

Vaccine Preventable Disease Program

Yellow Fever Vaccine Program Manual

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Yellow Fever Certification

According to International Health Regulations, yellow fever vaccine must be administered at certified yellow fever vaccination centers. Healthcare providers are authorized to administer the vaccine by state health departments and the states then report certified providers to the Centers for Disease Control and Prevention (CDC). The CDC maintains a registry of certified providers.

The New Jersey Department of Health (NJDOH), Vaccine Preventable Disease Program (VPDP) is responsible for managing the Yellow Fever Vaccine Program. Physicians licensed in New Jersey are permitted to apply for certification to participate in the program. Program participants are subject to the policies and procedures outlined in this document and the guidelines put forth by the CDC.

Certified Uniform Yellow Fever Stamp Holder

A Certified Yellow Fever Stamp Holder, hereby referred to as the Uniform Stamp Holder, is the physician that is certified by the NJDOH VPDP to administer yellow fever vaccine to the public and participate in the Yellow Fever Vaccine Program. This person must designate at least one medical facility as a Yellow Fever Vaccination Center where persons may go to receive the yellow fever vaccine. The Uniform Stamp Holder is responsible for the activities of the designated facility with regard to the yellow fever vaccine.

Certified Yellow Fever Vaccine Uniform Stamp

A Certified Yellow Fever Stamp, hereby referred to as the Uniform Stamp, is a stamp that contains a unique stamp number. This stamp is used by the designated Yellow Fever Vaccination Center(s) for international verification that a traveler has been vaccinated against yellow fever. This designation by NJDOH VPDP authorizes the center to administer yellow fever vaccine. Sanofi, the manufacturer of the vaccine, will only ship yellow fever vaccine to a designated Yellow Fever Vaccination Center

associated with an active Uniform Stamp Holder. A current NJDOH certification letter is required to order and administer yellow fever vaccine in the State of New Jersey. Note that the shipping address for the Yellow Fever Vaccination Center must match the physical address where the vaccine is being administered. If the addresses do not match, Sanofi will not authorize the Yellow Fever Vaccination Center to order. If this is a problem, please reach out to Sanofi to learn more at cammil-yf2@sanofi.com.

Who Can Apply?

Applicants must be a practicing physician who has a current New Jersey medical license and is in good standing with the New Jersey Board of Medical Examiners.

Application Requirements

The following must be completed to apply for participation in the New Jersey Yellow Fever Vaccine Program:

- 1. Application for Certified Yellow Fever Uniform Stamp (click here).
- **2. CDC Yellow Fever Training Course and Transcripts with Scores –** all transcripts should be attached to Application for Certified Yellow Fever Uniform Stamp.

The following staff must complete the current version of this course and the posttest:

- Uniform Stamp applicant this individual is also responsible for ensuring that all appropriate staff take the course
- Yellow Fever Coordinator
- Any other staff with responsibilities associated with the administration and storage and handling of yellow fever vaccine

The course is available through CDC TRAIN (click here).

For more information about the course and test, you can visit the CDC site (click here).

3. Enrollment in New Jersey Immunization Information System (NJIIS).

The Uniform Stamp Holder must enroll as a user in NJIIS and ensure that all administered vaccines are entered into the system. **Failure to enter all doses into NJIIS could result in the revocation of the Uniform Stamp.** The Uniform Stamp Holder is responsible for ensuring that all NJIIS requirements are met.

To enroll, please complete the online form (<u>click here</u>) or the PDF version (<u>click here</u>).

4. Sanofi New Customer Form.

Providers seeking to be Uniform Stamp Holders must also contact Sanofi (<u>cammil-yf2@sanofi.com</u>) to complete a New Customer Form and enroll as a customer.

Application Approval

Approval of providers for the Yellow Fever Vaccine Program is at the discretion of the NJDOH VPDP. After the application has been approved, the NJDOH VPDP will order a Uniform Stamp to be sent to the Uniform Stamp Holder and issue a certification letter with expiration date. The certification letter will be sent to both the Uniform Stamp Holder and Sanofi.

