TO: North Carolina Immunization Program (NCIP) Private Providers

FROM: Wendy Holmes, R.N., Immunization Branch Head

DATE: August 19, 2019

SUBJECT: Influenza Vaccine Product Availability and Ordering for the 2019-2020 Season

This memo is to inform private providers of the process for ordering flu vaccine for the 2019-20 influenza season and to make you aware of the available influenza products from the NCIP. The Advisory Committee on Immunization Practices (ACIP) recommends annual flu vaccination for everyone 6 months of age and older who do not have contraindications to influenza products. Receiving a seasonal flu vaccine each year remains the best way to protect against seasonal influenza and its potentially severe consequences.

The Centers for Disease Control and Prevention (CDC) conducts studies each year to determine how well the flu vaccine protects against flu illness. Recent studies have shown the following:

- Vaccination reduces the risk of flu illness by 40-60 percent in the overall population during seasons when most circulating flu viruses are well matched to the flu vaccine. No preference is given for any influenza vaccine product.
- Current flu vaccines tend to work better against influenza B and influenza A (H1N1) viruses and offer lower protection against influenza A (H3N2).
- On June 8, 2018, ACIP published the recommendations for use of Quadrivalent Live Attenuated Influenza Vaccine (LAIV4) for the 2019-2020 influenza season.
- ACIP will continue to review data concerning the effectiveness of LAIV4 as they become available.
- For the 2019–2020 U.S. influenza season, providers may choose to order and administer any licensed, age-appropriate influenza vaccine for those for whom it is appropriate.

Providers should carefully develop and regularly update your flu vaccine supply plans to ensure you have appropriate flu vaccine to meet the needs of your Vaccines For Children (VFC) patients and assess your ability to store the vaccines safely to help reduce vaccine waste. Providers will have a variety of vaccines to select from for the 2019-20 flu season. While this diversity of flu vaccine supplies leaves providers less vulnerable to individual manufacturer delays, it brings additional challenges because of uncertainty about when vaccine shipments will arrive and the need to maintain supplies of different flu vaccines for different indications. As a reminder, North Carolina Immunization Registry (NCIR) users will place vaccine orders directly through the NCIR. Influenza vaccine will be shipped separately from other NCIP vaccines.

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Available vaccines and anticipated timing of flu vaccine shipping:

- NCIP will attempt to fulfill orders in full if vaccine quantities are sufficient.
- In previous seasons we have not had large quantities available at the start of the flu season; however, we will distribute what we receive as quickly as possible.
- If your shipment does not fulfill your order request, please place an additional vaccine order(s) for the quantity you would like to receive.
- Providers should consider a vaccination plan that allows for the use of smaller amounts, different products and presentations of vaccine early in the season, until more vaccine becomes available.
- Providers willing to use a variety of products should select those in their initial order. Product substitutions may occur based on availability of vaccine. When possible, substitutions will be made using similar products with the same presentation.
- Providers should plan to have enough vaccine on hand before scheduling large flu vaccination clinics early in the season. NCIP will provide updates on vaccine supply, ordering and shipments when available, on our website.

Eligibility for NCIP Influenza Vaccines

Remember that influenza vaccine provided by the NCIP is only available for children, 6 months-18 years of age, who are VFC eligible.

NCIP supplied influenza vaccine will not be expanded universally for non-VFC eligible individuals. Private purchase influenza vaccine must be used to vaccinate non-VFC individuals, regardless of their age. For complete NCIP vaccine coverage criteria and VFC categories, go to: http://bit.ly/CoverageCriteria.

2019-2020 Seasonal Influenza Vaccine Product Availability from NCIP

During the 2019-2020 influenza season, the NCIP intends to offer several brands of influenza vaccine in various presentations. All influenza products provided by the NCIP will be quadrivalent. The quadrivalent flu vaccine is designed to protect against four different flu viruses; two influenza A and two influenza B viruses.

### Influenza products available through NCIP in the 2019-2020 influenza season:

<table>
<thead>
<tr>
<th>Vaccine Type</th>
<th>Trade Name</th>
<th>Dose Size</th>
<th>Presentation</th>
<th>Age Group Covered</th>
<th>Pres-free or Preservative-containing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quadrivalent inactivated influenza vaccine (IIV4)</td>
<td>Afluria® (Seqirus)</td>
<td>0.5 mL</td>
<td>0.5 mL prefilled syringes</td>
<td>VFC children 36 months through 18 years of age</td>
<td>Preservative-free</td>
</tr>
<tr>
<td>Quadrivalent inactivated influenza vaccine (IIV4)</td>
<td>Afluria® (Seqirus)</td>
<td>0.25 mL or 0.5 mL</td>
<td>Multi-dose vial containing 5.0 mL each</td>
<td>VFC children 6 months through 18 years of age</td>
<td>Preservative-containing</td>
</tr>
<tr>
<td>Quadrivalent inactivated influenza vaccine (IIV4)</td>
<td>Fluzone® (sanofi pasteur)</td>
<td>0.25 mL</td>
<td>0.25 mL prefilled syringes 10 pack</td>
<td>VFC children 6 months through 35 months of age</td>
<td>Preservative-free</td>
</tr>
<tr>
<td>Quadrivalent inactivated influenza vaccine (IIV4)</td>
<td>FluLaval® (GlaxoSmithKline)</td>
<td>0.5 mL</td>
<td>0.5 mL prefilled syringes 10 pack</td>
<td>VFC children 6 months through 18 years of age</td>
<td>Preservative-free</td>
</tr>
</tbody>
</table>
Fluarix®
(GlaxoSmithKline)
0.5 mL
0.5 mL prefilled syringes
10 pack
VFC children 6 months through 18 years of age
Preservative-free

