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**Oregon School/Facility Immunization Advisory
Committee:**

**Review of Influenza Vaccine Against Twelve
Criteria for
School/Facility/College Immunization
Requirements**

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Process for Reviewing Antigens for Potential Inclusion in OAR 333-050-0050, 333-050-0130 and 333-050-0140.

Request for the inclusion of additional antigens or vaccines can come from the Oregon Immunization Program, IPAT (Immunization Policy Advisory Team), or from the community. Proposed changes to vaccine requirements are discussed with IPAT either in a regularly scheduled meeting or through electronic communication. IPAT will submit their comments and a request for consideration to the Oregon Immunization School Law Advisory Committee.

The Oregon School/Facility Immunization Advisory Committee was established as a part of the school law immunization requirements when the original legislation was passed in 1980. This Committee is composed of immunization stakeholders from the fields of public health, school health, school administration, medicine, day care, child advocacy and consumers (parents). Through consensus, the committee determines what vaccines (antigens) should be included in Oregon school immunization requirements.

Information about new vaccines and the diseases they prevent, including transmission within schools, burden of disease, cost-effectiveness, effect on schools/counties and vaccine availability is presented at a scheduled meeting for committee consideration. The following criteria are an integral part of the discussion and the decision-making process. All 12 criteria must be considered. Members of the Committee are expected to rely on their professional and scientific judgment as well as available data when applying the criteria.

The Committee's recommendation is then submitted to the Oregon Immunization Program for consideration and possible action.

The 12 Criteria to Consider in Evaluating Influenza Vaccine

The following information is being presented for Committee consideration.

Consideration: Adding influenza vaccine to the school law requirements for school/facility/college attendance.

1. The vaccine containing this antigen is recommended by ACIP (Advisory Committee on Immunization Practices) and included on its recommended childhood and adolescent immunization schedule.

“Annual influenza vaccination is the most effective method for preventing influenza virus infection and its complications. Influenza vaccine can be administered to any person aged >6 months who does not have contraindications to vaccination to reduce the likelihood of becoming ill with influenza or of transmitting influenza to others. Trivalent inactivated influenza vaccine (TIV) can be used for any person aged ≥6 months, including those with high-risk conditions. Live, attenuated influenza vaccine (LAIV) may be used for healthy, nonpregnant persons aged 2--49 years. No preference is indicated for LAIV or TIV when considering vaccination of healthy, nonpregnant persons aged 2--49 years. Because the safety or effectiveness of LAIV has not been established in persons with underlying medical conditions that confer a higher risk for influenza complications, these persons should be vaccinated only with TIV. Influenza viruses undergo frequent antigenic change (i.e., antigenic drift); to gain immunity against viruses in circulation, patients must receive an annual vaccination against the influenza viruses that are predicted on the basis of viral surveillance data.”

For the 2008-2009 flu season, ACIP expanded the recommendation for influenza vaccination to cover all children 6 months through 18 years of age. In 2010, the recommendation was expanded again; all individuals 6 months of age and older are now recommended to receive annual influenza immunization.

CDC. Prevention and Control of Seasonal Influenza with Vaccines: Recommendations of the Advisory Committee on Immunization Practices (ACIP), 2009. *MMWR*. July 31, 2009 / 58(RR08);1-52 (pages 1-2)
Available at: <http://www.cdc.gov/mmwr/pdf/rr/rr5808.pdf>

2. The vaccine prevents disease with a significant morbidity and mortality in at least some subset of the Oregon's population.

From: FLU BITES Oregon's Weekly Surveillance Report for Influenza and other Respiratory Viruses, April 2, 2010, available at:
<http://egov.oregon.gov/DHS/ph/acd/flu/data/season2009-10.pdf>

- Since September 1, 2009, 1,314 patients have been hospitalized with laboratory-confirmed influenza statewide (957 adults; 357 children). Rates of hospitalization are substantially higher among individuals with underlying

- conditions, including pregnant women, children with neuromuscular disease or seizure disorder, and adults with chronic lung disease or diabetes.
- Since September 1, 2009, 67 people have died from influenza (63 adults; 4 children). Of the four pediatric deaths, all had neuro-developmental conditions. Of the 65 deaths for whom information about medical conditions is known, 59 (91%) had one or more underlying conditions.
 - Oregon's death rate for the entire pandemic period (since April, 2009) is 1.8 deaths per 100,000 Oregonians. The Centers for Disease Control and Prevention (CDC) estimate the national rate of H1N1-related deaths from April – February 13th to be 3.9 per 100,000."

