RULEMAKING REPORT TO LEGISLATURE

CLEARINGHOUSE RULE 19-079

Ch. DHS 144

Basis and Purpose of Proposed Rule

The department is required to carry out a statewide immunization program to eliminate mumps, measles, rubella (German measles), diphtheria, pertussis (whooping cough), poliomyelitis and other diseases that the department specifies by rule, and to protect against tetanus. Minimum immunization requirements for entry into Wisconsin schools and child care centers are established in ch. DHS 144. The department proposes to make the following revisions to the rule chapter:

1. Varicella (chicken pox) and meningococcal disease are identified by the department as vaccine-preventable diseases. However, a substantial outbreak of these diseases is not currently defined in ch. DHS 144. The department proposes to amend the definition of a “substantial outbreak” to include Varicella (chicken pox) and meningococcal disease, and to ensure consistency with CDC recommendations.

2. In recent years, mumps outbreaks have occurred in highly-vaccinated populations and in high-transmission settings, including elementary, middle, and high schools, colleges, and camps. A substantial outbreak of mumps is currently defined as an incidence of the disease exceeding 2% of the unvaccinated population. In 2012, the CDC revised the Manual for the Surveillance of Vaccine-Preventable Diseases, to define a substantial outbreak of mumps as three or more cases linked by time and place. The department proposes to amend the definition of a “substantial outbreak” of mumps to be consistent with the CDC Manual for the Surveillance of Vaccine-Preventable Diseases.

3. The department is proposing to move the current recommendation for Tdap from 6th grade to 7th grade to ensure that children are old enough to meet this age minimum (some children are 10 years old when starting 6th grade). This will reduce the number of children who enter 6th grade and are not vaccinated for Tdap, as some clinicians choose to wait until they are 11 years of age to vaccinate.

4. Neisseria meningitidis is a vaccine-preventable disease and a leading cause of bacterial meningitis and sepsis in the United States. The meningococcal vaccine is recommended by the Wisconsin Chapter of the American Academy of Pediatrics and the Wisconsin Academy of Family Physicians to reduce the incidence of bacterial meningitis and sepsis. Since 2005, the CDC Advisory Committee on Immunization Practices has recommended that the vaccine be administered at the 11-12 year old health care visit, along with other routine vaccinations such as Tdap. The department proposes to add the meningococcal vaccine to the list of vaccines required for students entering the 7th grade. This provision will ease the burden on families, providers, and schools by ensuring that both meningococcal and Tdap vaccines are receivedat the same visit and the same grade level. The department also proposes a booster dose for students entering 12th grade which is in accordance with ACIP recommendations. This will help to ensure students are fully vaccinated prior to leaving school.

5. Under the current rule, a parent or adult student may report a history of varicella disease as an acceptable exception to varicella vaccination. Recent studies have demonstrated that there is a high incidence of unvaccinated children who report a positive history of varicella that are not immune. The department proposes to allow the exception only when a history of varicella disease has been reported by a health care provider.

6. Chapter DHS 144 currently includes provisions relating to the 2008-2009 phase-in of Tdap and Varicella Vaccine coverage. The department proposes to eliminate these provisions because phase-ins are completed.

7. Curently, schools must only report compliance with program requirements and key indicators of vaccine-preventable disease and outbreaks to local health departments. The department proposes to add the state as a recipient of these reports which would be congruent with the current day care reporting requirements. This will improve the availability of important information and improve the department’s reporting to the legislature, under s. 252.04 (11), Stats..

8. Chapter DHS 144 has not been substantially revised since 1981. The department proposes to update, correct, or clarify any outdated provisions in order to reflect current definitions, standards, and best practices.

Department Response to Legislative Council Rules Clearinghouse Recommendations

All recommendations were accepted.

Final Regulatory Flexibility Analysis

The issues raised by each small business during the public hearing(s).

N/A

Any changes in the rule as a result of an alternative suggested by a small business and the reasons for rejecting any of those alternatives.

N/A

The nature of any reports and estimated cost of their preparation by small businesses that must comply with the rule.

N/A

The nature and estimated costs of other measures and investments that will be required by small businesses in complying with the rule.

N/A

The reason for including or not including in the proposed rule any of the following methods for reducing the rule's impact on small businesses, including additional cost, if any, to the department for administering or enforcing a rule which includes methods for reducing the rule's impact on small businesses and the impact on public health, safety and welfare, if any, caused by including methods in rules

N/A

Changes to the Analysis or Fiscal Estimate/Economic Impact Analysis

Analysis

N/A

Fiscal Estimate/Economic Impact Analysis

N/A

Public Hearing Summary

The department began accepting public comments on the proposed rule via the Wisconsin Legislature Administrative Rules website, and through the Department's Administrative Rules Website on July 15, 2019. A public hearing was held on July 26, 2019, in Madison, Wisconsin. Public comments on the proposed rule were accepted until July 26, 2019.

List of the persons who appeared or registered for or against the Proposed Rule at the Public Hearing.

