Washington Vaccine Association
Vaccine Committee Meeting
November 3, 2016; 12:30-1:30 p.m. PDT

I. Attendance. Participating in all or part of the meeting in person by telephone (T) were the following individuals:

Committee Members
Ed Marcuse, MD, Chairman
Rachel Wood, MD
Cathy Falanga, Aetna
John Dunn, MD
Michele Roberts, Department of Health
Rachel Wood, MD (T)
Jeffrey Gombosky (T)

Others
Sasha DeLeon, Department of Health
Dennis Kirkpatrick, President, WPAS
James Flood, Crowell & Moring
Scott Douglas, Crowell & Moring
Mary Kay O'Neill, MD, Mercer Consulting
Kristin Peterson, Esq., Department of Health

KidsVax®
Julia Walter, M.A., Esq., Executive Director
Ashley Kittrell, Communications Coordinator

II. Minutes

Welcome & Introductions

At 12:30 p.m., a quorum having been established, Chairman Ed Marcuse called the meeting to order. Julia Walter informed the Committee that the meeting is recorded for the benefit of the secretary and will be deleted following the approval of the minutes. Committee members introduced themselves, and Chairman Marcuse asked Sasha DeLeon to proceed with the Department of Health (DOH) updates.

Department of Health Updates

Ms. DeLeon, the DOH Vaccine Assurance Unit Supervisor updated the Committee on several items including flu allocation and ordering, the Advisory Committee on Immunization Practice's (ACIP) recommendation of HPV Gardasil 9 (HPV9), vaccine choice, and Meningococcal B. In preparation for the 2016/17 flu season, approximately 686,000 doses have been pre-booked. Because Flumist is no longer recommended by the ACIP, the stock has been replaced with Fluzone MDV and FluLaval MDV. As of November 1st, approximately 87% allocation to the state is available for ordering, and of the 686,000 doses pre-booked, 345,920 doses have been ordered and approximately 247,510 doses remain. Chairman Marcuse asked Ms. DeLeon to clarify the difference between vaccine allocation and ordering. Ms. DeLeon explained that the number of doses each local department of health estimates that it will need is written as an allocation and the DOH reserves the estimated amount.

Regarding allocation issues, Ms. DeLeon noted that initially, large organizations that cover different counties receive the same amount of vaccines, which is sent in either prefilled syringes or vials. This year, approximately 70% received prefilled syringes and 30% vials; however, the delay of prefilled syringes, the vials have had to replace the prefilled syringes. Michele Roberts added that the CDC did not inform the DOH that when it replaced Flumist, some manufacturers had to make new vaccine. Ms. DeLeon also noted that there has been an increased demand for pre-filled syringes by parents and naturopathic doctors looking for a preservative-free option. There is currently no known demand for cell-based and recombinant flu vaccines as these are usually used for patients with severe egg allergies. Discussion ensued regarding the demand for preservative-free flu vaccine and its possible effect on Flumist.

Ms. DeLeon continued to the discussion of HPV9, noting that the FDA recently approved HPV9 as a 2-dose series for adolescents between 9 and 14 years old. ACIP believes that the reduction from three to two shots will help facilitate series initiation and completion, as well as reduce office visits. Children younger than 9 who receive the series will still need to receive the three doses. Chairman Marcuse noted that this should result in savings for the WVA. Ms. Roberts replied that DOH will have to conduct an analysis to verify and will include it in the budget updates.

Ms. DeLeon continued with the review of the vaccine choice enrollment period, which began on October 17th and ends on November 4th. Because all forms are being faxed in this year, it is difficult to determine what vaccines have been selected and what providers are changing in comparison to the previous periods. From initial data analysis, there seems to be a change from Menveo to Menactra, and there has been little interest in switching to Hiberix.

Ms. DeLeon concluded the DOH updates by saying that the Department continues to see steady ordering, which is monitored closely because providers have to contact the DOH to order Meningoccoal B and has been steadily increasing.

