Oregon Immunization School/Children's Facility/College Law Advisory Committee:

Criteria for Reviewing Quadrivalent Meningococcal Conjugate Vaccine for Potential Inclusion in OAR 333-050-0050, 333-050-0130 and 333-050-0140 School/Facility/College Immunization Requirements

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Oregon School/Facility Immunization Advisory Committee: Review of Quadrivalent Meningococcal Conjugate Vaccine (MCV4) Against Twelve Criteria for School/Facility/College Immunization Requirements

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), Oregon legislature 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.

On September 23, 2015, the Immunization School/Facility/College Law Advisory Committee voted to recommend not requiring quadrivalent meningococcal conjugate vaccine for school or college attendance in Oregon.

The 12 Criteria to Consider in Evaluating Quadrivalent Meningococcal Conjugate Vaccine

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

   ACIP recommends routine vaccination of all persons aged 11-18 years with two doses of meningococcal conjugate vaccine (MCV4). One dose is also recommended for unvaccinated first year college students up through age 21 living in residential housing. These students are at a small increased risk for meningococcal disease caused by *Neisseria meningitidis* bacteria. MCV4 provides protection from 4 serogroups of bacteria, A, C, Y and W-135. Vaccination is also recommended for certain high-risk individuals in other age groups.

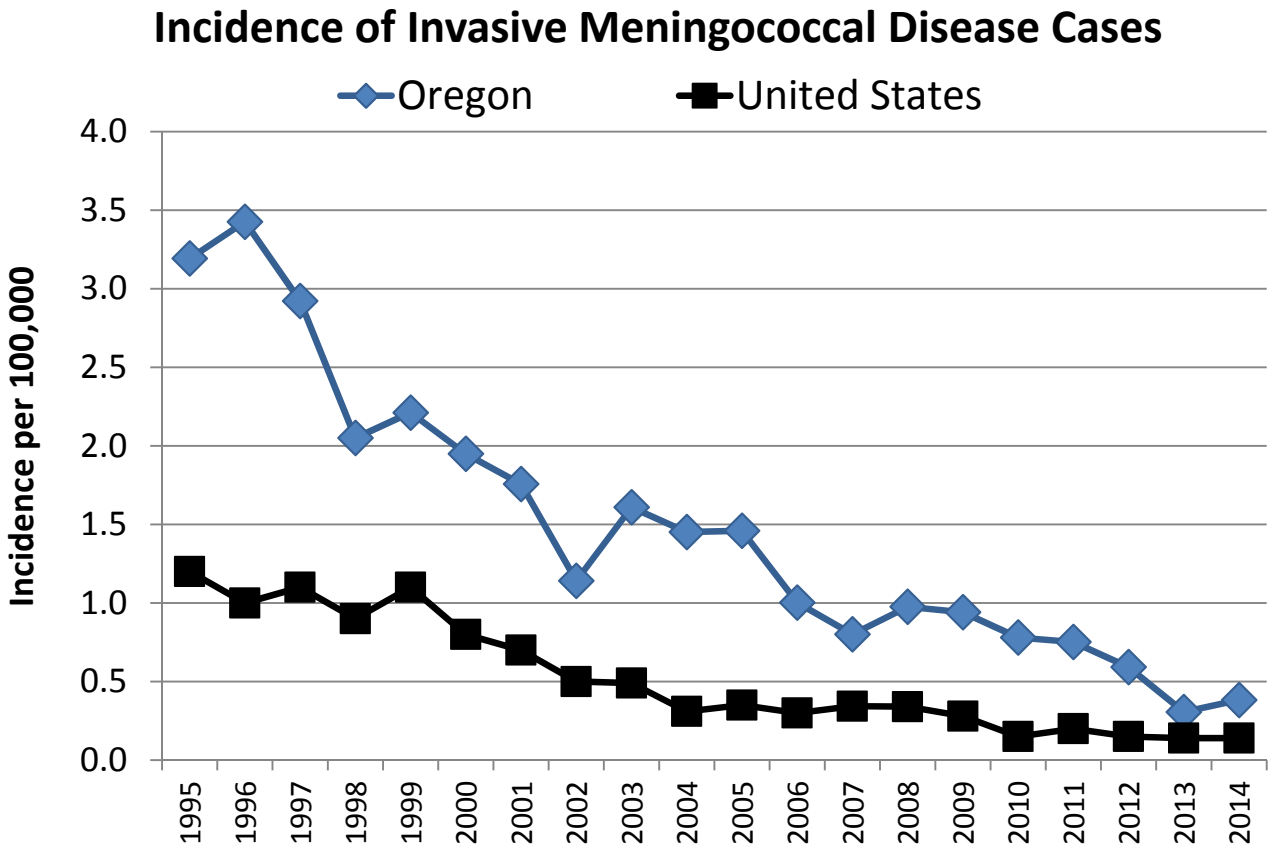
   CDC. *Epidemiology and Prevention of Vaccine-Preventable Diseases*, 13th Edition, pages 231-245. Available at http://www.cdc.gov/vaccines/Pubs/pinkbook/downloads/mening.pdf