Registrant	Position Taken (Support or Opposed)
Kevin Tuttle- Sun Prairie, WI	Opposed
Kari Pagel- Oconto, WI	Opposed
Donna Knutter	Supported
Erika Shaff-Bow	Opposed
Sarah Hardison	Opposed
Marty Young	Supported
Tara	Opposed
Jamie Bernander	Opposed
Denise Brusveen	Opposed
HJ Waukan with the WI Medical Society	Supported
Ann Lewandowski	Supported
Sarah Biskobing	Opposed
Justin Ziacore	Opposed
Andrea Wahhab	Opposed
Alesha Cowen	Opposed
Amber Psket	Opposed
Steve Puckette	Opposed
Judith Jolly- Pardiville, WI 53954	Opposed
Amy Heffernan	Opposed
Nathan Jackson	Opposed
Erin Runk	Opposed
Wade Anunson	Opposed
Dilson Bucl	Opposed
Lona Cook	Neither
Robin Baker	Neither
Lisa J. Barnett	Opposed
Shelby Lemke	Neither
Sarah Hillman	Neither
Arlis Fadt	Neither
Carl Landsness	Neither
Malanie Strauch	Opposed
Janel Retzlaft- Combined Locks, WI	Neither
Ruth Mueller	Supported
Colleen Marie Morhen	Neither

Elizabeth McLean	Opposed
Louise Wilson	Neither
Kelsey Anderson- University Health Services	Neither
Rebecca Lenz- University Health Service	Neither
Melanie Fritz	Opposed
Sarah Hughes	Supported
Steven Conway	Opposed
Amanda Haines	Opposed
Derek Ellerman- Office of State Rep. Shae Sortwell	Opposed

Summary of Public Comments to the Proposed Rule and the Agency's response to those comments, and an explanation of any modification made in the proposed rule as a result of public comments or testimony received at the Public Hearing.

Rule Provision	Public Comment	Department Response
	Overall, 460 individuals or entities provided comments. Many comments had more than one issue or concern, and for the purposes of the Department response, each concern was counted in the appropriate category below. Therefore, the number of comments do not add up to the total number of individuals /entities who provided a comment.	
144.01 (1)	DHS received 12 comments stating the proposed changes would benefit/protect the health and well-being of all our school-age children. These changes are essential for prevention. Generally speaking, these changes are good.	This is in alignment with the proposed rule changes.
144.02 (21) (i); 144.03-A; 144.03 (2) (k)	DHS received 11 comments stating that adding Meningococcal vaccines to the list of school requirements will help reduce/eliminate meningitis and its symptoms such as: hearing loss, amputations, kidney damage, and memory loss and death.	This is in alignment with the proposed rule change.
144.03 (20) (b) 144.03-A	DHS received 8 comments stating that moving Tdap requirements to the 7th grade will help families of children who don't become 11 until 5th or 6th grade. Also, this change will reduce confusion and conflict between families, schools, and providers on when to administer Tdap.	Because some students entering 6th grade are not yet age 11, some schools and students have had difficulty meeting this requirement and have had to be vaccinated at age 10 or sign a waiver. This results in additional work for the school, student, and parents. To ensure that children are 11 years old to meet this age minimum, we are proposing changing the requirement to 7th grade. This will ease the burden on the schools, students and parents and will be consistent with the Meningococcal vaccination requirement at grade 7.
144.03	DHS received 1 comment stating that currently, families receive non-compliance letters from schools when the provider won't vaccinate based on the CDC recommendations. Updating the polio rule in accordance with CDC recommendations will reduce frustration and confusion among families.	The proposed changes align with current CDC recommendations and should reduce the confusion about the requirement.
144.02 (21) (h) 144.03 (20) (g)	DHS received 2 comments stating that client's varicella histories being recorded by a medical provider will help with medical record accuracy and consistency	This is in alignment with our proposed change as well as with ACIP recommendations for evidence of immunity to varicella.

144.04 144.05	DHS received 6 comments stating that immunizations should be mandatory except for medical exemptions. Doing so protects the public and immunocompromised individuals. Other exemptions are not supported by science and should not be allowed.	The proposed changes do not include changes to the types of waivers currently allowed.
general	DHS received 2 comments stating that school immunization requirements are known to improve immunization rates.	Per CDC, state and local vaccination requirements for daycare and school entry are important tools for maintaining high vaccination coverage rates, and in turn, lower rates of vaccine-preventable diseases (VPDs).
general	DHS received 5 comments expressing appreciation of updates to the rule's language and definitions. These changes better reflect current public health practices and national guidelines. One respondent recommended DHS review and modernize these rules every 5 years, at least.	Even with the proposed changes, Wisconsin's school requirements are less than the vaccination requirements by ACIP, for example, HPV vaccine. The proposed changes will improve alignments with ACIP recommendations.
general	DHS received 4 comments stating the proposed rule changes would help attenuate the reemergence of vaccine preventable diseases. Sources of vaccine misinformation have reduced vaccination rates, contributing to a reduction in herd immunity and a rise in vaccine preventable diseases.	CDC states there is evidence to suggest that vaccine requirements have broad reach and they may help promote higher rates of vaccination coverage.
general	DHS received 4 comments stating meningococcal vaccination is recommended because of the severity of meningitis, not the rate of meningitis.	According to the CDC, "meningococcal disease can be devastating and often—and unexpectedly—strikes otherwise healthy people. Although meningococcal disease is uncommon, teens and young adults 16 through 23 years old are at increased risk. Meningococcal bacteria can cause severe, even deadly, infections like Meningitis (an infection of the lining of the brain and spinal cord), Bacteremia, or septicemia (bloodstream infections). About 1 in 5 people who survive their meningococcal infection have permanent disabilities. Reference Meningococcal Vaccination for Preteens and Teens: Information for Parents | CDC. (n.d.). Retrieved from https://www.cdc.gov/vaccines/vpd/mening/public/adolescent-vaccine.html
general	DHS received 1 comment stating these rule changes are appreciated because they will help prevent against expensive vaccine preventable diseases. Taxpayers do not want to pay for the healthcare costs associated with these diseases.	The *Journal of Market Access & Health Policy* published seven articles discussing how vaccines are economically beneficial. These articles show the overall benefits of vaccination on economic growth, sustainability, and efficiency of healthcare systems.

