WASHINGTON VACCINE ASSOCIATION

Ensuring Funds for Childhood Vaccines

What: WVA Payer Call: Special Purpose Meeting Agenda
When: September 26, 2023; 3:00-4:00 pm PT
Location: Webinar/Teleconference
Zoom Link: To register for the meeting, please review the Public Comment Protocol then email wvameetings@wavaccine.org at least two business days in advance of the meeting.

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

AGENDA

Approx. Time	*	Page	Topic/[Anticipated Action]	Presented by:
3:00-3:05 pm			1. Welcome & Introductions a) Notice of Meeting Recording	J. Zell
3:05-3:55 pm			2. Status Update	
	*	Pg. 2-3	a) Legislative change	J. Zell
	*	Pg. 4-6	b) Vaccine Committee Recommendations	
	*	Pg. 7-11	c) Financial Projection	P. Miller
			d) Voluntary Contribution Agreement Change	Any K. Griffith
			e) Discussion/Questions	
4:00 pm			3. Closing	J. Zell

*Indicates agenda item attached

BILL REQUEST - CODE REVISER'S OFFICE

BILL REQ. #: Z-0415.2/24 2nd draft

ATTY/TYPIST: MW:akl

AN ACT Relating to updating the Washington vaccine association's definitions; amending RCW 70.290.010; and declaring an emergency.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF WASHINGTON:

Sec. 1. RCW 70.290.010 and 2010 c 174 s 1 are each amended to read as follows:

The definitions in this section apply throughout this chapter unless the context clearly requires otherwise.

(1) "Association" means the Washington vaccine association.

(2) "Covered lives" means all persons under the age of nineteen in Washington state who are:

(a) Covered under an individual or group health benefit plan issued or delivered in Washington state or an individual or group health benefit plan that otherwise provides benefits to Washington residents; or

(b) Enrolled in a group health benefit plan administered by a third-party administrator. Persons under the age of nineteen for whom federal funding is used to purchase vaccines or who are enrolled in state purchased health care programs covering low-income children including, but not limited to, apple health for kids under RCW 74.09.470 and the basic health plan under chapter 70.47 RCW are not considered "covered lives" under this chapter.

(3) "Estimated vaccine cost" means the estimated cost to the state over the course of a state fiscal year for the purchase and distribution of vaccines purchased at the federal discount rate by the department of health.

(4) "Health benefit plan" has the same meaning as defined in RCW 48.43.005 and also includes health benefit plans administered by a third-party administrator.

(5) "Health carrier" has the same meaning as defined in RCW 48.43.005.

(6) "Secretary" means the secretary of the department of health.

(7) "State supplied vaccine" means vaccine purchased by the state department of health for covered lives for whom the state is purchasing vaccine using state funds raised via assessments on health carriers and third-party administrators as provided in this chapter.

(8) "Third-party administrator" means any person or entity who, on behalf of a health insurer or health care purchaser, receives or collects charges, contributions, or premiums for, or adjusts or settles claims on or for, residents of Washington state or Washington health care providers and facilities.

(9) "Total nonfederal program cost" means the estimated vaccine cost less the amount of federal revenue available to the state for the purchase and distribution of vaccines.

(10) "Vaccine" means ((~~a preparation of killed or attenuated living microorganisms, or fraction thereof, that upon administration stimulates immunity that protects against disease and is~~)) an immunization approved by the federal food and drug administration as safe and effective and recommended by the advisory committee on immunization practices of the centers for disease control and prevention for administration to children under the age of nineteen years.

NEW SECTION. **Sec. 2.** This act is necessary for the immediate preservation of the public peace, health, or safety, or support of the state government and its existing public institutions, and takes effect immediately.

