



## New York State COVID-19 Vaccination Program Reporting Vaccine Wastage

When COVID-19 vaccine doses are unused, spoiled, damaged, or expired they are considered vaccine wastage. The COVID-19 Vaccination Program requires providers to report wastage daily in NYSIIS. This is necessary to accurately maintain and report vaccine inventory.

### Responsible Wastage

The CDC released guidance on May 11, 2021, regarding wastage with the critical message to “take every opportunity to vaccinate every eligible person.” As more vaccination opportunities are created, the likelihood of leaving unused doses in a vial may increase. While enrolled providers must continue to follow best practices to use every dose possible, it should not be at the expense of missing an opportunity to vaccinate every eligible person when they are ready to get vaccinated. Once punctured, multidose vials must be used within:

- 12 hours [Moderna, Pfizer Pediatric (Orange Cap, age 5-11), Pfizer Adult/Adolescent Tris (Gray Cap, age 12+, no diluent)]
- 6 hours (Pfizer-BioNTech 12+ purple cap vials)
- 6 hours (refrigerated) or up to 2 hours at room temperature (J&J/Janssen). These times are NOT cumulative (i.e., you cannot store a punctured vial for 6 hours at refrigerated temperatures and then another 2 hours at room temperature).

### Wastage when administering Moderna booster doses

Despite the volume of the booster dose being 0.25 mL, providers should still report a full dose as administered in NYSIIS. NYSIIS inventory must only be reported in whole doses and providers should continue to maintain reporting of wastage in whole doses. Wastage should only be reported if the total doses administered from a vial, regardless of volume or series, is less than the vial dose count. For example, if one primary and five booster doses were administered from a 10-dose vial, 6 doses would be reported as administered and 4 doses wasted. If at least 10 doses (booster or primary) were administered from a 10-dose vial, no wastage would be reported even if there is vaccine remaining in the vial.

### Reporting Wastage in NYSIIS

Accurate reporting of wasted doses must be tracked to include information such as manufacturer, lot number, and wastage reason. **See Appendix A for a list of NYSIS COVID-19 vaccine wastage reasons and definitions.** Before getting started, please note:

- a. Tracking wastage each clinic day is necessary to be able to report in NYSIIS. The COVID-19 Vaccine Wastage Tracking Sheet in Appendix C may be used to document any vaccine waste throughout the day (this tracking sheet **MUST** be used daily for state run vaccination sites). At the end of each day, documentation of any wasted doses should be provided to the designated NYSIIS Administrative User who will enter the information in NYSIIS. Any questions regarding wastage reporting should be sent to the designated NYSIIS Administrative User who will contact [COVID19Vaccine@health.ny.gov](mailto:COVID19Vaccine@health.ny.gov), if necessary.
- b. COVID-19 vaccine wastage is reported in NYSIIS under the module called “Manage Returns and Wastage”. This module is also used for the Vaccines for Children (VFC) program. Under the VFC program, certain wasted vaccine is returned. This is **NOT** the case for COVID-19 vaccine. Expired or spoiled COVID-19 vaccine vials are **not** being returned to the manufacturer or the McKesson distribution center. For this reason, you must report any expired or spoiled COVID-19 vaccine doses as wastage, even if the reason fits a “return” category in NYSIIS. All COVID-19 vaccine wastage should be disposed as medical waste, such as by placing in a sharps container.
- c. In NYSIIS, the terminology for reporting wastage is called creating a “wastage request”. The word “request” here refers to requesting the Vaccine Program to review and approve the wastage report for proper reconciliation of inventory.
- d. Use the following instructions to report wastage. To begin, log in to NYSIIS from the Health Commerce System and navigate to NYSIIS Production. Note: You must be an Administrative user in NYSIIS to access the Inventory section to report wastage.

## Creating a Wastage Request in NYSIIS

Step 1: From the NYSIIS Home Page, click on **Manage Returns and Wastage** under the **Inventory** section on the side menu panel (Figure 1).

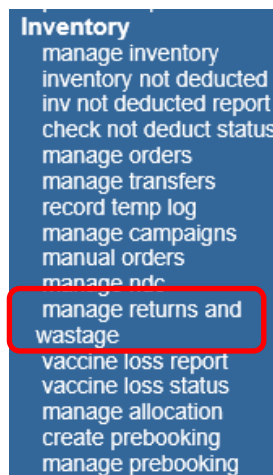


Figure 1

Step 2: On the **Manage Returns and Wastage Requests** screen (Figure 2), click on **Create Request** to create a new Wastage Request.