		Reference Pasteur, S. (2015). The Economic Value of Vaccination: Why Prevention is Wealth. *Journal of Market Access & Health Policy*, *3*(0). doi: 10.3402/jmahp.v3.29414
general	DHS received 1 comment stating politicians should support these rule changes because if a Wisconsin resident dies from a vaccine preventable disease, it will look bad for politicians who did not pass these rule changes.	The Department acknowledges this comment.
144.02 (2)	DHS received 1 comment stating that changing the word daycare to childcare is appreciated.	Early childhood professionals agree the term childcare is important, as not all parents work during the day and the term childcare is more inclusive than daycare. Childcare as a term better reflects the values and mission of the field, as supported by the National Association for the Education of Young Children. Reference Childcare vs. Daycare: What's the Difference? (And Why It Matters). (n.d.). Retrieved from https://www.rasmussen.edu/degrees/education/blog/childcare-vs-daycare/
general	DHS received 1 comment expressing support for surveillance of diseases for epidemiological purposes.	This is in alignment with the Division of Public Health, Bureau of Communicable Diseases responsibilities.
N/A	DHS received 1 comment stating vaccine requirements cannot prohibit accessing public education because education is a public right that is critical to health. If access to education is contingent on vaccinations, vaccines must be affordable and accessible.	The rule outlines the requirements for compliance with the school entry laws. As long as a child is compliant, they may attend school. Compliance entails one of the following: 1- being fully immunized, 2- has received the first dose of each series and is in the process of receiving subsequent doses or 3-has a valid waiver on file. The Affordable Care Act requires new health plans to cover preventative services, such as routinely recommended vaccines, and eliminates cost sharing (such as co-pays and deductibles). Therefore children with private insurance should have access to vaccines without significant cost barriers. For children who do not have health insurance, or are part of a select number of older and more limited plans not covered by the ACA, other mechanisms are in place to ensure access. For example, the Vaccines For Children (VFC) program. VFC is a federally funded program that provides vaccines at no cost to children who might not otherwise be vaccinated because of inability to pay.

		The State of Wisconsin's VFC program has approximately 730 health care providers, including local health departments and tribal clinics that are registered in the program throughout the state.
144.02 (21) (i); 144.03-A; 144.03 (2) (k)	DHS received 202 comments stating the meningococcal vaccination requirement update is unwarranted because there is no urgent public health crisis (i.e., meningitis is rare and/or not very contagious).	The proposed rule aligns with national recommendations. CDC's Advisory Committee on Immunization (ACIP) recommends meningococcal vaccination for all preteens and teens in the prevention of meningococcal disease. The first dose is recommended at 11-12 years of age and the booster at age 16 years. *Neisseria meningitidis* is a vaccine-preventable disease and a leading cause of bacterial meningitis and sepsis in the United States. The disease strikes quickly and can have serious complications, including death. Among survivors, as many as one in five will have permanent disabilities. Complications include hearing loss, brain damage, kidney damage, and limb amputations. Since 2005, the CDC Advisory Committee on Immunization Practices has recommended that the vaccine be routinely administered to all preteens at the 11-12 year old health care visit, along with other routine vaccinations such as Tdap. The meningococcal vaccine is also recommended by the American Academy of Pediatrics and American Academy of Family Physicians to reduce the incidence of bacterial meningitis. Rates of meningococcal disease have been declining in the United States since the late 1990s. In 2017, there were about 350 total cases of meningococcal disease reported. Anyone can get meningococcal disease, but rates of disease are highest in children younger than 1 year old, followed by a second peak in adolescence. Among adolescents and young adults, those 16 through 23 years old have the highest rates of meningococcal disease. Meningococcal disease spreads from person-to-person by coughing or coming into close or lengthy contact with someone who carries the bacteria. Up to one in 10 people carry meningococcal bacteria in their nose or throat without getting sick. Per AAP's Red Book, meningococcal disease remains as an important cause of septicemia in children 11 through 17 years of age. Household contacts of cases have 500 to 800 times the rate of disease for the general population. Per CDC data, Serogroups C, Y, or W, which are covered by meningococcal conjugate

		vaccines, included in the proposed changes, caused approximately two in three cases of meningococcal disease among persons 11 years old or older from 2007 to 2017. However, in 2017, serogroups C, Y, or W caused approximately 1 in 2 cases of meningococcal disease among persons 11 years old or older in the United States. Despite declines in the incidence of meningococcal disease in the United States, outbreaks continue to occur. An article published in Clinical Infectious Diseases in June 2018 found that outbreak-associated cases account for approximately 5% of all meningococcal disease cases in the United States and serogroup C is the primary cause of community-based outbreaks. References Prevention and Control of Meningococcal Disease: Recommendations of the Advisory Committee on Immunization Practices (ACIP). (2013). *Prevention and Control of Meningococcal Disease: Recommendations of the Advisory Committee on Immunization Practices (ACIP).*, 1–22. Mbaeyi, S. A., Blain, A., Whaley, M. J., Wang, X., Cohn, A. C., & Macneil, J. R. (2018). Epidemiology of Meningococcal Disease Outbreaks in the United States, 2009–2013. *Clinical Infectious Diseases*, *68*(4), 580–585. doi: 10.1093/cid/ciy548 Kimberlin D.W., Brady M.T., Jackson M. A., Long S. Sl, eds. *Red Book:2018 Report of the Committee on Infectious Diseases.* 31st ed. Itasca, IL: American Academy of Pediatrics, 2018: Meningococcal 550-561.
144.02 (21) (i); 144.03-A; 144.03 (2) (k)	DHS received 183 comments stating the meningococcal vaccination requirement update is unwarranted because meningococcal vaccine is dangerous (e.g., contains neurotoxins; causes side effects, adverse events, and deaths). Meningococcal vaccine taken in combination with other vaccines is unsafe.	Evidence shows that meningococcal vaccines are safe and as with any vaccine, side effects can occur. The most common side effects include redness and swelling at the injection site. There have been no documented deaths that have a direct correlation after meningococcal vaccination. The FDA has licensed two meningococcal vaccines for use in the United States, MenACWY-D (Menactra, Sanofi Pasteur), and MenACWY-CRM (Menveo, Novartis Vaccines). CDC's Pink Book lists the ingredients for every vaccine. Aside from the antigens, ingredient components of a vaccine include adjuvants, added to enhance the immune system