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Meeting Notes
Special RSV Vaccine Committee Meeting
September 21, 2023; 7:00-8:00 a.m. PT

I. Attendance. This meeting was conducted solely by webinar. Participating in all or part of the meeting were the following individuals:

Attendees
Ed Marcuse, MD, Emeritus Professor of Pediatrics, University of Washington
Amy Carter, MD, Allegro Pediatrics
Helen Chea, MD, Molina Healthcare
John Dunn, MD, Kaiser Permanente
Beth Harvey, MD, South Sound Pediatrics
Chad Murphy, Premera
Amy Person, MD, Benton-Franklin Health District
Kristi A. Rice, MD, Providence
Janel Jorgenson, Washington Department of Health
Michele Roberts, Washington Department of Health
Hailey Sly, Washington Department of Health
Sherri Zorn, MD, Independent Consultant
Jeff Gombosky, PhD, Pharmaceutical Research and Manufacturers of America
Pam Sheffield, MD, Aetna
Juliet Dang, PhD, Sequirus
Carrie Jenner, MD, Pierce County Immunization Coalition
Rick Hourigan, MHA, MD, Cigna
Breelyn Young, GSK
Frank Bell, MD, Swedish
Nicholas Fisher, Sanofi
Neil Kaneshiro, Premera
Julia G. Zell, MA, Esq., WVA Executive Director
Patrick Miller, MPH, WVA Administrative Director
Cheri Cagle, WVA Stakeholder Liaison
Ashley Ithal, MPH, WVA Project Support Leader
Leslie Walker, CPA, Mason+Rich

II. Summary of Actions Taken and/or Recommended

The Vaccine Committee voted to adopt the following recommendations to be presented to the Board of Directors:

1. WVA to Work with DOH to Make RSV Monoclonal Antibody Part of WA State Universal Vaccine Purchase Program.
2. WVA to Develop a Funding Mechanism to Protect Against Liability Pending Modification of Statute Governing WVA.
3. WVA to Collaborate with DOH, WCAAP, and Others to Modify Statute this Legislative Session to Update Definition of Vaccine.

III. Minutes

Welcome and Introductions
At 7:02 a.m. Dr. Marcuse called the meeting to order. Ms. Zell announced that the meeting would be recorded for the benefit of the minute taker, to be deleted once the minutes are approved.

Dr. Marcuse provided an overview of Nirsevimab, which was recommended by the Advisory Committee on Immunization Practices for inclusion on the CDC's immunization schedule and the Vaccines for Children program. It is a monoclonal antibody providing passive immunization in infants and toddlers against RSV. Dr. Marcuse reviewed the role of the WVA and the Vaccine Committee in making recommendations on which immunizations to purchase for the state universal vaccine program. He noted that virtually all universally available vaccines have been listed on federal contract and are available under the program. He discussed, however, that Nirsevimab presents a unique issue. Nirsevimab is not a vaccine that stimulates active immunity in the vaccinee but an antibody confers passive immunity. Therefore, it does not fit under the statutory definition of vaccine in the WVA's establishing statute. Dr. Marcuse confirmed that the purpose of today's meeting is for the Vaccine Committee to come to consensus on recommendation(s) that will be presented to the Board of Directors at the special board meeting on September 28, 2023.

WCAAP Presentations
Dr. Marcuse discussed the importance to obtain consultation from third-party, non board member experts to inform the Committee's deliberations and recommendations on this matter.

Dr. Marcuse introduced Dr. Frank Bell (Swedish), who is a pediatric infection disease specialist based in the Tacoma, Washington area. Dr. Bell discussed that RSV is the predominant cause of hospitalization of infants globally. He referenced statistics provided in materials that were circulated to Committee members in advance of today's meeting. Dr. Bell described RSV as a ubiquitous virus—one that all infants will have experienced by the end of their second RSV season. Some infants may have mild symptoms, but many have congestion of upper and/or lower airways, leading to respiratory distress and difficulty feeding. Dr. Bell noted that 1 to 3 percent of infants who experience RSV in their first winter season have required hospitalization to receive nutrition, intravenous fluids, respiratory support, and/or supplemental oxygen.

Dr. Bell next provided a clinical overview of immunization development for RSV since the virus was discovered about 30 years ago. He discussed how early attempts to produce an inactivated vaccine seemed to lead to more aggressive disease in infants subsequently infected by the virus, rather than abrogation or prevention. Dr. Bell also touched on the RSV monoclonal antibody currently on the market, Synagis, noting that while we have seen some success, this has proven to be a relatively costly strategy for a product that is and very difficult to deliver (monthly injections throughout the season). Dr. Bell discussed that we have gained a much better understanding of RSV and we have made extraordinary progress on immunization technologies. He views Nirsevimab to be highly effective, safe, without appreciative side effects, and "our best shot" to help infants against RSV.