   CDC. Prevention and Control of Meningococcal Disease: Recommendations of the Advisory Committee on Immunization Practices (ACIP). *MMWR*. March 22, 2013 / 62(RR02);1-22. Available at http://www.cdc.gov/mmwr/preview/mmwrhtml/rr6202a1.htm

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

   Although invasive meningococcal disease (IMD) is a serious disease, with a case-fatality rate of 10-15% even with appropriate antibiotic therapy, the disease is increasingly rare. In Oregon, the incidence has decreased 89% since 1996. However, Oregon still has a higher rate of meningococcal disease than the U.S. average (see chart below). The overall number of Oregon cases decreased 58% from 1996 to 2004, prior to licensure of MCV4 in 2005. During this nine-year period, Oregon reported an average of 69 cases a year. During the nine-year period after vaccine licensure, from 2006 through 2014, Oregon reported an average of 28 cases per year. From 2006 through 2014, 29 cases were reported in ages 5-17 years, for an average of 3 cases per year in this age group. From 2006 through 2014, 36 cases were reported in ages 18-24 years, for an average of 4 cases per year in this age group. From 2006 through 2010, of those cases with a serogroup determined, 45% in ages 5-17 years and 75% in ages 18-24 years were due to a serogroup included in quadrivalent meningococcal conjugate vaccine. The occurrence of disease during this time has not been constant and has demonstrated a general trend of decreasing incidence over recent years. Although the highest rates of disease occur among infants, the vaccine is

recommended only for infants at high risk; there is no universal recommendation for infants to receive meningococcal vaccine.



Oregon Acute and Communicable Disease Program, 2010, 2015.

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

In an article by Ortega-Sanchez et. al., comparing cost-effectiveness studies of vaccines recommended for adolescents, meningococcal vaccines (one dose) were the least cost-effective of all adolescent vaccines. Estimated costs for routine vaccination with MCV4 starting at 11 years of age were $121,000-205,000 per life-year saved (LYS) and $88,000-179,000 per quality-adjusted life year (QALY). For college freshmen living in dormitories, one study estimated the cost of vaccinating with MPSV4 to be $306,000 per LYS (no QALY estimate was provided). The estimated cost of vaccinating with MCV4 compared with MPSV4 would be expected to be lower because of the longer duration of immunity conferred.

At the October 2010 ACIP meeting, mean estimates for QALY saved were revised, as follows, given new information about waning of antibody titers in the years following vaccination: $281,000 for one dose of meningococcal vaccine given at 11 years of age,

$121,000 for one dose given at 15 years of age, and $157,000 for two doses given at 11 and 16 years of age. Caveat: the cost-effectiveness data are based on assumptions lacking biological plausibility, specifically that vaccine effectiveness holds steady at 93% for five years and then wanes to zero immediately at 5 years.

Ismael R. Ortega-Sanchez, Grace M. Lee, R. Jake Jacobs, Lisa A. Prosser, Noelle-Angelique Molinari, Xinzhi Zhang, William B. Baine, Mary M. McCauley, Ted Miller for the Working Group on Leading Economic Issues for New Vaccine for Adolescents. Projected Cost-effectiveness of New Vaccines for Adolescents in the United States. *Pediatrics*, Jan 2008; 121: S63 - S78.
Available at http://pediatrics.aappublications.org/cgi/content/abstract/121/Supplement_1/S63?eaf

CDC. Cost-Effectiveness of Meningococcal Vaccination Strategies for Adolescents in the United States. Presentation at ACIP, October 27, 2010.
Available at http://www.cdc.gov/vaccines/recs/acip/downloads/mtg-slides-oct10/02-3-mening-CostEffect.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.**

Nationally, incidence of invasive meningococcal disease has been decreasing since 1996. The vaccine is estimated to be 80-90% effective against the serogroups contained in the vaccine for at least three years. A second dose of quadrivalent meningococcal vaccine is now recommended for all adolescent 16-18 years of age because of waning immunity after the first dose.

CDC. Summary of Notifiable Diseases --- United States, 2007. *MMWR*. July 9, 2009: 56(53);1-94.
Available at http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5653a1.htm

CDC. Estimate of Effectiveness of Meningococcal Conjugate Vaccine (MCV4). Presentation at ACIP, June 24, 2009.
Available at http://www.cdc.gov/vaccines/recs/acip/downloads/mtg-slides-jun09/07-3-menin.pdf

CDC. Prevention and Control of Meningococcal Disease: Recommendations of the Advisory Committee on Immunization Practices (ACIP). *MMWR*. March 22, 2013 / 62(RR02);1-22.
Available at http://www.cdc.gov/mmwr/preview/mmwrhtml/rr6202a1.htm

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.**

Meningococcal disease can refer to any illness that is caused by the type of bacteria called *Neisseria meningitidis*, also known as meningococcus. These illnesses are often severe and include infections of the lining of the brain and spinal cord (meningitis) and bloodstream infections (bacteremia or septicemia). Meningococcus bacteria are spread through the exchange of respiratory and throat secretions like spit (e.g., by living in close quarters, kissing).

