



NEW YORK CITY DEPARTMENT OF
HEALTH AND MENTAL HYGIENE
Mary T. Bassett, MD, MPH
Commissioner

November 28, 2016

Jane R. Zucker, MD, MSc
Assistant Commissioner
Bureau of Immunization

42-09 28th Street, CN21
Queens, NY 11101-4132

Dear Colleague:

We are sending you this notice to remind you to complete the 2017 re-enrollment for the Vaccines for Children (VFC) program, if you have not already done so. We are also including additional information about the VFC program that is relevant for all providers, whether or not you have already completed re-enrollment. **You will need to complete annual re-enrollment by November 30, 2016** to maintain your ability to order vaccines distributed through VFC.

To re-enroll, you will need to complete and submit your 2017 VFC re-enrollment form in the VFC section of the CIR Online Registry at www.nyc.gov/health/cir. Prior to completing this form, the physician-in-charge, vaccine coordinator, and back-up vaccine coordinator at your facility will need to take the two required annual web-based trainings developed by the Centers for Disease Control and Prevention (CDC): *You Call the Shots Module 10: Vaccine Storage and Handling 2016 (Course #WB2596)* and *You Call the Shots Module 16: Vaccines For Children (VFC) 2016 (Course #WB2597)*. Course completion certificates must be saved onto your computer and uploaded to the "Training Requirement" section of your re-enrollment form.

Completing the training courses may take up to three hours per person, so we encourage you to complete them as soon as possible to meet the deadline. **Only certificates with a date in 2016 will be accepted.** For instructions on completing the trainings, obtaining certificates, and uploading certificates, refer to the attached "Accessing *You Call the Shots* Training Modules."

To assist you with re-enrollment, we are attaching the slides presented at the "2017 NYC VFC Re-enrollment" webinar held on Tuesday, October 25, 2016, along with answers to questions asked about VFC policy updates and re-enrollment (see two separate Frequently Asked Questions [FAQs] documents attached). Please note that the audio portion of the webinar is available on our website, at <http://www1.nyc.gov/site/doh/providers/nyc-med-cir/cir-vfc-webinar-from.page>.

We have been getting a lot of questions regarding the new storage and handling requirements that will be effective starting January 1, 2018. There is information on these requirements in part III of the attached Policy Update FAQs. We will be issuing further guidance on this issue shortly, but if you need immediate guidance prior to purchasing a new unit please call us at 347-396-2400.

Please email us at nycimmunize@health.nyc.gov or call 347-396-2404 if you have questions or need assistance.

We thank you for your cooperation.

Sincerely,

Jane R. Zucker, MD, MSc



2017 Vaccines for Children Program Re-enrollment

There are two parts to the Vaccines for Children (VFC) program re-enrollment process:

I. Required Annual Trainings

To ensure proper storage and handling of vaccine and compliance with VFC program policies, the NYC VFC program requires that the Physician-in-Charge (PIC), Vaccine Coordinator (VC) and Backup Vaccine Coordinator (BVC) complete two Centers for Disease Control and Prevention (CDC) *You Call The Shots* trainings every year.

1. *You Call The Shots Module Ten: Vaccine Storage and Handling* – 2016 (WB2596)
2. *You Call The Shots Module Sixteen: Vaccines for Children (VFC)* – 2016 (WB2597)

II. Re-enrollment Form

To complete re-enrollment, the VFC Re-enrollment Form must be submitted to the VFC program via the Citywide Immunization Registry (CIR) Online Registry at:

<https://immunize.nyc/provider-client/servlet/PC>. Make sure to carefully read the Vaccine Recipient Agreement found in the “Consent” section of the re-enrollment form. By submitting the form, providers are agreeing to all requirements outlined in the Vaccine Recipient Agreement. These requirements include offering all vaccines in the Advisory Committee on Immunization Practices (ACIP) recommended child and adolescent schedule, including human papillomavirus (HPV) vaccine and influenza. Please note that before the Re-enrollment Form can be submitted, certificates of completion for the required trainings must be uploaded for the following: PIC, VC, and BVC. Therefore, it is recommended that the required annual trainings be completed for all required persons prior to completing the re-enrollment form.

Please find Frequently Asked Questions regarding the enrollment process below.

I. Required Annual Trainings

1. **Last year, most of the providers completed trainings in December 2015. Do they need to take them again?**

Yes. Every year the required trainings are updated and must be taken by the PIC, VC, and BVC. Additionally, only certificates with a 2016 date will be accepted for 2017 re-enrollment.