<u>Flu Mist</u>

Chairman Marcuse then directed the Committee to the handout showing the history and background of LAIV, or Flumist. He noted that several Board members have expressed concern as to why it was not as effective as originally thought. LAIV was approved in 2003, and there are three to four components in the LAIV strain that is given through the nose. Flu strains change annually and in 2009, a pandemic strain was introduced. LAIV supposedly gave a greater cross protection. The data of efficacy decreased over the next three years when it became clear that LAIV 4 was inferior to other strains and gave no protection to the H1N1 strain. LAIV 3 and 4 are currently being used in Canada and Europe. Chairman Marcuse reviewed several hypotheses of why LAIV does not work, such as the addition of the fourth influenza and interfered with viral replication; however, there are no definite known reasons for the inefficacy of Flumist at this time. Ms. Roberts asked if there is any new data for the ACIP's review regarding why the vaccine was ineffective. Chairman Marcuse replied that he was not aware of any discussions regarding actual examination of data to determine the cause.

Dr. John Dunn proceeded to discuss optimal timing of annual flu vaccine.

Optimal timing of Annual Flu Vaccine

John Dunn began the discussion of optimal timing of flu vaccine and noted that in the past, the general rule was to avoid vaccination before October, especially for the elderly because of the rapid decline of the vaccine-induced antibody. In 2009, the general rule became that vaccines should be administered if possible by October to decrease the likelihood of contamination. That soon changed, however, and in 2010, it was recommended that flu vaccine should be administered as soon as it is available and continue for the remainder of flu season. The current CDC recommendation is that flu vaccination should begin after vaccine becomes available, if possible by October. Dr. Dunn explained that the optimal time to vaccinate has changed throughout the last several years and there are many factors that affect this. For example, peak influenza activity has occurred in or after January and February; yet in recent seasons, vaccine shipments have begun as early as July. The Committee discussed the difficulty of serving a high volume of children in as little as two months as recommended and it is necessary to vaccinate children when able in order to decrease the chance of missed opportunities.

KidsVax Updates

Chairman Marcuse thanked Dr. Dunn and asked if the representatives from Crowell and Moring (C&M) would like to give any updates regarding TRICARE's participation in universal vaccine purchase (UVP) states. Jim Flood, the chair of C&M's Government Affairs Group, thanked the Committee for allowing them to participate in the meeting and gave an update on the current legislation and 2017 plan for addressing the arrears. Mr. Flood gave an overview of the process throughout 2015 and 2016 to get legislation in the National Defense Authorization Act (NDAA). The provision is in the final Senate version and C&M is confident that it will be passed in the NDAA, which will be most likely be passed in December. C&M is currently strategizing with KV and other UVP representatives regarding legislation for the arrears in 2017.

Closing

There being no further business, the meeting adjourned at approximately 1:33 p.m.

WASHINGTON VACCINE ASSOCIATION

What:	Vaccine Committee Meeting
Date & Time:	Thursday, November 3, 2016; 12:30-1:30 p.m. PDT
Location:	Alki Conference Room. Ellis, Li, & McKinstry 2025 1st Ave, PH-A Seattle, WA 98121
Conference Line:	(267) 930-4000; Conference ID: 103063718#

