burden upon free clinics. The application provides the required information to enable HRSA to approve FTCA coverage for volunteers. These changes do not increase the burden on free clinics 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 Free Clinics utilize this newly eligible category of providers to meet the increased demand for COVID-19 vaccination and related services. Free Clinics are not required to obtain coverage or submit these applications. The proposed changes will allow free clinics 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**

## **Free Clinic Application Form**

### **a. Section III. Sponsoring Free Clinic Eligibility, Question 1., p. 1-2 – Clarification**

Clarified request: Added parenthetical to beginning to explain for whom question is required. Added the word nonprofit to modify documentation to clarify documentation type required and deleted outdated descriptor. An attachment instruction that was previously in section VIII, was inserted after question 1 so as to make clearer the needed attachment by including with the relevant question.

**Rationale:** The question as modified clarifies who is required to answer the question and the type of documentation needed. Also clarifies the documentation to be attached to demonstrate compliance.

### **b. Section IV, instruction, page 3 – Clarification**

Changed word order and inserted clarification that Section 4 is required for applications following initial applications as well as annual deeming applications.

**Rationale:** Clarifies cases in which section is applicable.

### **c. Section V, question 7, page 4 – Clarification**

Clarified question: Added phrase “or Risk Management” so as to include different descriptions may be used for the plan in which risk, patient safety, and quality are addressed. An attachment instruction that was previously in section VIII was inserted after question 7 so as to make clearer the needed attachment by including with the relevant question.

**Rationale:** Clarifies question and decreases potential for confusion. Also clarifies the documentation to be attached to demonstrate compliance.

### **d. Section VI, page 5-6 – 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

Added instructions and “Note” to clarify how a covered entity documents compliance and what documentation needs to be attached.

**Rationale:** This will enable Free Clinics to apply for coverage of the new category of providers and identify those providers so as to allow application of appropriate coverage requirements. It will also make clear the requirements and documentation to be attached to demonstrate compliance.

e. **Section VI, page 6 – 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 Free Clinic 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 Free Clinic vaccine program.

f. **Section VI, p. 7 – Modification**

Modified question and instructions regarding Licensure and/or Certification to include choice applicable to Free Clinics for Covid-19 Vaccination only volunteers.

**Rationale,** the modifications permit applicant to specify whether they are utilizing criteria based upon existing State regulation or pursuant to the new category and makes clear the requirements applicable to such individuals.

g. **Section VI, page 7-8 – Modification**

Modification: Added additional instructions to clarify requirements applicable to Covid-19 Vaccination only volunteers.

**Rationale:** This modification explains different methods of demonstrating and providing method of compliance with statutory requirements for Free Clinic Vaccine Only volunteers.

**Attachments:**

1. Tracked Changes from previously approved version.