**Manage Returns/Wastage Requests**

**Current Returns/Wastage**

| User | Submit Date | Status | Request # |
|------|-------------|--------|-----------|
|------|-------------|--------|-----------|

**Historical Returns/Wastage** (last 30 days by default)

Show Historical Requests by Date From:  To:

| User | Submit Date | Status | Request # |
|------|-------------|--------|-----------|
|------|-------------|--------|-----------|

Figure 2

Step 3: The bottom portion of the **Create Returns/Wastage** screen, or the *Public Lots Available* section (Figure 3), displays a table to record the quantity of each lot of COVID-19 vaccine that is to be reported as wastage, along with the reason.

- a. Identify the Lot that had wasted doses
- b. Select a Wastage Reason. **Do not choose any reason listed under 'Returns', only use 'Wastage' reasons. See Appendix A for a list of NYSIS COVID-19 vaccine wastage reasons and definitions.**
  - If you have more than one reason for a given lot, click Add Line (will add same vaccine information below). Two duplicate lots cannot be listed with the same Returns/Wastage Reasons for both.
- c. Enter the number of wasted doses in the "Quantity" box. You cannot enter a quantity that exceeds the number of Doses on Hand.

**Note:** This area displays all of your public lots with a quantity > zero in order of expiration date. This includes expired, not expired, active and inactive public lots. Lots that are listed in red have been expired >6 months.

| Trade Name               | Packaging                              | NDC Number    | Lot Number | Expiration Date | Doses on Hand | Returns/Wastage Reason  | Quantity  | Add Line                                |
|--------------------------|--|---------------|------------|-----------------|---------------|---|---|---|
| Pfizer COVID-19 Vaccine  | Pfizer COVID-19 Vaccine,975 dose       | 59267-1000-02 | EL3246     | 04/30/2021      | 1             | <b>--Returns--</b><br>Expired<br>Expired- Shortened expiration date<br>Failure to store properly upon receipt<br>Equipment failure (refrigerator/freezer)<br>Natural disaster/Power Outage<br>Refrigerator too cold<br>Refrigerator too warm<br>Freezer too warm<br>Spoiled- other<br>Recall<br>Returned: Other | <input type="text"/>  | <input type="button" value="Add Line"/> |
| Pfizer COVID-19 Vaccine  | Pfizer COVID-19 Vaccine,975 dose       | 59267-1000-02 | EL3248     | 04/30/2021      | 391           |   | <input type="text"/>  | <input type="button" value="Add Line"/> |
| Pfizer COVID-19 Vaccine  | Pfizer COVID-19 Vaccine,975 dose       | 59267-1000-02 | EL9266     | 05/31/2021      | 220           |   | <input type="text"/>  | <input type="button" value="Add Line"/> |
| Pfizer COVID-19 Vaccine  | Pfizer COVID-19 Vaccine,975 dose       | 59267-1000-02 | EL9264     | 05/31/2021      | 1             |   | <input type="text"/>  | <input type="button" value="Add Line"/> |
| Pfizer COVID-19 Vaccine  | Pfizer COVID-19 Vaccine,975 dose       | 59267-1000-02 | EN6201     | 06/30/2021      | 975           |   | <input type="text"/>  | <input type="button" value="Add Line"/> |
| Moderna COVID-19 Vaccine | Moderna COVID-19 Vaccine 10 MDV carton | 80777-0273-99 | 011L20A    | 07/03/2021      | 88            |   | <b>--Wastage--</b><br>Broken vial/syringe<br>Lost or unaccounted for vaccine<br>Non vaccine product (e.g., IG , HBIG, Dil)<br>Open vial but all doses not administered<br>Vaccine drawn into syringe but not admin<br>Wasted: Other | <input type="text"/>                    |
| Moderna COVID-19 Vaccine | Moderna COVID-19 Vaccine 10 MDV carton | 80777-0273-99 | 012L20A    | 07/06/2021      | 223           | <input type="text"/>  |   | <input type="button" value="Add Line"/> |
| Moderna COVID-19 Vaccine | Moderna COVID-19 Vaccine 10 MDV carton | 80777-0273-99 | 029L20A    | 07/13/2021      | 304           | <input type="text"/>  |   | <input type="button" value="Add Line"/> |

Figure 3

- d. Enter a Request Note to describe the waste being reported. This is **required** if you have selected “Wasted: Other.” (Figure 4)

**Request Notes:**  
Enter text 150 character maximum.

Unable to draw 6th dose from 70 vials.  
 One vial (6 doses) nonviable due to passed Beyond Use Date (refrigerated longer than 120 hours)

**Public Lots Available**

| Trade Name              | Packaging                    | NDC Number    | Lot Number | Expiration Date | Doses on Hand | Returns/Wastage Reason          | Quantity | Add Line    |
|-------------------------|------------------------------|---------------|------------|-----------------|---------------|---------------------------------|----------|-------------|
| Pfizer COVID-19 Vaccine | CARTON, 195 MULTI-DOSE VIALS | 59267-1000-02 | xyz123     | 12/31/2021      | 751           | Lost or unaccounted for vaccine | 70       | Add Line    |
| Pfizer COVID-19 Vaccine | CARTON, 195 MULTI-DOSE VIALS | 59267-1000-02 | xyz123     | 12/31/2021      | 751           | Wasted: Other                   | 6        | Delete Line |

Figure 4

Step 4: Once all daily waste has been entered through selecting *Reason*, entering *Quantity*, and adding a *Request Note*, click on **Save and Submit**. Note: if you click Save, the request is not yet submitted. You must submit for the request to be processed to update your inventory.