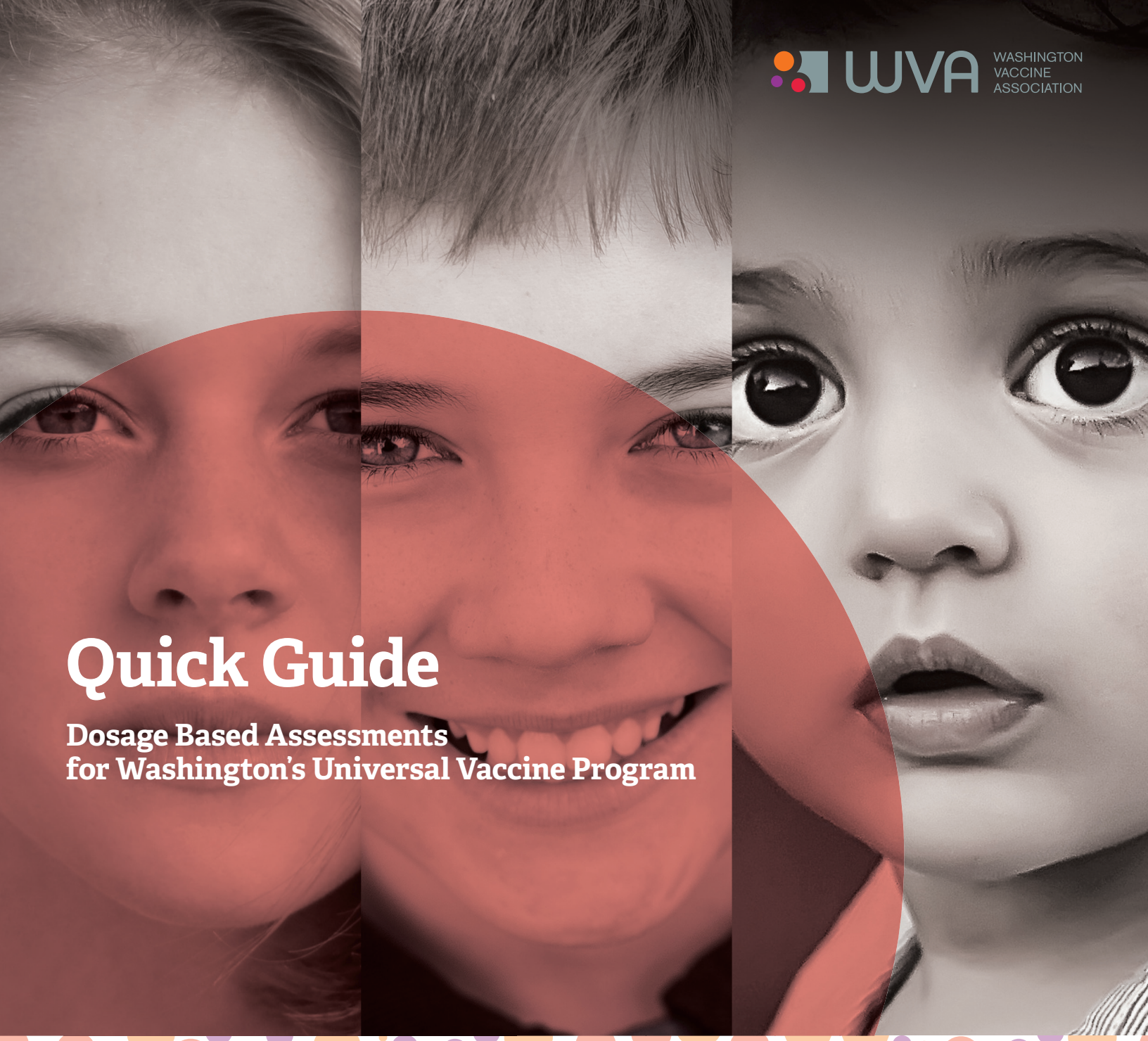
Notice: The meeting may be recorded for the benefit of the secretary. The WVA intends to delete the recording after the minutes of the meeting are approved.

AGENDA for Vaccine Committee Meeting (in person attendance if possible)

Approx. Time		Topic/[Anticipated Action]	Presented by:
12:30-12:35 p.m.		1. Welcome & Introductions a. Survey of Other Topics	E. Marcuse
12:35-1:00 p.m.		2. Department of Health a. Flu Allocation and Ordering b. Preservative-Free Flu Vaccine c. Cell-free and recombinant Flu Vaccines d. Meningococcal B Vaccine e. HPV2 f. Current Vaccine Choice Period g. Additional Vaccine Supply Updates	S. DeLeon
1:00-1:05 p.m.		3. Flu Mist	E. Marcuse
1:05-1:20 p.m.		4. Optimal Timing of Annual Flu Vaccine	J. Dunn
1:20-1:25 p.m.	*	5. KidsVax Updates a. WVA Provider Communications	J. Walter
1:25-1:30 p.m.		6. Closing	E. Marcuse