Flucelvax®
(Seqirus)
0.5 mL
0.5 mL prefilled syringes
10 pack
VFC children 4 years through 18 years of age
Preservative-free

Fluzone®
(sanofi pasteur)
0.5 mL
0.5 mL prefilled syringes
10 pack
VFC children 6 months through 18 years of age
Preservative-free

Fluzone®
(sanofi pasteur)
0.5 mL
0.5 mL single-dose vials
10 pack
VFC children 6 months through 18 years of age
Preservative-free

Fluzone®
(sanofi pasteur)
0.25 mL or 0.5 mL
Multi-dose vial containing 5.0 mL each
VFC children 6 months through 18 years of age
Preservative-containing

Fluzone® Age Recommendation Change:
The U.S. Food and Drug Administration (FDA) expanded the age indication for Fluzone® Quadrivalent Influenza 0.5mL vaccine to include use in persons 6 months of age and older. Previously, the vaccine was only approved in persons 3 years of age and older. Fluzone® influenza 0.25 mL vaccine is for children who are 6 months to 35 months of age and will also be available to order. Education should be conducted with staff about both presentations being available and how to administer the correct dosage. There are now four brands of influenza vaccine available for persons who are 6 months through 18 years of age.

Some suggestions for determining the amount of influenza vaccine to order for the 2019-2020 flu season:
- Children 8 years of age and younger, who are receiving flu vaccine for the first time, will need to receive two doses. The doses should be given at least four weeks apart.
- Use the information from the North Carolina Immunization Registry (NCIR) to determine the amount of flu vaccine administered last flu season. This information can be retrieved from the Vaccine Usage Report.
- Consider the Advisory Committee on Immunization Practices (ACIP) recommendations for vaccination of all children 6 months – 18 years of age. This information can be found at: https://www.cdc.gov/vaccines/hcp/acip-recs/index.html

For seasonal influenza vaccine, providers may use the one-way borrowing policy and use private stock, seasonal influenza vaccine for VFC eligible individuals, if VFC influenza is not yet available. Provider’s private stock vaccine given to VFC eligible individuals will be replaced when VFC vaccine becomes available. This one-directional borrowing is unique to seasonal influenza vaccine only. All occurrences of borrowing must be documented on the VFC vaccine borrowing report form located on the NCIP website at: http://bit.ly/BorrowingForm.

Please note: all doses to be replaced, including total number of doses by vaccine type/brand/presentation and eligibility must be documented on the borrowing report form every time borrowing occurs. The dose for dose replacement requires vaccine replacement with the same product type. For example, private quadrivalent vaccine(s) will be replaced with VFC quadrivalent vaccine(s) only, which cover the same age groups. If a provider
uses private vaccine for a 2-year-old patient, it should be replaced with a VFC vaccine indicated for children 2 years of age.

Reminder: All 2018-19 seasonal influenza vaccine(s) have expired as of June 30, 2019. Providers who have NCIP expired influenza vaccine on hand must transfer all expired inventory to McKesson in accordance with the current NCIP vaccine return policy. Return instructions are available at: http://bit.ly/WastedVaccine.

All vaccine providers, public or private, are required by the National Vaccine Childhood Injury Act (NCVIA – 42 U.S.C. § 300aa-26) to give the appropriate Vaccine Information Statements (VISs) to the patient (or parent or legal representative) prior to every dose of specific vaccines regardless of how the vaccine was purchased. VISs are information sheets produced by CDC and explain both the benefits and risks of a vaccine. The CDC announced flu VISs are no longer updated annually. The current VIS edition date for both inactivated (IIV) and live attenuated (LAIV) influenza vaccine is 8/15/2019. Additional information on VIS requirements may be viewed at: http://www.immunize.org/vis/.

If you have any questions or need additional vaccine information or assistance, please contact the Immunization Branch Help Desk at 1-877-873-6247 and press option 6.

cc: SMT, Regional Immunization Staff, CO, Vaccine Manufacturers, Elizabeth Hudgins, Frank Skwara, Erin Elsworth, Terri Pennington, Peter Graber, Harita Patel, Taryn Edwards, Ann Nichols