Dr. Marcuse next introduced Dr. Amy Carter (Allegro Pediatrics), who is a pediatrician and Chief Medical Officer practicing at one of the largest pediatric practices in Washington State, to provide a clinician's perspective about the demand and the feasibility of administering Nirsevimab as part of primary care. Dr. Carter noted that pediatricians and patients are very excited about Nirsevimab; she views this as the beginning of a paradigm shift in RSV prevention.

Dr. Carter provided estimates of the number of infants Allegro expects to see across the two groups for which ACIP recommendations have been issued (infants under 8 months of age entering their first RSV season, and high-risk infants between 8 and 19 months of age entering their second RSV season)—approximately 32,000 patients. She believes it would be feasible for Allegro to administer Nirsevimab to these patients if it is included in the state universal vaccine program. She noted that this is a well-known and trusted system throughout the State, and that providers already have standing working relationships and proven workflows for ordering and distribution.

Dr. Carter next discussed her concerns if WVA does not fund Nirsevimab. Ultimately, she believes that a two-product system would place significant burdens (in terms of ordering costs, storage space, staffing, and workflows); would increase the risk of error and impact patient safety; and would lead to disparities in access and health outcomes. In particular, she discussed that providers would need to adjust a lot of capital on short notice if they were to have to privately purchase Nirsevimab for this upcoming season. For Allegro, she estimates a $1.5 million outlay. She noted that the cost of Nirsevimab is significant enough to cause providers to be conservative in any private purchasing to avoid "over-ordering," and that this could lead to a lack of supply in the middle of the season.

Dr. Carter closed her remarks by noting the public health policy behind the state universal vaccine program. She cautioned against further eroding the public's trust in science and in vaccines by failing to include Nirsevimab in the program. She also noted that equitable access to Nirsevimab will take pressure off our urgent care and emergency room providers to treat infants who can now be protected from severe disease.

Dr. Marcuse called on Janel Jorgenson to discuss the position of the Washington State Department of Health (DOH). Ms. Jorgenson discussed that the state universal vaccine program has been in place for over 30 years. She discussed what this program provides for Washington: equitable access to vaccines regardless of insurance statute; reduction in state expenditures by purchasing via CDC federal contract (on average, 30% savings over all); mitigation of financial, staffing, inventory, and related burdens on providers under a two-product system: i.e, one for VFC eligible patients and one for all others.. Ms. Jorgenson acknowledged the issue unique among ACIP immunization recommendations to Nirsevimab, because it does not fall within WVA's statutory definition of a vaccine. She confirmed that DOH is seeking a statutory change to align the State's definition with ACIP's replacing the term vaccine with immunization which would allow products like Nirsevimab to be added to the state universal vaccine program if recommended by ACIP and covered by VFC. DOH requests WVA to support the DOH's efforts to include Nirsevimab in the state universal vaccine program.

Dr. Marcuse called on Ms. Zell to discuss the challenges with providing Nirsevimab for the upcoming season, as well as the longer-term strategy to include this in the program moving forward. Ms. Zell confirmed that WVA has determined that the statutory definition would not encompass Nirsevimab, and that WVA is working closely with the DOH and the State AG to effectuate the statutory change. She also discussed WVA's efforts to identify funding approaches for the upcoming season that could be presented to the Board of Directors on September 28 for consideration. She discussed in particular the potential for payers to commit to voluntarily fund Nirsevimab for this season, so that assessments do not begin until the legislation passes. She also discussed the potential for WVA to secure other appropriate funding to avoid use of its reserves before the legislation has passed. She noted that all of these options are subject to approval of the Board of Directors, which will meet on September 28. Kiran Griffith provided additional comments on legal risks to WVA with funding Nirsevimab before the legislation passes and what is being considered to mitigate these risks while supporting equitable access to the product.