*Indicates agenda item attached
Red text indicates an action item

WAvaccine.org
P 1.888.928.2224 • F 1.888.928.2242
PO Box 94002 • Seattle WA 98124-8402



WVA WASHINGTON VACCINE ASSOCIATION

Quick Guide

Dosage Based Assessments for Washington's Universal Vaccine Program

Ensuring Universal Purchase of Childhood Vaccines in Washington

The Washington Vaccine Association (WVA) and the Department of Health work together in a public/private partnership to support Washington's universal Childhood Vaccine Program. The state uses a combination of federal and state funds to make vaccine available at no cost to all children in Washington.

Removing cost as a barrier assures that all Washington children have ready access to life-saving vaccines.

Providers make this possible by including the Dosage Based Assessment (DBA) process with their claims submission. This critical step allows physicians, clinics, hospitals, and other providers to receive vaccine for all children at no cost.

It's important that provider office billing staff understand how to complete the DBA process. For your convenience, we created this Quick Guide.

Completing the DBA Process

BY MAIL

You will be filling out the Health Insurance Claim Form twice, filling it out once as the Administration Claim Form and once as the HCFA1500/DBA Form.

STEP 1

Fill out the HCFA 1500 as the Administration Claim Form

Fill out HCFA 1500 Form for the administration of the vaccine, office visit, and other charges. This claim should include only the administration codes, office call or other charges.

Do not include vaccine codes and modifiers.

STEP 2

Fill out HCFA 1500 as the DBA Form.

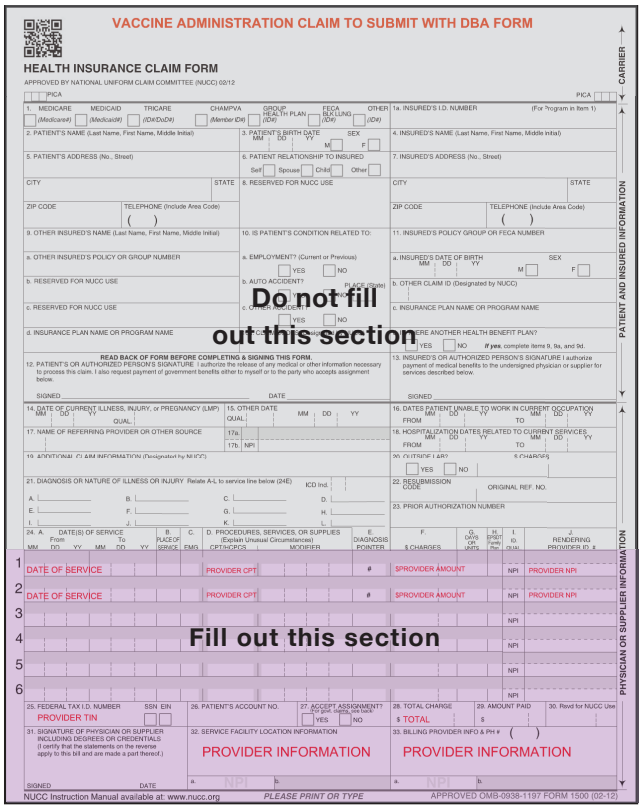
The DBA Form must include:
Box 21 Enter "Z 23"
(this is the only diagnosis required).
Box 24d Enter CPT code for the state-supplied vaccine given (Do not include modifiers)
Box 24f Enter WVA charge based on the current grid, found online at *wavaccine.org/wavaccine.nsf/pages/AssessmentGrid.html*
Box 24j Enter WVA NPI (1699092718)
Box 25 WVA TIN (27-2251833)
Boxes 31&32 Complete both areas with the same information that is on the administration claim
Box 32a Enter Provider NPI
Box 33 Washington Vaccine Association, PO Box 94002, Seattle, WA 98124-9402
Box 33a Enter the WVA NPI (1699092718)