2. **How do I access the *You Call The Shots* courses?**

Courses are accessed online at:

- **Vaccine Storage and Handling – 2016 (WB2596)**
 - Go to: <http://www2a.cdc.gov/nip/isd/ycts/mod1/courses/sh/start.asp>
- **Vaccines for Children (VFC) – 2016 (WB2597)**
 - Go to: <http://www2a.cdc.gov/nip/isd/ycts/mod1/courses/vfc/start.asp>



These links are available in **Section A** of the *Accessing You Call The Shots* Training Modules instructions found on our website here:

<http://www1.nyc.gov/assets/doh/downloads/pdf/imm/you-call-inst.pdf>.

3. I forgot my password. How do I get into my CDC Training and Continuing Education Online (TCEO) account?

If you know your Login Name, go to the Forgot Password webpage to enter your Login Name and a temporary password will be sent to the email you used to set up your account.

The Forgot Password webpage can be found here:

<https://www2a.cdc.gov/TCEOnline/forgotpasspart.asp>.

If you do not know your Login Name, you can contact the CDC via email (ce@cdc.gov) or phone (1-800-41-TRAIN) to regain access to your account. Their hours of operation are Monday through Friday, 8:00 am to 4:00 pm. Please note that this service is closed for lunch from 11:30am to 12:30pm. If you leave a voicemail, they will return your call the following business day.

If you do not know your Login Name AND have not heard back from the CDC, you can search the inbox of the email you used to set up your account for an email from ce@cdc.gov. Whenever CDC sets up an account, they send a confirmation email containing your Login Name to the email address used to set up the account. If you still have this email in your inbox, you can retrieve your Login Name, return to the Forgot Password webpage, and reset your password.

4. We completed the training modules before re-enrollment opened and didn't save the certificates. How can we retrieve them?

Certificates of completion remain in your TCEO account and can be retrieved by doing the following:

- a. Go to <http://www2a.cdc.gov/TCEOnline/>
- b. Click on **Participant Login**
- c. Enter your Login Name and Password
- d. Once you successfully log in, you will be on the **Participant Services** page. Click on the **Transcript & Certificate** icon. Your certificates will be on the next page that loads.

5. I failed the posttest. Does this mean I cannot get a certificate?

No. The first time you fail a posttest, you are allowed one more chance to retake it within the next 30 days from the day you failed the posttest or by the CE expiration date (whichever comes first). If you fail the posttest for the second time, you will need to re-register for the course under a different CE credit option, and retake the evaluation and posttest. Once you retake and pass the posttest, you will be given a certificate. Please note that you will not have to retake the course. You can use the same verification code you got when you initially completed the course to retake the evaluation and posttest.



6. I completed the courses and got my verification codes, but there are no certificates in the “Transcript & Certificate” section of my CDC TCEO account.

If there are no certificates in the **Transcript and Certificate** section of your CDC TCEO account, it means that you have not completed the evaluation and posttest. After you complete the trainings and have verification codes for both courses, you will need to log into your account and use the verification codes to take the evaluation and posttest. For instructions on how to take the evaluation and posttest, go to **Section D (Taking the Evaluation & Posttest)** of the **Accessing You Call The Shots Training Modules** instructions, found on our website: <http://www1.nyc.gov/assets/doh/downloads/pdf/imm/you-call-inst.pdf>.

II. VFC Re-enrollment Form

7. How do I access the VFC Re-enrollment Form?

The VFC Re-enrollment Form is accessed by doing the following:

- Go to <https://immunize.nyc/provider-client/servlet/PC>
- Log into your CIR Online Registry account
- Click on the **VFC** tab found on the top right of the screen
- Click on the **2017 VFC Re-enrollment Form** link found on the top far right of the screen.

8. Every site must designate a PIC, VC and BVC. Can the PIC and BVC be the same person?

Yes, the PIC can be the VC **OR** BVC but **not** both. At most, the PIC can account for two roles, one of which must be PIC.

- If the PIC is also the BVC, then someone else has to be designated as the VC.
 - You can indicate this by selecting the **Same as Physician-in-Charge** box in the BVC section of the Re-enrollment Form.
- If the PIC is also the VC, then someone else has to be designated as the BVC.
 - You can indicate this by selecting the **Same as Physician-in-Charge** box in the VC section of the Re-enrollment Form.

9. How do I upload certificates to the VFC Re-enrollment Form?

Individual certificates for the PIC, VC and BVC must be uploaded for both courses in the **Training Requirement** section of the Re-enrollment Form. Please note that you will need to use the same computer that you saved your certificates on to upload your certificates. For instructions on how to upload your certificates go to **Section F (Uploading Your Certificates to Your Online 2017 Re-enrollment Form)** of the **Accessing You Call The Shots Training Modules** instructions, found on our website here: <http://www1.nyc.gov/assets/doh/downloads/pdf/imm/you-call-inst.pdf>.