		response; antibiotics, to prevent contamination during the manufacturing process; and preservatives and stabilizers. Per the FDA, prior to approval, vaccines undergo a rigorous and extensive development program in the laboratory, as well as in animal studies and human clinical trials to determine their safety and effectiveness. Highly trained FDA scientists and clinicians carefully evaluate all of the information in a marketing application and make a determination whether to license (approve) a vaccine before it can be used in the United States. Prior to licensure, as part of FDA's evaluation, FDA takes all of the ingredients of a vaccine into account, including the active ingredients as well as other substances. The benefit-risk profile of each vaccine is assessed constantly during the entire duration of its use. After licensure, adverse events are submitted to the Vaccine Adverse Events Reporting System (VAERS) by parents, healthcare providers, and regulatory authorities. VAERS is maintained jointly by CDC and FDA. Per an article in *Seminars in Pediatric Infectious Diseases*, allegations that administration of multiple vaccines can impair the immune system have been found not to be supported by scientific evidence. Per the Immunization Action Coalition, CDC experts state, "All vaccines can be administered at the same visit. There is no upper limit for the number of vaccines that can be administered during one visit. ACIP and AAP consistently recommend that all needed vaccines be administered during an office visit. Vaccination should not be deferred because multiple vaccines are needed." References Centers for Disease Control and Prevention. *Epidemiology and Prevention of Vaccine-Preventable Diseases*. Hamborsky J, Kroger A, Wolfe S, eds. 13th ed. Washington D.C. Public Health Foundation, 2015. Kimberlin D.W., Brady M.T., Jackson M. A., Long S. Sl, eds. *Red Book:2018 Report of the Committee on Infectious Diseases.* 31st ed. Itasca, IL: American Academy of Pediatrics, 2018: Meningococcal 550-561. Halsey, N. A. (2002). The science of evaluation of adverse events associated with vaccination.

		Seminars in Pediatric Infectious Diseases, *13*(3), 205–214. doi: 10.1053/spid.2002.125864 Ask the Experts. (n.d.). Retrieved from https://www.immunize.org/askexperts/administering-vaccines.asp
144.02 (21) (i); 144.03-A; 144.03 (2) (k)	DHS received 24 comments stating the meningococcal vaccination requirement update is unwarranted because meningococcal vaccine is expensive.	Under the Affordable Care Act (ACA), all commercial payers programs are to provide coverage of ACIP-routinely recommended vaccines and this includes meningococcal vaccine. Additionally, children who are not insured are eligible to receive the vaccine free of charge through the Vaccines for Children program (see above for a complete description of the program). References Office of Adolescent Health. (2019, August 6). Where and How to Get Vaccines. Retrieved from https://www.hhs.gov/ash/oah/adolescent-development/physical-health-and-nutrition/vaccines/where-and-how-to-get-vaccines/index.html Sanchez, I. R. O., Meltzer, M. I., Shepard, C., Zell, E., Messonnier, M. L., Bilukha, O., Messonnier, N. E. (2008). Economics of an Adolescent Meningococcal Conjugate Vaccination Catch-up Campaign in the United States. *Clinical Infectious Diseases*, *46*(1), 1–13. doi: 10.1086/524041
144.02 (21) (i); 144.03-A; 144.03 (2) (k)	DHS received 40 comments stating the meningococcal vaccination requirement update is unwarranted because meningococcal vaccine is available to anyone who wants it.	Under Wisconsin Statute Chapter 252.04 (1), “The department shall carry out a statewide immunization program to eliminate mumps, measles, rubella (German measles), diphtheria, pertussis (whooping cough), poliomyelitis and other diseases that the department specifies by rule, and to protect against tetanus.” School requirements have been shown to be an effective way of increasing immunization rates, and thereby protection of individuals from vaccine-preventable diseases. Per CDC, state school requirements help to promote higher rates of vaccination which equates to lower rates of vaccine preventable disease. The percent of Wisconsin adolescents aged 13-18 years who have received one dose of meningococcal vaccine in 2018 was 72.03% and the percent of adolescents who were up-to-date was 46.02%. Wisconsin is below the Healthy People 2020 goal of 80.0% for adolescents who have received one dose of meningococcal vaccine.

		References State Vaccination Requirements | CDC. (n.d.). Retrieved from https://www.cdc.gov/vaccines/imz-managers/laws/state-reqs.html Immunization and Infectious Diseases. (n.d.). Retrieved from https://www.healthypeople.gov/2020/topics-objectives/topic/immunization-and-infectious-diseases/objectives
144.02 (21) (i); 144.03-A; 144.03 (2) (k)	DHS received 146 comments stating the meningococcal vaccination requirement update is unwarranted because the meningococcal vaccine is ineffective.	Per CDC, since 2005 when the recommendation was made from ACIP for adolescents to receive a meningococcal vaccine, the incidence of meningococcal disease in adolescents has decreased by over 90%. Per an article in *Pediatrics*, meningococcal vaccines were 79% effective in the initial year postvaccination, 69% at 1 to less than 3 years, and 61% at 3 to less than 8 years. The overall effectiveness rate estimate for 0 to 8 years postvaccination was 69%. The vaccine effectiveness estimates data informed ACIP in its decision to add a booster dose at 16 years of age. References Meningococcal Vaccination | What You Should Know | CDC. (n.d.). Retrieved from https://www.cdc.gov/vaccines/vpd/mening/public/index.html#how-well-they-work Cohn, A. C., Macneil, J. R., Harrison, L. H., Lynfield, R., Reingold, A., Schaffner, W., … Messonnier, N. E. (2017). Effectiveness and Duration of Protection of One Dose of a Meningococcal Conjugate Vaccine. *Pediatrics*, *139*(2). doi: 10.1542/peds.2016-2193
144.02 (21) (h) 144.03 (20) (g)	DHS received 32 comments stating the varicella vaccination requirement update is unwarranted because there is no provision for titer confirmation.	While not stated implicitly in the proposed Administrative Rule, a titer could be ordered by a health care provider and if positive, would provide evidence of immunity, allowing the health care provider to indicate on the form that the individual had a history of disease and was immune.
144.02 (21) (h) 144.03 (20) (g)	DHS received 74 comments stating clinicians should not be required to diagnose patients with suspected varicella infections because of the risk varicella-infected individuals would pose to others at a health care facility.	Per CDC, immunity against from varicella would include any of the following criteria: • Documentation of age-appropriate chickenpox vaccination • Laboratory evidence of immunity or laboratory confirmation of disease • Birth in the United States before 1980 • Diagnosis or verification of a history of varicella by a healthcare provider