STEP 3

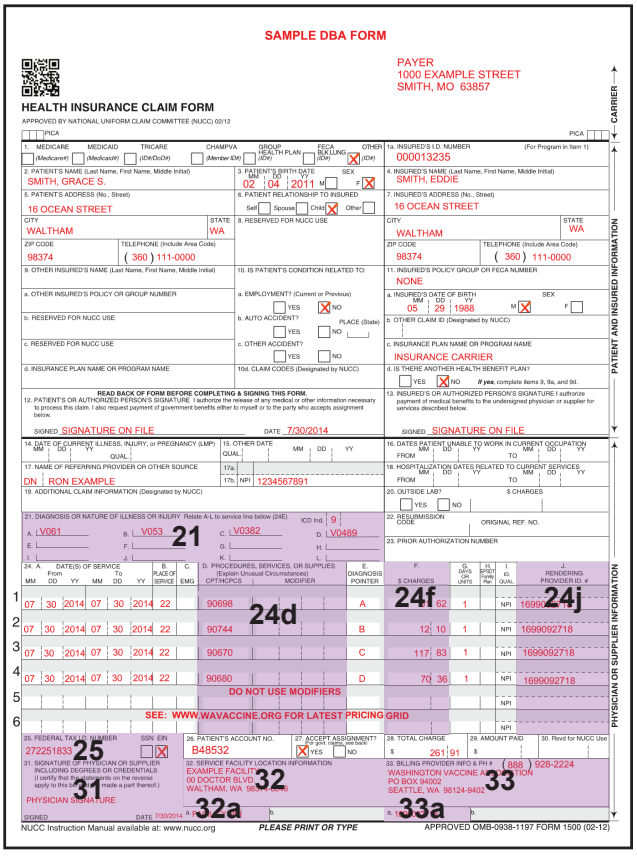
Submit via Mail

Mail the Administrative Claim Form and DBA Form to the payer (health plan, insurance company, or third-party administrator) — not to the WVA.

Do not submit to WVA.



Step1: Administration Claim Form



Step 2: DBA Form

- Submit the Administration Claim Form with the DBA Form to the payer—not WVA.

You have the option of filling out the Forms electronically (preferred) or by mail.

WASHINGTON VACCINE ASSOCIATION

ELECTRONIC

STEP 1

Fill out the DBA Form electronically

The Form must include:

1. Billing provider Federal Tax ID Number
2. Billing provider information
3. Patient account number
4. Signature of physician or supplier
5. Service facility location & facility NPI
6. Service line and date of service
7. CPT Code
8. Charges

STEP 2

Submit Electronically

Submit the Administrative Claim Form and DBA Form to the payer (health plan, insurance company, or third-party administrator) via your company clearinghouse—not to the WVA.

Do not submit to WVA.

DENIED CLAIMS

If the administrative claim is denied for incorrect demographic or eligibility information, please re-file the WVA claim with the corrections. The WVA relies on provider offices to ensure that any denied claims are re-filed correctly.

QUESTIONS?

You can find answers to many questions on the "FAQs" page at **www.wavaccine.org**.

Note for first time electronic filers

The first time you use the electronic DBA process, please notify your claim clearinghouse that you intend to submit the electronic Form using the DBA process with WVA's name, Tax ID, and NPI.