10. What file formats are accepted in the “Training Requirement” section?



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Only certificates saved in the following format types can be uploaded to the VFC Re-enrollment Form: *pdf, doc, docx, html, htm, mht, xps, jpg, jpeg, png, gif* and *tif*.



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Vaccines for Children Program Policy Updates

There are 3 updates to the Vaccines for Children (VFC) program that were shared in the re-enrollment notice that went out to providers via email on October 4, 2016:

<http://www1.nyc.gov/assets/doh/downloads/pdf/imm/2017-vfc-re-enrollment.pdf>.

The updates are as follows:

I. Vaccine Replacement Policy Update

The Centers for Disease Control and Prevention (CDC) has required that our Vaccines for Children (VFC) Program Vaccine Replacement Policy be updated to require that 100% of vaccines spoiled and expired due to negligence or mismanagement must be replaced on a dose-per-dose basis. This policy takes effect on December 1, 2016. The updated policy document can be found on the New York City (NYC) VFC website at:

<http://www1.nyc.gov/assets/doh/downloads/pdf/imm/vaccine-reimbursement-policy.pdf>

II. Thermometer Policy Update

The CDC has required the use of continuous digital data logger (DDL) thermometers with a buffered encased probe to monitor VFC vaccine storage units, effective January 1, 2018.

III. Storage Unit Policy Update

Use of stand-alone freezers and stand-alone refrigerators will be required effective January 1, 2018. Combined units that have separate temperature controls for the refrigerator and freezer compartments are also acceptable. The only exception is if your combined household refrigerator style unit is able to demonstrate stable temperatures in the refrigerator compartment with a continuous digital data logger (DDL) thermometer and your receive prior approval from the VFC program.

Please find Frequently Asked Questions regarding these updates below.

I. Vaccine Replacement Policy Update

1. **For what reasons will VFC vaccine replacement be required?**

Vaccine replacement is required for VFC vaccines spoiled or expired due to negligence or mismanagement. The circumstances of each case of vaccine loss are carefully reviewed by the Bureau of Immunization and a determination is made. Providers are not asked to replace vaccines lost due to circumstances beyond the provider's control, such as a power outage caused by a hurricane. An example of a circumstance under which a provider is asked to replace spoiled vaccines is a failure to promptly place vaccines in appropriate storage units upon delivery to the correct address and within the provider's stated hours of operation.



2. What does vaccine replacement on a dose-per-dose basis mean?

Dose-per-dose basis means that for all VFC vaccine doses spoiled or expired due to negligence or mismanagement, the same number of doses (preferably of the same vaccine) must be privately purchased by the provider and used to vaccinate a VFC-eligible child.

3. How about flu vaccines? Will we be required to replace expired flu vaccines?

Expired flu vaccines are excluded from the vaccine replacement policy.

4. How do you report expired vaccine if it expires over the weekend or while the office is on vacation?

VFC providers are required to report all spoiled and expired VFC vaccines on the VFC Vaccines Returns/Wastage Form in the Citywide Immunization Registry (CIR) Online Registry. If vaccine expires over the weekend or while the office is closed or on vacation, providers will need to report this as soon as possible upon returning to the office. For instructions, go to: <http://www1.nyc.gov/assets/doh/downloads/pdf/imm/report-vaccine.pdf>

5. Why must expired vaccines be replaced?

Providers are expected to order only the amount of vaccines they will need for their VFC-eligible population. The CIR Online Ordering Tool offers recommendations to help providers avoid over-ordering and potential vaccine loss. Vaccine replacement is therefore requested when large quantities of vaccines are spoiled and expired due to negligence or mismanagement. The number of expired vaccine is assessed using a predetermined threshold, based on facility size, and if a provider's expired vaccine is above the threshold, they will be asked to replace the vaccine on a dose-per-dose basis. With that said, if you realize that you have a large quantity of vaccine that is expiring soon, please contact the NYC VFC program as soon as possible via email (nycimmunize@health.nyc.gov) or phone (347-396-2404) for assistance.

6. Is it possible to transfer VFC vaccine that is expiring soon to another VFC site?

It is possible but the request must be approved in advance. Requests should be submitted to the VFC program **at least 6 months before** the vaccine will expire. Requests may be submitted via email (nycimmunize@health.nyc.gov) or phone (347-396-2404).