- a. A dialog box will appear which asks “Are you sure you want to submit list?”

Step 5: Confirm the information then click on **OK** to proceed (Figure 5).

**Create Returns/Wastage** ✕

**Are you sure you want to submit list?**

| Trade Name              | Packaging                    | NDC Number    | Lot Number | Exp Date   | Doses On Hand | Returns/Wastage Reason          | Quantity |
|-------------------------|------------------------------|---------------|------------|------------|---------------|---------------------------------|----------|
| Pfizer COVID-19 Vaccine | CARTON, 195 MULTI-DOSE VIALS | 59267-1000-02 | xyz123     | 12/31/2021 | 751           | Lost or unaccounted for vaccine | 70       |
| Pfizer COVID-19 Vaccine | CARTON, 195 MULTI-DOSE VIALS | 59267-1000-02 | xyz123     | 12/31/2021 | 751           | Wasted: Other                   | 6        |

*Note: NYSIIS will automatically decrement doses from your inventory once the returns/wastage request is "Final-Approved" by the VFC.*

Ok
Cancel

Figure 5

**IMPORTANT:** DO NOT ATTEMPT TO GO INTO YOUR PUBLIC INVENTORY AND MAKE MODIFICATIONS TO LOT QUANTITIES THAT WERE IMPACTED BY RETURNS/WASTAGE REQUESTS. **When your request reaches a “Final-Approved” status, your inventory will decrement automatically.**

Step 6: After the request has been submitted, you will be automatically redirected back to the *Manage Returns/Wastage Requests* screen (Figure 6).

- a. Your request will display in the *Current Returns/Wastage* section with a *Pending* status\*. The request has been submitted to the NYS Vaccine Program.
- b. Once the Vaccine Program opens your request, the status will change to *Under View by VFC*. Vaccine Program reviews requests each morning Monday-Friday.

- c. When the request is approved you will see a status of *Final-Approved*. **This is when the quantity deducts from your inventory.**
- d. If the Vaccine Program need the provider to modify the request (such as incorrect reason selected, or insufficient information provided) the status will change to *Denied*. Vaccine Program will contact you with instructions.

\* See Appendix B for a description of all request Statuses

**Manage Returns/Wastage Requests**

[Create Request](#)

**Current Returns/Wastage**

| User                  | Submit Date | Status                         | Request # |
|-----------------------|-------------|--------------------------------|-----------|
| Lyndsey Hoyt          | 02/15/2021  | <a href="#">PENDING</a>        | 13        |
| Lori Isabella-Rhoades | 02/14/2021  | <a href="#">FINAL-APPROVED</a> | 12        |

**Historical Returns/Wastage** *(last 30 days by default)*

Show Historical Requests by Date From:  To:  [Refresh List](#)

| User            | Submit Date | Status                   | Request # |
|-----------------|-------------|--------------------------|-----------|
| Julie Schenkman | 07/15/2016  | <a href="#">SHIPPED</a>  | 11        |
| Julie Schenkman | 07/14/2016  | <a href="#">COMPLETE</a> | 10        |

Figure 6

## Appendix A

### NYSIIS Wastage Reasons and Definitions

| Reason  | Definition/Example  |
|---|---|
| Broken vial/syringe                             | <p>Vaccine vial or syringe that was damaged. Example: If an entire Pfizer 12+ vial is broken, report 6 doses wasted.</p> <p>Syringe dropped on floor.</p>   |
| Lost or unaccounted for vaccine                 | <p>Unable to draw standard dose count from a vial. <i>Examples: If staff are only able to draw 5 doses from a 6-dose vial (not enough vaccine remaining for a full 6<sup>th</sup> dose), report 1 dose wasted. If staff are only able to draw 9 doses from a 10-dose vial, report 1 dose wasted.</i></p> <p>Vaccine that was lost or unaccounted for (such as a shipping shortage).</p>   |
| Open vial but all doses not administered        | <p>An open multi-dose vial of vaccine, with doses remaining that passed the beyond use time (time limit after mixing or puncturing vial).</p>   |
| Vaccine drawn into syringe but not administered | <p>Vaccine that was drawn into a syringe but was not administered.</p>  |
| Wasted: Other                                   | <p>Vaccine that became non-viable due to a temperature excursion (too cold or too warm).</p> <p>Vaccine that has passed the expiration date or the refrigerated beyond-use date (BUD).</p> <p>Vaccine that is contaminated (discolored, contains particulates, etc.)</p> <p><b>NOTE:</b> If there is no example listed that covers the wastage reason, categorize as "Wasted - Other" and enter a Request Note with explanation for all wastage categorized as "Other".</p> |