Responsibilities of Uniform Stamp Holder

A Yellow Fever Vaccination Center is approved by the NJDOH VPDP; the Uniform Stamp Holder is responsible for the stamp and for ensuring the site is in compliance with the program requirements. Any time a Uniform Stamp Holder is no longer associated with a Yellow Fever Vaccination Center, the designation is no longer valid. The Uniform Stamp Holder must notify the NJDOH VPDP of any changes to the information on record for the Uniform Stamp Holder or any designated Yellow Fever Vaccination Center.

A Uniform Stamp Holder can be responsible for more than one Yellow Fever Vaccination Center. For each additional center, an Application for Certified Yellow Fever Uniform Stamp (click here) must be completed. The Stamp Holder must designate a medically trained staff member for each site to serve as the Yellow Fever Vaccine Coordinator.

The Yellow Fever Vaccine Coordinator must be an individual who is licensed by a health-related board within New Jersey and whose scope of practice includes vaccination (i.e., physician, nurse, pharmacist, or physician's assistant). A change of the Yellow Fever Vaccine Coordinator must be reported to the NJDOH. The Uniform Stamp Holder may also serve as the Yellow Fever Vaccine Coordinator for up to two designated Yellow Fever Vaccination Centers. Yellow Fever Vaccine Coordinators who are not also the Uniform Stamp Holder may serve as the Coordinator for up to two designated Yellow Fever Vaccination Centers.

Staff at a designated Yellow Fever Vaccination Center is expected to be familiar with yellow fever vaccine administration standards, as well as the recommended recordkeeping and storage procedures that are outlined in the CDC Yellow Fever Vaccine Course. The Uniform Stamp Holder is responsible for ensuring that the site is in compliance with CDC Vaccine Storage and Handling Toolkit available (click here).

The NJDOH VPDP may revoke a center's designation or a Uniform Stamp Holder's certification if the center does not conform to the conditions of the program or if the Uniform Stamp Holder fails to renew their certification according to the guidelines. Facilities that lose their designation will be removed from the CDC central registry of Yellow Fever Vaccination Centers and will be removed from the list of providers able to purchase yellow fever vaccine from Sanofi.

Period of Certification/Recertification

Uniform Stamp Holders must apply for recertification every three (3) years and complete the Application for Certified Yellow Fever Uniform Stamp (click here). Uniform Stamp Holders must complete and submit this form by December 31 of the expiration year indicated on the certification letter. Failure to submit the form will result in the removal of the Uniform Stamp Holder and/or designated Yellow Fever Vaccination Center from the CDC central registry of Yellow Fever Vaccination Centers and from the list of providers able to purchase yellow fever vaccine from Sanofi. Approval for renewal in the Yellow Fever Vaccine Program is at the discretion of the NJDOH VPDP.

Responsibilities of Yellow Fever Vaccine Coordinator

The Yellow Fever Vaccine Coordinator must be an individual who is licensed by a health-related board within New Jersey and whose scope of practice includes vaccination (i.e., physician, nurse, pharmacist or physician's assistant). This person is responsible for ensuring that the site is in compliance with all requirements under the direction of the Uniform Stamp Holder. Responsibilities are listed under the "Standards, Recordkeeping, and Storage" section, and include but are not limited to, ensuring the following activities occur: proper storage and handling of vaccine, completion of online CDC training for all pertinent staff, maintaining required documentation and records (i.e. Standing Orders, Vaccine Management Plan, Temperature Logs, transcripts for CDC Yellow Fever Vaccine Course). The Yellow Fever Vaccine Coordinator also serves as the contact person for the Yellow Fever Vaccination Center and the NJDOH VPDP.

The Uniform Stamp Holder may also serve as the Yellow Fever Vaccine Coordinator at no more than two designated Yellow Fever Vaccination Centers. Yellow Fever Vaccine Coordinators who are not also the Uniform Stamp Holder may serve as the Coordinator at no more than two designated Yellow Fever Vaccination Centers. A change of the Yellow Fever Vaccine Coordinator must be reported to the NJDOH VPDP.

CDC Yellow Fever Vaccination Clinic Registry

After a Uniform Stamp Holder is certified and has designated a Yellow Fever Vaccination Center, the VPDP will provide the center's information to the CDC. The Uniform Stamp Holder can opt for the vaccination center's information to be posted on the CDC's public website (click here). This registry enables the general public to locate Yellow Fever Vaccination Centers in their area. Uniform Stamp Holders should review the information on the public website to ensure that accurate information is posted.