The communicability of meningococcal disease is generally limited. Recognized environments increasing the risk of meningitis include college freshmen living in dorms and household contacts of persons with meningococcal disease. According to CDC, "In studies of households in which a case of meningococcal disease has occurred, only 3%–4% of households had secondary cases. Most households had only one secondary case. Estimates of the risk of secondary transmission are generally 2–4 cases per 1,000 household members at risk. However, this risk is 500–800 times that in the general population." For this reason, antibiotics are routinely given to household members of persons with meningococcal disease, so as to eradicate the organisms before they can cause invasive disease.

CDC Meningococcal Disease website, accessed 9/16/2015.
Available at http://www.cdc.gov/meningococcal/index.html

CDC. *Epidemiology and Prevention of Vaccine-Preventable Diseases*, 13th Edition, pages 231-245.
Available at http://www.cdc.gov/vaccines/Pubs/pinkbook/downloads/mening.pdf

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.**

Requiring the vaccine would have a significant impact on vaccine coverage for adolescents. As of May 2015, 70.3% of adolescents ages 13-17 had at least one dose of MCV4; 49.5% were up-to-date with the recommended number of doses (1 or 2)

based on age and previous vaccination history. National Immunization Survey – Teen 2014 estimates one dose MCV4 coverage for 13-17 year olds in Oregon at 68.4% (±6.0) compared to 79.3% (±1.1) for the U.S.

Oregon ALERT Immunization Information System, 2015.

CDC. National, Regional, State, and Selected Local Area Vaccination Coverage Among Adolescents Aged 13–17 Years — United States, 2014. *MMWR*. July 31, 2015 / 64(29);784-792

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

   Uptake of MCV4 has increased in the Oregon Sentinel Region in 13-17 year olds from 41.5% in 2010 quarter 4 to 76% in 2015 quarter 1. (The Oregon Sentinel Region consists of six contiguous counties in the Upper Willamette Valley: Clackamas, Marion, Multnomah, Polk, Washington and Yamhill.)

   4th Quarter Sentinel Report, 2010. Oregon Immunization Program
   1st Quarter Sentinel Report, 2015. Oregon Immunization Program

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 cost projections for the next fiscal cycle, the costs for providing MCV4 would be about $1.2 million dollars for one school-aged cohort per year for a requirement for only one dose of vaccine. A single dose of vaccine current costs the state $83. For two doses of vaccine or for college students, no estimate has been prepared. Factors that would need to be considered in making an estimation would include the number of first year college students living in residential housing, the uptake of vaccine in first year college students, the proportion with insurance covering MCV4, the number of students coming from other states and the number of freshmen over 18 years of age as these

students would not be eligible for the VFC program. Currently, the booster dose of the vaccine is not covered under 317 funding in Oregon for healthy adolescents unless they are in a specified high risk group.

317 Funded Vaccine—Effective October 1, 2015. Oregon Health Authority, Public Health Division, Immunization Program.

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

There is a stable and adequate supply of vaccine at this time. Menactra (sanofi pasteur) was licensed in 2005, and a second quadrivalent meningococcal conjugate vaccine, Menveo (Novartis) was licensed in 2010. A combination vaccine with Hib (Menhibrix) was licensed in 2012. Menhibrix is recommended only for high risk children from 2 through 18 months of age.

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 used by schools, child care programs and local health authorities for data collection and reporting are not currently designed to accept meningococcal vaccines, so programming changes would be extensive. Exclusion orders and Certificate of Immunization Status forms would 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. Oregon law prohibits local health departments from charging parents or students a fee for the vaccine or administration if they are financially unable to pay, and this has a financial impact on the counties. Adding more vaccines when still phasing in other vaccines can then lead confusion and frustration that can potentially overwhelm the partners in the process which may weaken the effectiveness of school law enforcement. The phasing in of Hepatitis A for students in grades PreK - 12 will not be complete until the year 2021.

At this time, measles is the only state-mandated vaccine for college students. Many colleges do not have an electronic method for tracking and enforcement of immunization requirements, so the process is time intensive. Additional requirements at the college level would require more staff time. A requirement only for first year

students living in dormitories, sororities, fraternities and apartment complexes could pose additional tracking difficulties for colleges.

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

    For adolescents, MCV4 can be administered with other recommended immunizations, including Tdap. Tdap is currently required for 7th grade students, so one additional clinic visit would be necessary to receive the second dose of vaccine if a two-dose requirement was implemented. 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 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.

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

    Meningococcal quadrivalent vaccine doses are documented for all ages submitted to ALERT and forecast for 11 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?