



September 2022

Dear Health Care Professional:

Sanofi, in consultation with the US Food and Drug Administration (FDA), is notifying you of a potential formatting error for electronic scanners to transcribe the 2-D matrix barcode (QR code) on the container (syringe) label of various Fluzone® High-Dose Quadrivalent (Influenza Vaccine) doses. The affected product lot numbers are listed in the Appendix below.

Please note that there are no vaccine quality, patient safety or efficacy issues associated with the doses impacted by the barcode issue.

This notice is being sent to customers who have previously received doses from the affected lots and is being provided to customers as they receive shipments containing doses from affected lots.

The 2-D matrix barcode (see Fig 1A) is designed to be read by GS1 compliant scanners and carries information including the National Drug Code (NDC), lot number, and the product expiration date. There is a potential formatting error in the 2-D barcode affecting some doses making the data unreadable to electronic scanners. While the NDC and product expiration date are the same for all 2022-2023 Fluzone® High-Dose Quadrivalent (Influenza Vaccine) doses, lot numbers can vary. Only the NDC is carried by the linear barcode (Fig 1B) and scans appropriately. The human readable information on the label including the NDC, lot number and expiration date are correct.

Please see the Appendix below for a list of the affected lots and a corrected 2-D matrix barcode for each lot number. Each barcode is unique to a specific lot number. For customers who scan this information electronically, please use the updated barcodes below. Please verify you are using the correct barcode for the lot number printed on each dose (Fig 1A). For customers who manually enter this information as printed on the label, there is no change to the process.

For customers who distribute product throughout their facility or have multiple locations where vaccine may be administered, please ensure the information in this notice, including the corrected 2-D matrix barcode, is provided to persons responsible for recording vaccination information.

Sanofi recognizes the disruption this potential error may introduce into your medical practice, and we sincerely apologize for the inconvenience. Corrective and preventive actions are being implemented to avoid this error in future vaccine labeling.

Please visit [VaccineShoppe.com](https://www.vaccineshoppe.com) where an electronic copy of this letter is also available. If you have further questions, please contact us at 1-800-VACCINE (1-800-822-2463).



Sincerely,

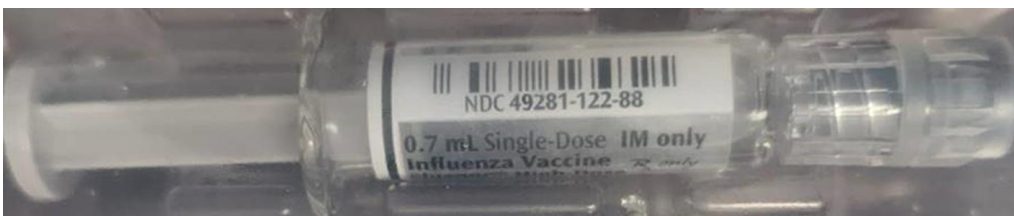
Michael Greenberg, MD, MPH
Head of Medical, Vaccines
North America

Figure 1. The label on each prefilled syringe of Fluzone® High-Dose Quadrivalent (Influenza Vaccine) contains two barcodes: **2-D Matrix/QR code** (NDC + lot number + expiration embedded) & **Linear Bar Code** (NDC embedded)

A. Below is an example of a 2-D barcode that may not be decoding properly. This image also shows the location of the printed lot number (L) and product expiration date (E) which are correct.









B. Below is an example of the linear barcode that contains only the NDC, and is recognized by scanners. However, lot and expiration date are not embedded in this code.





Appendix. Corrected 2-D barcodes

Please verify you are using the correct barcode for the lot number printed on each dose.

<p>UT7714AA</p> 	<p>UT7714BA</p> 
<p>UT7714CA</p> 	<p>UT7714DA</p> 
<p>UT7715AA</p> 	<p>UT7715BA</p> 

UT7715CA



UT7718AA



UT7718BA



UT7718CA










UT7729AA



UT7729BA



UT7729CA 	UT7733AA 
UT7733BA 	UT7733CA 
UT7743AA 	UT7743BA 
UT7743CA 	



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