## Appendix B

### Returns/Wastage Requests: Statuses and Descriptions

| Status                            | Description  |
|-----------------------------------|--|
| <b><i>Saved</i></b>               | The request has been created by the provider and has been saved but not yet submitted. The request can still be modified or cancelled by the requesting provider organization. If not submitted, saved requests will automatically be cancelled 30 days after the create date and will display with a <b><i>Cancelled</i></b> status.  |
| <b><i>Pending</i></b>             | The request has been submitted by the provider organization and it will now appear in the Pending list for the NYS Vaccine Program. The request has not yet been viewed by the NYS Vaccine Program and can still be modified or cancelled by the requesting provider organization.   |
| <b><i>Cancelled</i></b>           | The request was cancelled by the requesting organization or was not opened and modified within 30 days of the save or deny date. Requests can be cancelled by the provider organization only during the <b><i>Saved</i></b> or <b><i>Pending</i></b> status. Once a request is cancelled, it can no longer be submitted, and is considered a historical request.   |
| <b><i>Under review by VFC</i></b> | The request has been received and opened/viewed by the NYS Vaccine Program. This request can no longer be edited or cancelled by the provider organization. The NYS Vaccine Program can approve or deny the request in this status. (“VFC” in the status name refers broadly to the Vaccine Program, not just the Vaccines for Children Program.)  |
| <b><i>Final-Approved</i></b>      | The request has been reviewed and finalized by the NYS Vaccine Program and is ready to be included on an export file. This type of request can no longer be modified but is considered a non-historical or current request. Decrements from the provider’s public inventory lots occur at this point.  |
| <b><i>Denied</i></b>              | The NYS Vaccine Program staff sent the request back for Provider to modify. The provider must then modify and save and submit the request to send it back to NYS Vaccine Program again and restart the approval cycle. If the provider does not re-open and make modifications to this request within 30 days of the date it was denied, the status will automatically change to <b><i>Cancelled</i></b> . |
| <b><i>Completed</i></b>           | This status will show when the request has been uploaded to CDC. Completed requests show in the historical Returns/Wastage area.   |

## Appendix C

### COVID-19 Vaccine Wastage Tracking Sheet

Use this sheet to record wastage as it occurs. Provide completed sheets to designated individual to data enter into NYSIS at the end of each day.

Vaccine Administration Site Name: \_\_\_\_\_

PIN #: \_\_\_\_\_

Name of Individual Reporting Wastage: \_\_\_\_\_

Date: \_\_\_\_\_

| Wastage Reason                                      | Definition/Example(s)   |
|---|---|
| 1 = Broken vial/syringe                             | Vaccine vial or syringe that was damaged. <i>Example: If an entire Pfizer 12+ vial is broken, report <u>6</u> doses wasted.</i><br>Syringe dropped on floor.  |
| 2 = Lost or unaccounted for vaccine                 | Unable to draw all doses that need to be accounted for from a vial. <i>Examples: If staff are only able to draw 5 doses from a 6-dose vial (not enough vaccine remaining for a full 6<sup>th</sup> dose), report 1 dose wasted. If staff are only able to draw 9 doses from a 10-dose vial, report 1 dose wasted.</i><br>Vaccine that was lost or unaccounted for (such as a shipping shortage).                            |
| 3 = Open vial but not all doses administered        | An open multi-dose vial of vaccine, with doses remaining that passed the beyond use time (time limit after mixing or puncturing vial).  |
| 4 = Vaccine drawn into syringe but not administered | Vaccine that was drawn into a syringe but was not administered.   |
| 5 = Wasted: Other                                   | Vaccine that became non-viable due to a temperature excursion (too cold or too warm).<br>Vaccine that has passed the refrigerated beyond use date or expiration date.<br>Vaccine that is contaminated (discolored, contains particulates, etc.)<br>NOTE: If there is no example listed that covers the wastage reason, categorize as "Wasted: Other"<br>Enter a note of explanation for all wastage categorized as "Other". |

| Manufacturer | Lot Number | Wastage Reason # | Quantity (Doses) | If wastage reason is #5 "Other" briefly explain: |
|--------------|------------|------------------|------------------|--|
|              |            |                  |                  |  |
|              |            |                  |                  |  |
|              |            |                  |                  |  |
|              |            |                  |                  |  |