

**Summary of Public Comments and Departments' Responses
& List of Changes Made to the Provisional Major Substantive Rule Adoption**

IMMUNIZATION REQUIREMENTS FOR SCHOOL CHILDREN

On March 1, 2017, the Department of Health and Human Services (DHHS), Maine Center for Disease Control and Prevention and the Maine Department of Education (DOE) published with the Secretary of State a major substantive rule proposal for the joint rule: Immunization Requirements for School Children, 10-144 C.M.R., Chapter 261 (DHHS) and 05-071 C.M.R., Chapter 126 (DOE). The agencies set a comment deadline of March 21, 2017. The agencies republished notice of this rulemaking proposal with the Secretary of State on April 5, 2017, so as to conduct a public hearing as required under 5 M.R.S. § 8052(1) on April 25, 2017. The republished notice set a new comment deadline of May 5, 2017. The Summary of Comments below includes the agencies' responses to: (1) written comments received between the original March 1 publication and March 21 comment deadline (note: the agencies confirmed with commenters their intention to have these comments considered given the republication); (2) written comments received between the April 5 republication and May 5 comment deadline; and (3) oral testimony received at the April 25 public hearing.

TABLE OF COMMENTERS

ID #	Commenter	Date Received and Format
1	Lynn Bozof, President, National Meningitis Association	3/5/2017 (written)
2	Peter P. Michaud, J.D., R.N., Chair, Maine Immunization Coalition (original written submission via Caroline Zimmerman, Director of Grant Development, Maine Primary Care Association)	3/20/17 (written) and 4/25/17 (oral & written)
3	Cassandra Cote Grantham, MA, Director, Child Health and Raising Readers, Community Health Improvement, MaineHealth	4/7/2017 (written)
4	Jeri Brooks Greenwell, M.O.M.s, National Meningitis Association	4/24/17 (written) and 4/25/17 (oral & written)
5	Tanisha Carino, Vice President, U.S. Public Policy, GlaxoSmithKline (via Paul Graml, Rph, MBA, Director, State Government Relations, Northeast Region, GlaxoSmithKline)	4/19/17 (written)
6	Elizabeth M. Frazier and Andrea Cianchette Maker, Pierce Atwood LLP, Counsel for Sanofi Pasteur S.A.	3/20/17 (written), 4/25/17 (oral & written), and 5/4/17 (written)
7	Andrew Antrobus, Senior Director, US Government Relations, Pfizer Inc. (via Michele MacLean, Capitol Strategies)	5/4/2017 (written)
8	Abigail Rogers, Director, Advocacy and Government Affairs, March of Dimes Northeast	5/5/2017 (written)

Commenters' written and oral comments have been summarized and are included below. The joint responses of DHHS and DOE follow each summary and explain whether the suggestions (if any) were incorporated by the Departments in the provisional rule adoption. The list of changes following the summary of comments and responses identifies additional changes resulting from further review by the Departments and the Office of the Attorney General.

GENERAL COMMENTS

- 1. Comment:** All Commenters expressed support for the addition of meningococcal meningitis to the list of diseases requiring immunization under this rule. Commenters **3, 4, 5,** and **7** also provided statistics on meningococcal disease and vaccination rates, and noted the effect the rule changes would have in boosting childhood immunizations. Additionally, Commenters **1** and **4** shared personal stories in support of the rule changes.

Response: DHHS and DOE thank the Commenters for these remarks. No specific changes are being made to the joint rule adoption as a result of these comments.

- 2. Comment:** Commenter **4** and **7** recommend the Departments include a requirement in the rule to educate parents and caregivers on meningococcal disease and all meningococcal vaccines recommended by the Advisory Committee on Immunization Practices (ACIP) before a student enters 12th grade. Specifically, the Commenters recommend the Departments create materials to communicate with parents and caregivers on: (1) meningococcal disease (severity, serotypes, symptoms, risks, and treatment); (2) availability, benefits, risks, and limitations of all meningococcal vaccines recommended by the ACIP; and (3) a recommendation that students receive meningococcal vaccines in accordance with the ACIP guidelines.