Oregon Acute and Communicable Disease Program, 2010.

3. The vaccine (antigen) is cost-effective from a societal perspective in Oregon.

"Economic studies of influenza vaccination are difficult to compare because they have used different measures of both costs and benefits (e.g., cost-only, cost-effectiveness, cost-benefit, or cost-utility). However, most studies find that vaccination reduces or minimizes health care, societal, and individual costs and the productivity losses and absenteeism associated with influenza illness. One national study estimated the annual economic burden of seasonal influenza in the United States (using 2003 population and dollars) to be \$87.1 billion, including \$10.4 billion in direct medical costs."

"Cost analyses have documented the considerable financial burden of illness among children. In a study of 727 children conducted at a medical center during 2000--2004, the mean total cost of hospitalization for influenza-related illness was \$13,159 (\$39,792 for patients admitted to an intensive care unit and \$7,030 for patients cared for exclusively on the wards). A strategy that focuses on vaccinating children with medical conditions that confer a higher risk for influenza complications are more cost-effective than a strategy of vaccinating all children. An analysis that compared the costs of vaccinating children of varying ages with TIV and LAIV indicated that costs per QALY saved increased with age for both vaccines. In 2003 dollars per QALY saved, costs for routine vaccination using TIV were \$12,000 for healthy children aged 6--23 months and \$119,000 for healthy adolescents aged 12--17 years compared with \$9,000 and \$109,000 using LAIV, respectively. Economic evaluations of vaccinating children have demonstrated a wide range of cost estimates, but have generally found this strategy to be either cost-saving or cost-beneficial."

CDC. Prevention and Control of Seasonal Influenza with Vaccines: Recommendations of the Advisory Committee on Immunization Practices (ACIP), 2009. *MMWR*. July 31, 2009 / 58(RR08);1-52 (page 24)
Available at: <http://www.cdc.gov/mmwr/pdf/rr/rr5808.pdf>

How do the morbidity/mortality statistics and cost-effectiveness estimates support or oppose the addition of this vaccine to school/facility/college requirements?

4. **The vaccine (antigen) has been used in the general population to demonstrate reduction in disease activity with similar level of effectiveness to that demonstrated prior to FDA approval.**

A new trivalent influenza vaccine is manufactured prior to each flu season. In years when there is a good match between the components of the vaccine and the strains of virus circulating, the efficacy of the vaccine in preventing influenza infection is higher; if the match is poor, the efficacy is lower.

5. **The vaccine is necessary to prevent diseases known to be spread in schools or facilities, respectively and will increase safety in the school/facility environment.**

"Healthy children 5 through 18 years of age are not at increased risk of complications of influenza. However, children typically have the highest attack rates during community outbreaks of influenza. They also serve as a major source of transmission of influenza within communities. Influenza has a substantial impact among school-aged children and their contacts. These impacts include school absenteeism, medical care visits, and parental work loss. Studies have documented 5 to 7 influenza-related outpatient visits per 100 children annually, and these children frequently receive antibiotics."¹

Influenza vaccination has also been shown to reduce illness and increase class attendance in college settings.²

CDC. *Epidemiology and Prevention of Vaccine-Preventable Diseases*, 11th Edition, page 139. Available at <http://www.cdc.gov/vaccines/pubs/pinkbook/downloads/flu.pdf>

Kristin L. Nichol; Sarah D'Heilly; Edward P. Ehlinger. Influenza Vaccination Among College and University Students: Impact on Influenza-like Illness, Health Care Use, and Impaired School Performance. *Arch Pediatr Adolesc Med.* 2008;162(12):1113-1118.

Would this vaccine requirement have the potential to reduce the spread of disease in the school/facility/college setting, or is the goal to reduce disease in the community at large? Would this vaccine requirement have the potential to reduce the number of cases of disease, or would it have the potential to prevent outbreaks?

6. Requiring the vaccine for school law will make a significant difference in vaccine coverage in the preschool/school/college populations and vaccinating the infant, child, adolescent or young adult against this disease reduces the risk of person-to-person transmission.

Of children in the ALERT IIS, 16% of 6 month – 18 year olds received at least one dose of flu vaccine during the 2008-2009 flu season. This ranged from 49.8% of 6-23 month olds to 7.7% of 13-18 year olds.