Dr. Marcuse proposed that the Vaccine Committee consider and vote on the following recommendations to the Board regarding Nirsevimab:

1. WVA to Work with DOH to Make RSV Monoclonal Antibody Part of WA State Universal Vaccine Purchase Program this respiratory season.
2. WVA to Develop a Funding Mechanism to Protect Against Liability Pending Modification of Statute Governing WVA.
3. WVA to Collaborate with DOH, WCAAP, and Others to Modify Statute this Legislative Session to Update Definition of Vaccine.

Dr. Marcuse then opened the meeting up for general discussion. Key questions and comments included the following:

- What are the WVA's reserves and what are these amounts meant to be used for?
- What is the scope of WVA's authority to collect assessments under the statute? What is the legal risk to WVA to use reserves to pre-fund Nirsevimab before the statute is changed? What risk mitigation steps could be taken?
- Recognition that the Vaccine Committee's role is focused on clinical considerations and public health impact relating to a vaccine under proposed recommendations #1 and #3. Proposed recommendation #2 raises other legal and funding considerations beyond the focus of this Committee, but it is important context for the Committee to consider given the legal risks to the organization.

Next Steps

Upon motion duly made and seconded, it was unanimously:

VOTED: 11 in favor of proposed recommendations #1 and #3, no opposition. 10 in favor of proposed recommendation #2, no opposition.

IV. Public Comments

No public comments.

V. Closing

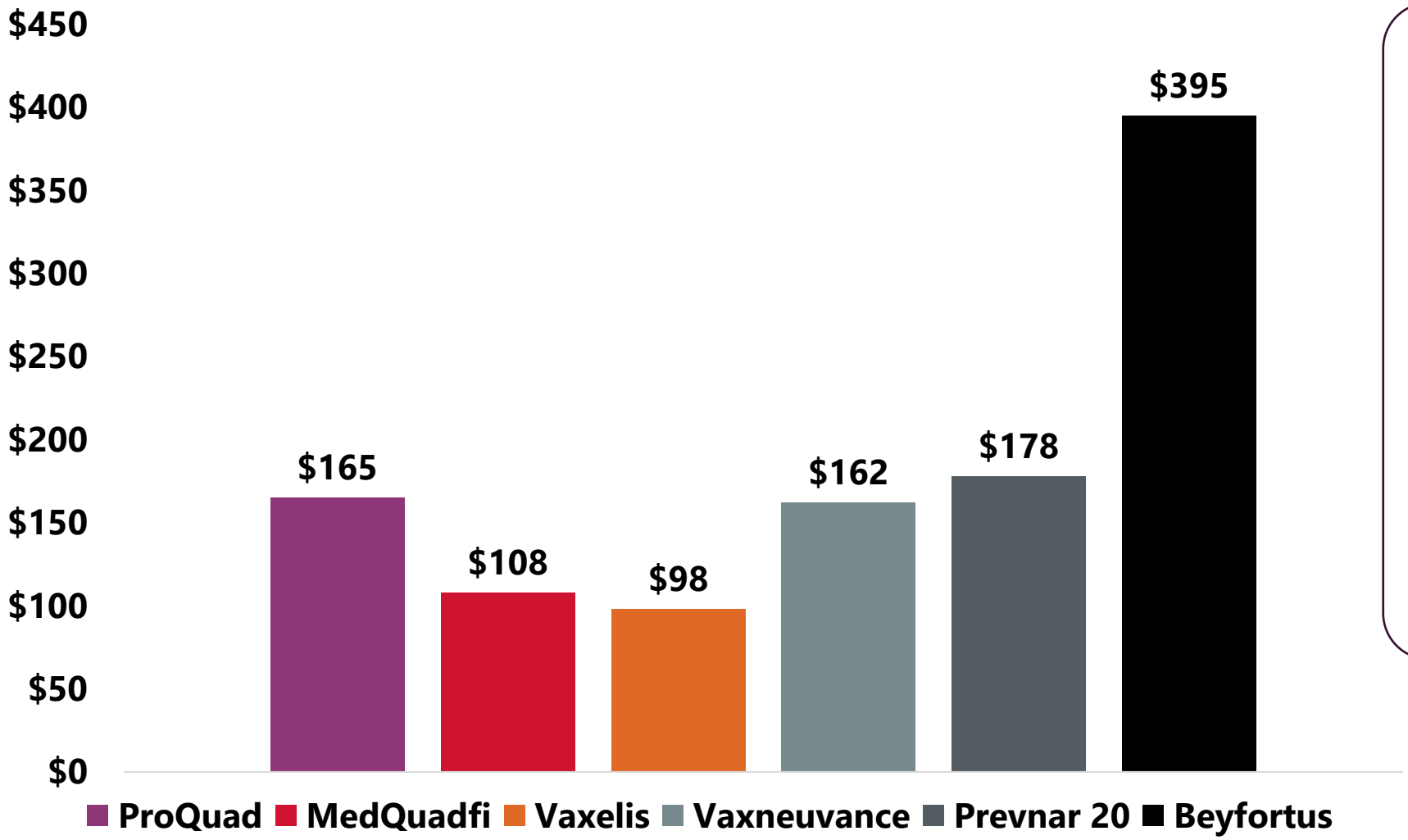
The meeting adjourned at 7:57 a.m. PT.