		The administrative rule change proposal does not dictate that a student be seen by a health care provider while ill with varicella. The health care provider may verify the disease with a history of symptoms or laboratory confirmation.
144.02 (21) (h) 144.03 (20) (g)	DHS received 22 comments stating the varicella vaccination requirement update is unwarranted because it would force patients and their families into an unwanted relationship with unknown health care providers.	The proposed wording does not specify which health care providers a family must use. Families are free to choose their health care provider based on their own preferences, insurance coverage, etc.
144.02 (21) (h) 144.03 (20) (g)	DHS received 54 comments stating the varicella vaccination requirement and provider verification is unwarranted because it is expensive to the parents. Costs include co-pays, laboratory fees, time off work, & transportation.	The administrative rule change proposal does not dictate that a student be seen by a health care provider while ill with varicella. The health care provider may verify the disease with a history of symptoms. In the past, the predictive value of a self-reported positive disease victory for varicella was extremely high in adults in the pre-vaccine era for their children. As disease incidence decreases and the proportion of vaccinated persons with varicella having mild cases increases, varicella will be less readily recognized clinically. A recent study demonstrated that only 75% of unvaccinated children aged 12 months through 4 years who reported a positive history of varicella were in fact immune (confirmed by serological testing), compared with 89% of children aged 5 through 9 and 10 through 14 years. To limit the number of false-positive reports and ensure immunity, ACIP recommends that evidence of immunity should be either a diagnosis of varicella by a health care provider or a health care provider verification of a history of disease rather than parental or self-reporting. Another study published in *Pediatrics,* found that after the introduction of childhood varicella immunization there was a significant reduction in varicella-related hospitalizations and thus a corresponding reduction in hospital charges. *The Journal of Infectious* Diseases reported a substantial societal cost savings with a varicella vaccination program and reduction in morbidity, hospitalization, and mortality due to varicella. References Perella, D., Fiks, A. G., Jumaan, A., Robinson, D., Gargiullo, P., Pletcher, J., … Spain, C. V. (2009). Validity of Reported Varicella History as a Marker for Varicella Zoster Virus Immunity Among Unvaccinated Children, Adolescents, and Young Adults in the Post-Vaccine Licensure Era. *Pediatrics*, *123*(5). doi: 10.1542/peds.2008-3310

		Davis, M. M. (2004). Decline in Varicella-Related Hospitalizations and Expenditures for Children and Adults After Introduction of Varicella Vaccine in the United States. *Pediatrics*, *114*(3), 786–792. doi: 10.1542/peds.2004-0012 Zhou, F., Ortega-Sanchez, I. R., Guris, D., Shefer, A., Lieu, T., & Seward, J. F. (2008). An Economic Analysis of the Universal Varicella Vaccination Program in the United States. *The Journal of Infectious Diseases*, *197*(s2). doi: 10.1086/522135

144.02 (21) (h)
144.03 (20) (g)
	DHS received 25 comments stating the varicella vaccination requirement update is unwarranted because it will create distrust between parents and school staff for reporting.	Per CDC, evidence of immunity to varicella includes any of the following:
		
		• Documentation of age-appropriate varicella vaccination
		  ○ Preschool-age children (i.e., age 12 months through 3 years): 1 dose
		  ○ School-age children, adolescents, and adults: 2 doses
		• Laboratory evidence of immunity or laboratory confirmation of disease*
		• Birth in the United States before 1980 (should not be considered evidence of immunity for healthcare personnel, pregnant women, and immunocompromised people)
		• Diagnosis or verification of a history of varicella or herpes zoster by a healthcare provider
		
		In the past, the predictive value of a self-reported positive disease victory for varicella was extremely high in adults in the pre-vaccine era for their children. As disease incidence decreases and the proportion of vaccinated persons with varicella having mild cases increases, varicella will be less readily recognized clinically.
		
		To limit the number of false-positive reports and ensure immunity, ACIP recommends that evidence of immunity should be either a diagnosis of varicella by a health care provider or a health care provider verification of a history of disease rather than parental or self-reporting.
		
		This will result in more accurate status of immunity for children within the school.
		