Change Notifications

Certification or designation to administer yellow fever vaccine cannot be transferred from person to person or from site to site. Any change to the information on record with the VPDP must be reported immediately by completing an Application for Certified Yellow Fever Uniform Stamp (click here). Failure to submit an application when there is a change to the information on record with the VPDP could inhibit the ability to order vaccine and/or remain in the Yellow Fever Vaccine Program. The information will be updated accordingly on the CDC website and with Sanofi.

Replacement Stamp

Uniform Stamps may be replaced if they are lost or damaged. Uniform Stamp Holders may request a replacement stamp by contacting the VPDP, which will order a new stamp. If the stamp was damaged, please return it along with the request. If a lost stamp is found after a replacement is ordered, please notify the VPDP.

Standards, Recordkeeping, and Storage

Yellow Fever Vaccination Centers must conform to acceptable standards and must adhere to the manufacturer's instructions, ACIP guidelines, and VPDP requirements. Yellow Fever Vaccination Centers may be audited by the VPDP. Failure to provide any required documentation upon request may result in the inability to order vaccine or the cancellation of the Uniform Stamp and designation of the Yellow Fever Vaccination Centers associated with the stamp.

Vaccine Storage

The Uniform Stamp Holder is ultimately responsible for the safe storage of the vaccine in conjunction with the Yellow Fever Vaccine Coordinator. See the CDC Vaccine Storage and Handling website for recommendations (click here).

Standing Orders

All Yellow Fever Vaccination Centers are required to develop Standing Orders for Administering Yellow Fever Vaccine, which must be signed by the Uniform Stamp Holder and kept at the Designated Vaccination Center.

Vaccine Management Plan

All Yellow Fever Vaccination Centers are required to develop a Vaccine Management Plan for the storage and handling of the yellow fever vaccine. This Management Plan should include guidelines for emergencies such as power outages to ensure the vaccine remains at proper temperature. The Vaccine Management Plan should be kept at the Designated Vaccination Center.

• Temperature Logs

All Yellow Fever Vaccination Centers are required to maintain an up-todate vaccine temperature log for each storage unit containing yellow fever vaccine. Temperatures should be recorded twice daily with any temperature excursions reported to Sanofi for assistance with determining vaccine viability.

• Reporting of Adverse Events

Providers should report all suspected adverse events after vaccine administration to the Vaccine Adverse Event Reporting System (click here). Healthcare providers should also report these events to the manufacturer.

• Training/Education

Uniform Stamp Holders, the Yellow Fever Vaccine Coordinator, and any staff with responsibilities associated with the administration of yellow fever vaccine must complete the current CDC Yellow Fever Vaccine Course. Following completion of the course, all individuals are required to complete the evaluation and test, print the transcript with scores, and submit the transcript to the Yellow Fever Vaccine Program by attaching to the Application for Certified Yellow Fever Uniform Stamp (click here). The Uniform Stamp applicant is responsible for ensuring that all appropriate staff take the course.

The course is available through CDC TRAIN (<u>click here</u>). For more information about the course and test, you can visit the CDC site (<u>click here</u>).

• Vaccine Information Statement (VIS)

As required by the National Childhood Vaccine Injury Act of 1986, all Yellow Fever Vaccination Centers are required to provide persons with the most recent version of the VIS (click here) for yellow fever prior to vaccine administration. The VIS provides information about the risks and benefits of the vaccine.

• New Jersey Immunization Information System (NJIIS)

The Uniform Stamp Holder must enroll as a user in NJIIS and ensure that all administered vaccines are entered into the system. The Uniform Stamp Holder is responsible for ensuring that all NJIIS requirements are met. **Failure to enter all doses into NJIIS could result in the revocation of the Uniform Stamp.** To enroll, please complete the online form (click here) or the PDF version (click here).

• International Certificate of Vaccination (ICV) or Prophylaxis Card
Each Yellow Fever Vaccination Center must have ICV cards to distribute
to patients that receive the yellow fever vaccine. The cards can be
purchased through the United States Government Bookstore (click here).

• Certification Letter

Each Yellow Fever Vaccination Center must retain the certification letter issued by NJDOH VPDP as proof of certification until the expiration date indicated on the letter.