2008-2009 Influenza Report. Oregon Immunization Program

7. The vaccine is acceptable to the Oregon medical community and the general public.

As the data above indicate, influenza vaccine uptake in children is low. However, the recommendation for all children to receive influenza vaccine is recent. In a survey of 600 individuals statewide conducted in April 2010, approximately 55% responded that they would be very likely or somewhat likely to get the seasonal flu vaccine next year; 46% responded that they or someone in their care (child, parent, spouse) received the H1N1 vaccine this year.

ODHS H1N1 Vaccine Survey, April 2010. Davis, Hibbitts & Midghall, Inc.

What level of provider/public acceptance and vaccine uptake are necessary so that addition of this vaccine to school/facility/college law would be most effective? If uptake and acceptance are very high, the requirement would have little impact, and if very low, the requirement would face a lot of resistance.

8. Ensure that sufficient funding is available on a state level to purchase vaccines for children who would need to meet the new law requirements.

A vaccine cannot be added to school law requirements unless it is assured that every child has access to the vaccine and that it is affordable. If the cost of the vaccine exceeds the funding available through federal programs, it will be necessary for the state to set aside funds to purchase the proposed required vaccine. Based on projections developed during the spring of 2009 for SJR1 legislation, the biennial costs for providing influenza vaccine would be about \$1,352,635. For college students, no estimate has been prepared. Factors that would need to be considered in making an estimation would include the number of college students, the uptake of vaccine in college students, the proportion with insurance covering influenza vaccination, and the number of students over 18 years of age as these students would not be eligible for the VFC program.

9. There is a stable and adequate supply of vaccine.

Supply of influenza vaccine is unpredictable. In some years, there is plenty of vaccine. In other years, the demand for vaccine is greater than the supply, or the vaccine isn't available until late fall.

10. The administrative burdens of delivery and tracking of vaccine and Oregon school/facility rule implementation is reasonable in light of any other vaccines currently being phased in to law.

For schools and children's facilities, whenever new immunization requirements are added, schools have to contact more families about needed vaccines and spend time educating parents. Computer software upgrades must be made and paid for, and in turn must be approved by the state. Computer programs are not currently designed to accept influenza vaccines, so programming changes would be extensive. Exclusion orders and Certificate of Immunization Status forms would also require revision. Local health departments would have to prepare and mail more exclusion orders, provide more community clinics and communicate with local providers and parents about the new rule changes to ensure that children will not be excluded from school. Health plans need to cover the costs of the vaccines when feasible to improve access. Oregon law prohibits local health departments from charging an administrative fee if parents are financially unable to pay, and this has a financial impact on the counties. Adding more vaccines when still phasing in other vaccines complicates the entire process that can then lead to errors, confusion, and frustration that can potentially overwhelm the partners in the process which may weaken the effectiveness of school law enforcement.

A requirement for influenza vaccination poses unique challenges. All students would be required to receive a dose of vaccine every year, with students 8 years and younger potentially receiving two doses, depending on their previous influenza vaccination history. Depending on vaccine availability and supply, children may not be able to receive the vaccine until October, November, or even later. The requirement for a dose every year for every single student and the potential late availability of the vaccine would substantially increase the administrative burdens for schools and childcares for tracking influenza doses and providing parent notifications.

11. The burden of compliance for the vaccine is reasonable for the parent/caregiver.

Since influenza vaccination is recommended annually, a clinic visit would likely be necessary each year. ORS 433.269 states that if a vaccine is required for school attendance, local health departments must provide vaccines in convenient areas and at convenient times and “no person shall be refused service because of inability to pay.” However, providers do request an administrative fee. Although the amount of money requested is modest and the student must be able to receive the vaccine at no cost, some parents feel responsible to pay fees they may not be able to afford. Because flu vaccines are received every year, dates are not always added to immunization records. This would put an additional burden on parents to find those dates since vaccine history is important in determining if one or two doses of vaccine would be needed.

12. The vaccine is included in Oregon ALERT IIS for tracking and reporting purposes.

Influenza vaccine doses are documented for all ages submitted to ALERT and forecast September 1-June 30 each year through 18 years of age.

What is a reasonable administrative burden for the school/facility/college, and would a new requirement for this vaccine create an acceptable or unacceptable burden on schools/facilities/colleges? What is a reasonable burden for the parent/caregiver?