		References
		Chickenpox | For Healthcare Professionals | Varicella | CDC. (n.d.). Retrieved from

		https://www.cdc.gov/chickenpox/hcp/index.html#assessing-immunity Perella, D., Fiks, A. G., Jumaan, A., Robinson, D., Gargiullo, P., Pletcher, J., … Spain, C. V. (2009). Validity of Reported Varicella History as a Marker for Varicella Zoster Virus Immunity Among Unvaccinated Children, Adolescents, and Young Adults in the Post-Vaccine Licensure Era. *Pediatrics*, *123*(5). doi: 10.1542/peds.2008-3310
General	DHS received 23 comments that broadly stated (i.e., generalized to all vaccines), the Department's claim that these rule changes will have "little to no economic impact" is wrong. These changes would have a negative economic impact on families.	The Economic Impact Assessment conducted by the Department in accordance with the Department of Administration, using form DO-2049, requires assessment of the impact on the State's economy, local government units, specific businesses/sectors, public utility rate payers and small businesses. The analyses found that there would be "little to no economic impact" on all groups. The impact to families was a consideration of the Department outside this assessment. The vaccines being proposed are all routinely recommended by the Advisory Committee on Immunization Practices at the proposed ages and therefore are covered by insurance policies that provide coverage for immunizations, which is nearly all plans. Additionally, for families without insurance, or whose insurance does not cover these vaccines, they are eligible for the Vaccines for Children program, which provides vaccines to children who are uninsured, underinsured, on Medicaid, Alaskan Native or American Indian, regardless of the ability to pay through a network of approximately 730 health care providers, local public health and tribal clinics.
144.07 (4) (b)	DHS received 5 comments that broadly stated (i.e., generalized to all vaccines), DHS should modify the timeline schools use for reporting vaccination compliance to the state. For example, one respondent stated, "Schools are currently reporting vaccine compliance rates to the health department by day 40 of the school year and no follow up data is required or even submitted to the health dept. Records obtained by the schools on day 40 are not necessarily indicative of records received by Day 90, when those children considered in progress must submit updated records. If the health department would like the state to receive the reports then we would suggest that schools be required to submit the data by Day 40 and again at 120. The second submission requirement by	While requiring more than one "snapshot" of student vaccination compliance per school year would result in a more accurate assessment, it would create a significant burden on school staff to do the reporting twice in a given school year. Therefore, Wisconsin only requires information is reported once. Students whose compliance status changes will be recorded in the next school year. All states generate an annual immunization status report based on one report and this information is available on state websites and on CDC's website. References SchoolVaxView | School Vaccination Requirements and Exemptions | CDC. (n.d.).

	the state would reflect a more accurate assessment of vaccine rates within schools."	Retrieved from https://www.cdc.gov/vaccines/imz-managers/coverage/schoolvaxview/requirements/index.html
144.02 (21)	DHS received 48 comments stating the substantial outbreak classification change for mumps is unwarranted because the mumps vaccine is ineffective.	In 2012, CDCs Manual for the Surveillance of Vaccine Preventable Disease was updated. In this revision, a mumps outbreak is now defined as three or more cases linked by time and place. In recent years, mumps outbreaks have occurred in highly vaccinated populations in high transmission settings, including elementary, middle, and high schools, colleges, and camps. Especially in these setting, rapid detection and investigation of cases, and implementation of control measures may reduce the magnitude of outbreaks. The proposed changes are in alignment with the current, national guidance. Evidence shows that the MMR vaccine is very safe and effective. The mumps component of the MMR vaccine is about 88% effective when a person gets two doses and 78% effective when a person gets one dose. References Schaffzin, J. K., Pollock, L., Schulte, C., Henry, K., Dayan, G., Blog, D., & Smith, P. (2007). Effectiveness of Previous Mumps Vaccination During a Summer Camp Outbreak. *Pediatrics*, *120*(4). doi: 10.1542/peds.2006-3451 Mumps Vaccination | CDC. (n.d.). Retrieved from https://www.cdc.gov/vaccines/vpd/mumps/index.html Kimberlin D.W., Brady M.T., Jackson M. A., Long S. SI, eds. *Red Book:2018 Report of the Committee on Infectious Diseases.* 31st ed. Itasca, IL: American Academy of Pediatrics, 2018: Mumps 567-573.
144.02 (21) (h) 144.03 (20) (g)	DHS received 79 comments stating the varicella vaccination requirement update is unwarranted because varicella infection is a mild infection and treatable at home.	Varicella can be serious, even life-threatening. Severe bacterial complication of primary varicella in children, such as skin infections, thrombocytopenia, bacteremia, prolonged fever and prolonged hospitalization are risks of contracting varicella. Moreover, other serious complications of the disease include encephalitis (estimated 1.8 per 10,000 cases) which may lead to seizures and coma, and death in 1 out of 60,000 cases. ACIP recommends that healthy people who do not have evidence of immunity to varicella be vaccinated.

		References Aebi, C., Ahmed, A., & Ramilo, O. (1996). Bacterial Complications of Primary Varicella in Children. *Clinical Infectious Diseases*, *23*(4), 698–705. doi: 10.1093/clinids/23.4.698 Ziebold, C., Kries, R. von, Lang, R., Weigl, J., & Schmitt, H. J. (2001, November 1). Severe Complications of Varicella in Previously Healthy Children in Germany: A 1-Year Survey. Retrieved from https://pediatrics.aappublications.org/content/108/5/e79.short Fleisher, G. (1981). Life-Threatening Complications of Varicella. *Archives of Pediatrics & Adolescent Medicine*, *135*(10), 896. doi: 10.1001/archpedi.1981.02130340008004 Jackson, M. A., Burry, V. F., & Olson, L. C. (1992). Complications of varicella requiring hospitalization in previously healthy children. *The Pediatric Infectious Disease Journal*, *11*(6), 441–444. doi: 10.1097/00006454-199206000-00004 Centers for Disease Control and Prevention. *Epidemiology and Prevention of Vaccine-Preventable Diseases*. Hamborsky J, Kroger A, Wolfe S, eds. 13th ed. Washington D.C. Public Health Foundation, 2015.
general	DHS received 38 comments stating the DHS' public notification of these proposed rules was insufficient—that parents of school-aged children were not well notified.	The Department of Health Services followed all rule promulgation processes and requirements, including public notification. The Statement of Scope was published and available for comment for nearly two years, beginning on July 31, 2017, and was open through the close of business on July 26, 2019, the day of the public hearing. Additionally public notices for the three advisory committee meetings were done in accordance with state rules and each meeting had time in the agenda set aside specifically to receive public comment. An administrative "rule" is defined in s. 227.01 (13), Stats. The authority to create new rules, or to revise and repeal existing rules (promulgation), is delegated to the Department of Health Services (DHS) by the Wisconsin State Legislature. Rules must be promulgated according to a process established by the Legislature in ch. 227, Stats., by the Governor in various Executive Orders (link is external), and by the Courts in various precedents. DHS must obtain approval from the Governor to begin any