Important Numbers

WVA National Provider Identifier (NPI):
1699092718

WVA Tax Identification Number (TIN):
27-2251833

837 Electronic Claim - Professional

	X12N 837, Version 5010A1 Claim - Field Description	Loop	Segment/ Element	Qualifier	Qualifier Description	Data for WVA DBA Process
1	**Billing Provider**					
	Federal Tax ID Number (TIN)	**2010AA**	REF01	EI	for EIN	
				SY	for SSN	
	TIN	2010AA	REF02			**27-2251833**
2	**Billing Provider Information**	**2010AA**	NM101	85		
	Billing Provider Entity Type	2010AA	NM102	2		
						Washington
	Billing Organizational Name	2010AA	NM103			**Vaccine Association**
	Identification Code Type	2010AA	NM108	XX	NPI	
	National Provider Identifier (NPI)	2010AA	NM109			**1699092718**
	Billing Provider Address	2010AA	N3			**leave blank**
	Billing Provider Address - Line 1	2010AA	N301			**Marketplace Tower PH-A**
	Billing Provider Address - Line 2	2010AA	N302			**2025 First Ave**
	Billing Provider City, State, ZIP Code					
	City	2010AA	N401			**Seattle**
	State	2010AA	N402			**WA**
	Zip Code	2010AA	N403			**981213125**
						Washington
	Pay-To Address Name	2010AB	NM101	87		**Vaccine Association**
	Pay-to Entity Type	2010AB	NM102	2		
	Pay-To Address	2010AB	N3			
	Pay-To Address - Line 1	2010AB	N301			**PO Box 94002**
	Pay-To Address - Line 2	2010AB	N302			
	Pay-To City, State, ZIP Code		N4			
	City	2010AB	N401			**Seattle**
	State	2010AB	N402			**WA**
	Zip Code	2010AB	N403			**981249402**
3	**Patient Account Number**	**2300**	CLM01			
	Total Charge	**2300**	CLM02			**Total Charge Amount**
4	**Rendering Provider Name**	**2310B**	NM1			
	Rendering Provider Name	2310B	NM102	82		**Rendering**
		2310B	NM103			**Rendering Provider Name**
5	**Service Facility Location Information**	**2310C**				
	Service Facility Identifier	2310C	NM101	77	Location	
						Office Address of
				FA	Facility	**Service Facility**
	Service Facility Type	2310C	NM102	2		
	Non-Person Name, or Person Last Name	2310C	NM103			
6	**Service Line, Service Date(s)**	**2400**	DTP01	472		
	Service From - To Dates	2400	DTP02	RD8		
	Format as: CCYYMMDD-CCYYMMDD	2400	DTP03			
7	**Procedures, Services, Supplies**	**2400**	SV1			
	Product/Service ID	2400	SV101-1	HC		
	Procedure - CPT/HCPCS Code	2400	SV101-2			
8	Line Item $ Charge Amount	2400	SV102			

You make the program work!

When you use the DBA process, it allows the WVA to collect the necessary assessments from insurance carriers and third party administrators.

With your help, Washington can continue to provide vaccines to protect all children in our state.

Stay Connected

For more information, visit **www.wavaccine.org** and sign up for email alerts.

info@wavaccine.org
Ph. 888-928-2224
Fax. 888-928-2242

History of LAIV Relative to Circulating Strains

- **Aug 2003**

  LAIV3 approved by FDA

- **Apr 2009**

  A/H1N1pdm2009 circulated in United States

- **Feb 2012**

  LAIV4 approved by FDA

- **2013-14 influenza season**
- **2014-15 influenza season**

  "When immediately available, LAIV should be used for healthy children aged 2 through 8 years who have no contraindications."

- **2015-16 influenza season**

  "No preference is expressed for LAIV or IIV for any person aged 2 through 49 years for whom either vaccine is appropriate."

- **2016-17 influenza season**

  "In light of the evidence for poor effectiveness of LAIV in the U.S. over the last 3 influenza seasons…, for the 2016-17 season, ACIP makes the interim recommendation that LAIV should not be used"

Adapted from C Meissner, IDSA 2016

Possible Explanations Why VE of LAIV Has Been Low for 3 Seasons

- Vaccine virus interference in quadrivalent vaccine
- Limited thermostability of A/H1N1pdm09 LAIV strain
- Pre-existing influenza immunity interferes with vaccine strain replication
- Reduced replication of A/H1N1pdm09 LAIV strain in human respiratory cells

Adapted from C Meissner, IDSA 2016

OPTIMAL TIMING OF ANNUAL FLU VACCINE

WHERE WE'VE BEEN ...