RSV Nirsevimab Discussion

Payer Special Meeting

September 26, 2023

CDC Prices of Recent ACIP Additions



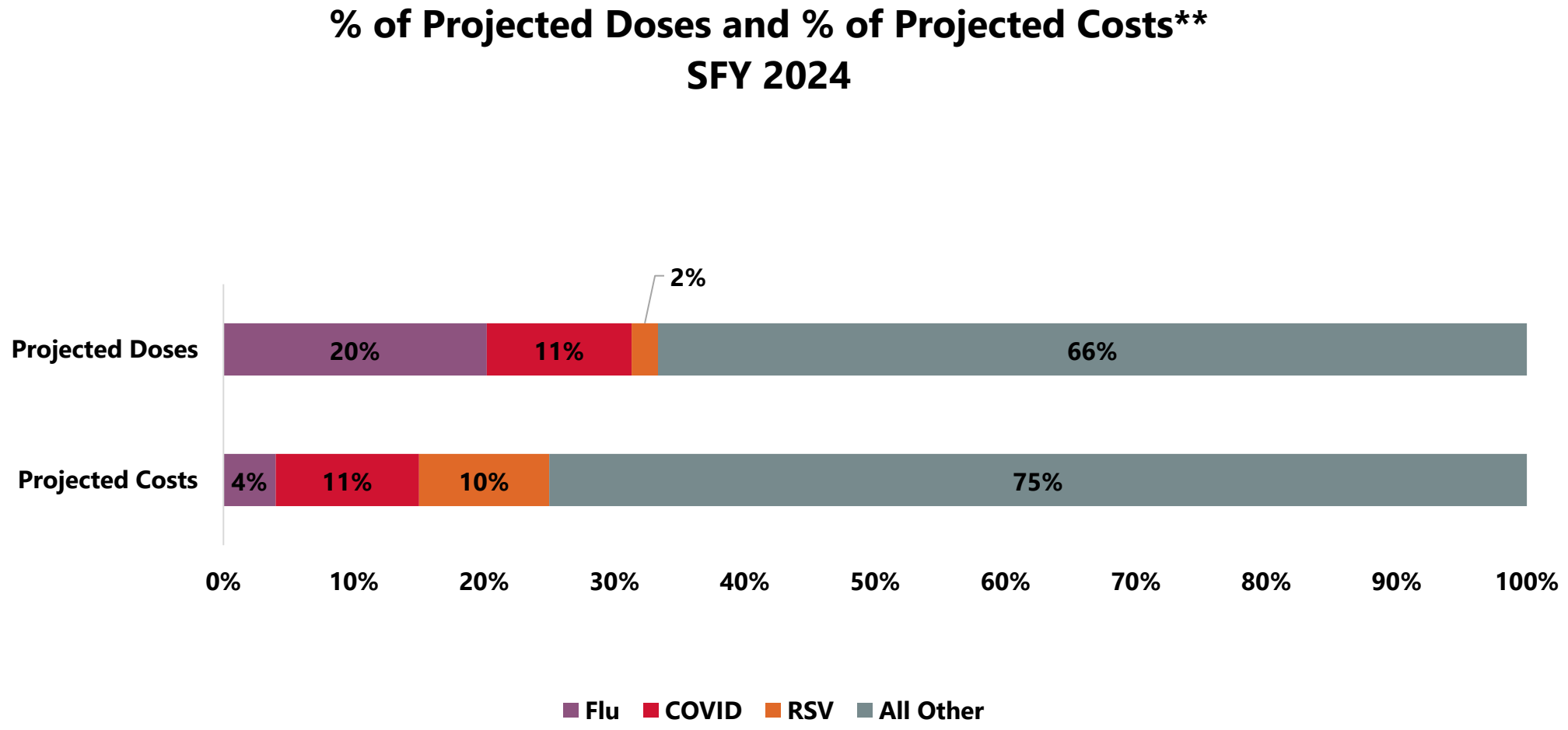
Excluding Beyfortus, Average of Recent Additions = $142/Dose