		project to create new rules, or to revise or repeal current administrative rules. DHS must also submit final proposed rules to the Wisconsin State Legislature for review prior to enactment. Reference Administrative Rules. (2018, November 29). Retrieved from https://www.dhs.wisconsin.gov/rules/index.htm
general	DHS received 34 comments stating that changing vaccine requirements via the rule change process bypasses legislators' role in the legal process. Legislators need to be allowed to vote on this, as they are accountable to their voting constituents.	Rules must be promulgated according to a process established by the Legislature in ch. 227, Stats. The Department of Health Services followed the outlined process. Reference Wisconsin State Legislature ch. 227, Stats. https://docs.legis.wisconsin.gov/statutes/statutes/227/I/01
general	DHS received 203 comments that broadly stated (i.e., generalized to all vaccines), these changes would infringe on parent's autonomy over care decisions for their children and general personal freedoms.	The Department is proposing adding vaccines to an already established list of required vaccines. The authority to do so is based on Wisconsin Statute section 252.04, which was created in 1975 and which has been amended many times in response to changing public health needs. Therefore, the proposed actions are not setting new precedence but rather amending long-standing requirements implemented to protect the safety and health of Wisconsin's children. Wisconsin allows for medical, religious, and personal conviction waivers and changes to waivers are not included in the proposed changes.
general	DHS received 17 comments with personal anecdotes about the adverse effects of vaccinations.	Per CDC, any vaccine can cause side effects. For the most part these are minor (for example, a sore arm or low-grade fever) and go away within a few days. Additional information regarding each vaccine is available on the CDC's Vaccine Information Statements (VISs). Vaccines are continually monitored for safety, and like any medication, vaccines can cause side effects. However, a decision not to immunize a child also involves risk and could put the child and others who come into contact with him or her at risk of contracting a potentially deadly disease. Reference Vaccine Information Statement | Home | VIS | CDC. (n.d.). Retrieved from https://www.cdc.gov/vaccines/hcp/vis/index.html

144.02 (21) (i); 144.03-A; 144.03 (2) (k)	DHS received 79 comments stating the meningococcal vaccination requirement update is unwarranted because mandating the meningococcal vaccine is not supported by valid research or data.	Wisconsin follows the recommendations of the national Advisory Committee on Immunization Practices (ACIP), which reviews relevant safety and efficacy data and provides evidence-based recommendations regarding vaccines. Per the Immunization Action Coalition, the majority of states already have meningococcal ACWY state mandates. In June 2007, ACIP recommended vaccination of all adolescents with meningococcal vaccine beginning at age 11. The ACIP meningococcal vaccine workgroup reviewed data on the epidemiology of meningococcal disease, safety, and the cost-effectiveness of meningococcal vaccine. On the basis of that data, expert opinion of the workgroup members, and feedback from partner organizations, this recommendation was approved. In January 2011, ACIP recommended that all adolescents receive a booster dose at 16 years of age. After licensure, additional data on bactericidal antibody persistence, trends in meningococcal disease epidemiology in the United States, and vaccine effectiveness have indicated many adolescents might not be protected for more than 5 years. Therefore, persons immunized at age 11 or 12 years might have decreased protective immunity by ages 16 through 21 years, when their risk for disease is greatest. References ACIP home page: https://www.cdc.gov/vaccines/acip/index.html State Information. (n.d.). Retrieved from https://www.immunize.org/laws/menin_sec.asp Revised Recommendations of the Advisory Committee on Immunization Practices to Vaccinate All Persons Aged 11-18 Years with Meningococcal Conjugate Vaccine. (2007). *PsycEXTRA Dataset*. doi: 10.1037/e669332007-003 Updated Recommendations for Use of Meningococcal Conjugate Vaccines --- Advisory Committee on Immunization Practices (ACIP), 2010. (2011, January 28). Retrieved from https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6003a3.htm
144.02 (21) (i); 144.03-A; 144.03 (2) (k)	DHS received 32 comments stating the meningococcal vaccination requirement update is unwarranted because the purposed age group	ACIP's Meningococcal Vaccines Work Group initially recommended a single dose of vaccine to be given at the ages of 11 to 12 years as