- Initial concern about timing pertained to vaccination of the elderly
    - From at least the 1990s until the current decade, ACIP cautioned that vaccine-induced antibody to Influenza declines more rapidly in the elderly than in young adults
    - "Vaccination **before October** should therefore should **be avoided**"
- Later evidence that antibody level at a point several months after vaccination does not necessarily correlate with clinical vaccine effectiveness
    - Review showed no compelling evidence of quicker decline of vaccine-induced antibody in the elderly compared with young adults
    - No evidence that seroprotection was lost at 4 months if it was initially achieved after immunization.
    - Lack of evidence for late-season outbreaks among vaccinated persons that can be attributed to waning immunity
- 2009: "In general, health-care providers should begin offering vaccination **soon after** vaccine becomes available and **if possible by October**."
    - Although peak Influenza activity generally does not occur until January-March, flu season can occasionally begin as early as October.
    - Controlling spread of Influenza requires having as many people as possible immunized before the virus appears in the community (this will limit the number of people that can act as vectors for transmission to others).
- By 2010: "Vaccination efforts should begin **as soon as vaccine is available** and continue through the influenza season, which typically extends through April."
    - H1N1 Pandemic demonstrated shortfalls in earlier approach, and more robust surveillance demonstrated that flu viruses circulate at some level year-round.
    - Concern that when an opportunity-to-vaccinate is deferred until later in the season, it might be missed entirely (e.g. because a given individual may not show up in the office again for six months)
    - Concern that process problems associated with vaccinating large numbers in a limited time frame (e.g. long wait times, inadequate staffing, vaccine shortages) may prevent optimal vaccination of all of those for whom it is necessary.
- NOW: Some shift back ...

WHERE WE ARE …

- Current CDC recommendation: "Flu vaccination should begin **soon after** vaccine becomes available, **if possible by October**. However, as long as flu viruses are circulating, vaccination should continue to be offered throughout the flu season, even in January or later."
- GOAL: Ensure the vaccination of as many persons as possible before influenza activity in the community begins
    - In any given season, the optimal time to vaccinate cannot be predicted precisely
    - May be as early as October; however …
    - In 74% of influenza seasons since 1982, peak influenza activity occurred in or after January (February or later in 59% of seasons)
- In recent seasons, initial shipments of vaccine have arrived as early as July.
    - Again raises questions related to the ideal time to begin vaccination
    - Newer observational studies (2011-2015) report decreased vaccine protection within a single season (especially against A-H3N2), and a more-pronounced decline in protection among older adults
        - Castilla 2013: Decline in vaccine effectiveness from 61% in 0-100 days post-vaccination > 42% 100–119 days out > -35% (95% CI = -211–41) after 120 days. Primarily affected persons ≥65 years old – OR for influenza in this group was 20.81 (95% CI = 2.14–202.71; p = 0.009) for persons vaccinated >120 days before diagnosis compared to those vaccinated <100 days before diagnosis.
        - Pebody 2013: Vaccine effectiveness against A(H3N2) = 53% if vaccinated <3 months ago vs 12% if vaccinated ≥3 months ago.
        - Belongia 2015: Modest but significant increase in the OR for A(H3N2) influenza with time-since-vaccination among young children age 2 & adults age 75. OR increases by 1.2 every 14 days after vaccination for children, & by 1.3 for each 14-day interval for adults aged 75 years.
    - This has not been observed consistently across age groups and across all flu seasons
    - Observed decline in protection could be attributable to other factors, e.g. increased circulation of antigenically drifted variants over the course of the influenza season.
- UPSHOT: "**Inconsistent evidence** for intraseason waning of influenza vaccine protection **makes drawing conclusions difficult**, and further evaluation of this effect in larger studies and different seasons is needed."
    - Delaying vaccination until later in the season might result in greater immunity later in the season
    - Deferral might also result in missed opportunities to vaccinate and difficulties in vaccinating a population within a more constrained time period.
    - GUIDANCE: "Community vaccination programs should balance **maximizing likelihood of persistence of vaccine-induced protection** through the season with **avoiding missed opportunities** to vaccinate or vaccinating after onset of influenza circulation occurs."