RSV Projections – Source: WA DOH (09/14/23)

Fund Type Categories	If uptake is 100% of eligible population - number of doses annually	If uptake is 100% of eligible population - cost annually	Assume 70% uptake - number of doses annually	Assume 70% uptake - cost annually	Assume 50% uptake - number of doses annually	Assume 50% uptake - cost annually
Total Estimated: total 0 population plus 2 additional doses for 8-19-month-olds who are immunosuppressed and/or AI/AN.	109,793	$43,368,108	76,855	$30,357,676	54,896	$21,684,054
Breakdown by Fund Source						
VFC (50%)	54,896	$21,684,054	38,427	$15,178,838	27,448	$10,842,027
WVA (47%)	**51,603**	**$20,383,011**	**36,122**	**$14,268,108****	**25,801**	**$10,191,505**
CHP/CHIP (3%)	3,294	$1,301,043	2,306	$910,730	1,647	$650,522
Total Estimate Cost Annually	109,793	$43,368,108	76,855	$30,357,676	54,896	$21,684,054

**Assumes $395/dose from CDC Price List. Private Market would be $495/dose or $17,880,287.

Doses and Costs – Summary



**Excludes Indirect and Cost Recovery Fees

Impacts by Party: 2 Options – Summary

Party	Option 1: Voluntary Payer Contribution Funds Interim RSV Strategy Until Statute is Updated	Option 2: No Interim Funding / No State Supply Until Statute is Updated
WVA	▪ Communications Plan → "No DBA Now"; "Planned Assessment Date 7/1/2024 Pending Statute Update" ▪ New Vaccine Bank Account Management ▪ Backend Settlement Reporting and Collections ▪ Compliance Program ▪ Increased Audit Complexity and Costs ▪ Government Relations Firm Retained	▪ Communications Plan → "No State Supply"; "No DBA Now"; "Planned Assessment Date 7/1/2024 Pending Statute Update" ▪ Process DBAs Once Statute is Updated ▪ Government Relations Firm Retained
DOH	▪ Communications Plan → "No DBA Now"; "Planned Assessment Date 7/1/2024 Pending Statute Update" ▪ Legislation Champion/Lead Organizer ▪ IIS Set Up for Nirsevimab Orders	▪ Communications Plan → "No State Supply"; "No DBA Now"; "Planned Assessment Date 7/1/2024 Pending Statute Update" ▪ Legislation Champion/Lead Organizer ▪ IIS Set Up for Nirsevimab Orders Post Statute Update
PAYERS	▪ Unplanned Medical Costs @ $395/Dose ▪ Set Up Adjudication Systems to Deny Payment Until 7/1/2024 Pending Statute Update	▪ Unplanned Medical Costs @ $495/Dose ▪ Set Up Adjudication Systems to Pay Provider
PROVIDERS	▪ No Change / Order Per Normal Course ▪ Dual Supply Chain/Vaccine Management ▪ Preserves Access to Patients	▪ Fund Up Front Nirsevimab Purchases ▪ Dual Supply Chain/Vaccine Management ▪ Bill the Payers with Possible Mark Up ▪ Potentially Restricts Access to Patients