Response: The Departments make no changes to the joint rule based on this comment because current practices already provide the information referenced by the Commenter. For example, DHHS provides materials, by request and at no cost, to provider offices enrolled with the Immunization Program and to school nurses. Information related to the immunization program, vaccine safety, immunization rates and resources for parents and providers is also available on DHHS's website at <http://www.maine.gov/dhhs/mecdc/infectious-disease/immunization/>. Additionally, regional annual trainings conducted by DHHS include discussion and education about changes implemented by the U.S. Centers for Disease Control and Prevention and requirements necessary to comply with the ACIP recommendations. DHHS will continue to provide updated information about immunizations, including meningococcal vaccines on the Maine CDC website and at trainings, as appropriate.

- 3. Comment:** Commenters **2, 3,** and **4** recommend clarifying language in the joint rule in Sections 3 and 5 to specify "quadrivalent meningococcal conjugate vaccine" to align with terminology used by the Advisory Committee on Immunization Practices (ACIP).

Response: DHHS and DOE have reviewed ACIP guidelines and agree with this recommended change. In Sections 3 and 5 of the joint provisional rule adoption, the agencies have replaced the term "Meningococcal vaccine" found in the rule proposal with the term "Quadrivalent meningococcal conjugate vaccine." This change in language is necessary to specify that the required vaccine is for the protection against serogroups A, C, W, and Y. DHHS and DOE have also incorporated the abbreviation MCV4 (also known as MenACWY) into the rule for further clarification.

SECTION 1

- 4. Comment:** Commenter **2** notes that, per the U.S. CDC, having "meningitis" does not necessarily equate with having "meningococcal disease" and vice versa. The Commenter recommends changing the definition of "Disease" by replacing the term "meningitis" with the term "meningococcal disease."

Response: DHHS and DOE are in agreement with this recommended change and have updated the definition of “Disease” in Section 1 to include meningococcal meningitis.

SECTION 5

- 5. Comment:** Commenters **2, 3, and 4** requests a correction be made to the typographic error in the spelling of “meningoccal”.

Response: The Department is in agreement and has corrected this error.

- 6. Comment:** Commenters **1, 2, 3, 4, 5, and 6** request adding language to be in line with the U.S. Center for Disease Control and Prevention (U.S. CDC) and the Advisory Committee on Immunization Practices (ACIP) recommendation of receiving an additional dose of meningococcal vaccine at age 16 prior to entering into grade 12.

Response: DHHS and DOE have reviewed current U.S. CDC and ACIP recommendations. The agencies agree with the recommendation of the Commenters to require a booster prior to entering into grade 12. The joint rules have been amended to require that, beginning with the 2018 school year: “Any child entering 12th grade is required to receive two doses of MCV4. The first dose shall have been received on or after the 11th birthday, and the second dose shall have been received on or after the 16th birthday, at least eight weeks after the first dose. If the first dose is administered when the child is 16 years of age or older, only one dose is required.”

LIST OF ADDITIONAL CHANGES RESULTING FROM FURTHER DEPARTMENTAL & OFFICE OF THE ATTORNEY GENERAL REVIEW:

SECTION 3. EXCEPTIONS

- For clarity, the joint rule has been amended to spell in words some of the numbers referenced in Section 3(B), Pertussis vaccine.

SECTION 5. IMMUNIZATION DOSAGE

- For clarity, the joint rule has been amended to spell in words some of the numbers referenced in Section 5 immunization schedules for: Diphtheria/Tetanus/Pertussis (DTP), Td, Tetanus/Diphtheria/Pertussis (Tdap), Measles/Mumps/Rubella (MMR), Poliomyelitis, and Four doses of inactivated polio vaccine (IPV).
- In addition to updating the immunization dosage for quadrivalent meningococcal conjugate vaccine in response to public comments (see above), the Departments are amending the joint rule for this vaccination to become effective for the start of school year 2018 instead of school year 2017 as originally noted in the April 5, 2017, republished rule proposal. The basis for this change is because this joint rulemaking is major substantive pursuant to 20-A M.R.S. § 6358 and will not be ready for final adoption in advance of the 2017 school year.

SECTION 6. EXCLUSION FROM SCHOOL

- For clarity, the joint rule has been amended to replace “10” with “ten” in Section 6(C).