II. Thermometer Policy Update

7. Is a DDL thermometer the same as a digital thermometer?

No. A digital thermometer shows only the current and minimum and maximum temperatures, while a DDL thermometer continuously monitors and records all temperatures at customizable intervals (typically every 15 minutes). These detailed temperature log recordings are stored either on the DDL or on a website and are available for daily review by the provider's staff. DDLs may expose temperature excursions that are not seen when temperatures are checked only twice per day. Storage units with temperature excursions outside the acceptable range must be replaced. Stand-alone refrigerators and stand-alone



freezers are proven to better maintain stable, in-range temperatures, compared to combined refrigerator/freezer units.

8. Where can we find DDL courses, training guides and resources?

The CDC has information on DDLs on pages 15-17 of its online *Vaccine Storage & Handling Toolkit* at: <http://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf>. Additionally, the Association of Immunization Managers (AIM) has DDL webinars at: <http://www.immunizationmanagers.org/page/VirtualExhibitHall>.

9. Can we have a list of the DDL thermometers piloted by the NYC VFC program?

Yes. The list of DDL thermometers that have been piloted by the NYC VFC program is below. Please note that while these DDLs were piloted, the NYC VFC program does not endorse any particular DDL brand. Be aware that each device has its own advantages and disadvantage, so choose devices that are appropriate for your facility. Additionally, as you research which DDL will work for your site, make sure that its certificate of calibration is in accordance with the National Institute of Standards and Technology (NIST) or the American Society for Testing and Materials (ASTM) Standards. For a certificate of calibration checklist go to our website: <http://www1.nyc.gov/assets/doh/downloads/pdf/imm/thermo-checklist.pdf>.

- **LogTag TRED30-7R Fridge & Freezer** (approximately \$257)
 - Link to product: <http://www.logtagrecorders.com/products/tred30-7.html>
 - Link to training resources:
 - http://www.logtagrecorders.com/files/quickstart/TRID30-TRED30-Quick_start_guide.pdf
 - <http://www.vfcdataloggers.com/LogTag/Tred30%20spec.pdf>
 - https://www.youtube.com/watch?v=a27Q1m_A20
- **Berlinger FridgeTag2 & FreezerTag2** (approximately \$272)
 - Link to product: <http://www.berlingerusa.com/fridgetag2/>
 - Link to training resources:
 - <http://www.berlingerusa.com/support/>
 - <http://www.berlingerusa.com/fridgetag2/supportvideos/>
 - <https://www.youtube.com/watch?v=92S5i885F8E>
 - https://www.youtube.com/watch?v=9h_YsyrWA2Q
- **Dickson DWE** (approximately \$350+)
 - Link to product: <http://www.dicksondata.com/products/DWE>
 - Link to training resources: <http://support.dicksonone.com/>
- **Dickson TWE** (approximately \$524+)
 - Link to product: <http://www.dicksondata.com/products/TWE>
 - Link to training resources: <http://support.dicksonone.com/>
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III. Storage Unit Policy Update

10. Why are stand-alone units being required?

Stand-alone units are proven to better maintain stable, in-range temperatures. Using stand-alone units will help you avoid temperature excursions commonly identified by DDL thermometers in household, combined units. Excursions often lead to vaccine spoilage and recall of patients for revaccination. Please be aware that as you set out to purchase stand-alone refrigerator units, you will need to be careful to avoid mistaking dormitory-style refrigerators for stand-alone refrigerators. Dormitory-style refrigerators are single-door refrigerators that have a freezer section within the refrigerator. Dormitory-style refrigerators are prohibited and should never be used to store vaccines.

11. Where can I find more literature on acceptable storage units for vaccine storage?

Below please find links to storage and handling findings from studies conducted by NIST:

- <https://www.nist.gov/sites/default/files/documents/pml/div685/grp01/NIC-2012-Dual-Zone-Unit-for-Simultaneous-Refrigerated-and-Frozen-Vaccine-Storage.pdf>
- <https://www.nist.gov/sites/default/files/documents/pml/div685/grp01/Guidelines-for-Storage-and-Temperature-Monitoring-of-Refrigerated-Vaccines.pdf>

You can also refer to pages 13 to 32 of the CDC online Vaccine Storage & Handling Toolkit: <http://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf>. CDC is developing a certification process for storage units; we will share this information when it becomes available.

12. Will combined storage units, where only the refrigerator compartment is being used, be accepted under this new requirement?

Any use of combined units will be acceptable only if the units are able to demonstrate stable temperatures with a DDL thermometer. Prior approval from the NYC VFC program is required for you to be permitted to continue to use this type of unit.