	(11 and 12 year olds) misses the target age group for which demographic group is at risk.	more adolescents in this age group have preventive care visits, it would be given in tangent with Tdap and HPV vaccines, and it was expected the vaccine would provide protection through the entire period of risk. After licensure, additional data indicated that after 5 years, waning of protection from disease occurs. The Work Group considered 2 options from this data, 1) moving the dose at age 11 or 12 years to age 14 or 15 years, or 2) vaccinating at age 11 or 12 years and providing a booster dose a age 16 years. Although a single dose at age 14 or 15 years likely would protect most adolescents through the higher risk period at ages 16 through 21 years, the opportunities to administer vaccine at age 14 or 15 years might be more limited. Data indicate that as adolescents grow older, they are less likely to visit a health-care provider for preventive care. Adding a booster dose to the recommended schedule would provide more opportunities to increase vaccination coverage, while persons aged 11 through 13 years would continue to be protected. An economic analysis comparing the three adolescent vaccination strategies concluded that administering a booster dose has a cost per quality-adjusted life year similar to that of a single dose at age 11 years or age 15 years but is estimated to prevent twice the number of cases and deaths per CDC data. These recommendations are in accordance with the national guidelines put forth by the Advisory Committee on Immunization Practices. Reference Updated Recommendations for Use of Meningococcal Conjugate Vaccines --- Advisory Committee on Immunization Practices (ACIP), 2010. (2011, January 28). Retrieved from https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6003a3.htm
144.02 (21) (i); 144.03-A; 144.03 (2) (k)	DHS received 17 comments stating the meningococcal vaccination requirement update is unwarranted because meningitis is treatable.	Vaccination with the meningococcal vaccine is the best way to prevent very serious infections caused by the bacterium *Neisseria meningitidis*. Per CDC and AAP, meningococcal meningitis and bloodstream infections can be very serious, even deadly. The infections progress quickly. The case-fatality ratio of meningococcal disease is 10% to 15%, even with appropriate antibiotic therapy. The case-fatality ratio of meningococcemia is up to 40%. As many as 20% of survivors have permanent sequelae, such as hearing loss, neurologic damage, or loss of a limb.

		References Hamborsky, J., Kroger, A., & Wolfe, C. (S. (2015). *Epidemiology and prevention of vaccine-preventable diseases*. United States: U.S. Dept. of Health & Human Services, Centers for Disease Control and Prevention. Meningococcal Disease Chapter. Kimberlin D.W., Brady M.T., Jackson M. A., Long S. Sl, eds. *Red Book:2018 Report of the Committee on Infectious Diseases.* 31st ed. Itasca, IL: American Academy of Pediatrics, 2018: Meningococcal 550-561.
general	DHS received 26 comments that broadly stated (i.e., generalized to all vaccines), that mandating vaccines is intended to benefit (e.g., financially) Industry/Government.	Vaccines are intended to benefit children and adults by preventing disease. They are credited with saving millions of lives. The CDC estimates that by vaccinating children between 1994-2018, 419 million illnesses, 26.8 million hospitalizations, and 936,000 early deaths will be prevented. Per the U.S. Department of Health & Human Services, immunizations can save a family time and money. A child with a vaccine-preventable disease can be denied attendance at schools or child care facilities. Some vaccine-preventable diseases can result in prolonged disabilities and can take a financial toll because of lost time at work, medical bills or long-term disability care. In contrast, getting vaccinated against these diseases is a good investment and usually covered by insurance. Reference Five Important Reasons to Vaccinate Your Child. (n.d.). Retrieved from https://www.vaccines.gov/getting/for_parents/five_reasons
144.02 (21) (i); 144.03-A; 144.03 (2) (k)	DHS received 8 comments stating the meningococcal vaccination requirement update is unwarranted because meningococcal vaccine does not provide herd immunity.	It is important for individuals to be vaccinated for protection against disease. CDC first recommended preteens and teens get a MenACWY vaccine in 2005. Since then, rates of meningococcal disease in teens caused by serogroups C, Y, and W has decreased by over 90%. This is a larger percent decline than seen in other groups for which CDC does not recommend routine MenACWY vaccination. These data suggest MenACWY vaccines provide protection to those vaccinated, but probably not to the larger, unvaccinated community (herd immunity). Reference

		Meningococcal Vaccination | What You Should Know | CDC. (n.d.). Retrieved from https://www.cdc.gov/vaccines/vpd/mening/public/index.html
144.02 (21) (i); 144.03-A; 144.03 (2) (k)	DHS received 27 comments stating the meningococcal vaccination requirement update is unwarranted because Meningococcal vaccine has never been tested against a placebo.	The meningococcal vaccine, like all licensed vaccines, has undergone rigorous testing prior to licensure, with studies done to evaluate both safety and effectiveness. Moreover, vaccines continue to be monitored post-licensure and are routinely re-assessed to ensure they meet standards set forth in each of these areas. Per CDC, effectiveness of the three meningococcal conjugate vaccines was inferred by comparing serum bactericidal antibody assay (SBA) measurements of the new vaccine with corresponding antibody responses of the U.S.-licensed meningococcal vaccine representing the standard of care at the time (among persons aged 2 through 55 years) or by achieving a seroresponse at or above a predefined bactericidal antibody titer (among children aged 2 through 23 months). A study that was published in *The Lancet*, compared meningococcal vaccine (MenACWY) to meningococcal serogroup B. This study randomly assigned university students ages 18 through 24 years to one of three groups. One group received Japanese Encephalitis vaccine (controls), meningococcal serogroup B vaccine, or meningococcal vaccine (MenACWY). References Hamborsky, J., Kroger, A., & Wolfe, C. (S. (2015). *Epidemiology and prevention of vaccine-preventable diseases*. United States: U.S. Dept. of Health & Human Services, Centers for Disease Control and Prevention. Meningococcal Disease Chapter. Read, R. C., Baxter, D., Chadwick, D. R., Faust, S. N., Finn, A., Gordon, S. B., Borrow, R. (2014). Effect of a quadrivalent meningococcal ACWY glycoconjugate or a serogroup B meningococcal vaccine on meningococcal carriage: an observer-blind, phase 3 randomised clinical trial. *The Lancet*, *384*(9960), 2123–2131. doi: 10.1016/s0140-6736(14)60842-4
144.02 (21) (h) 144.03 (20) (g)	DHS received 15 comments stating the varicella vaccination requirement update is unwarranted because varicella vaccine is ineffective	The varicella vaccine has been demonstrated to be effective. Per CDC and AAP, the effectiveness of 1 dose of varicella vaccine is about 82% against any

		clinical varicella and 98% against severe disease. Two doses of vaccine demonstrated 92% effectiveness against any clinical varicella. Immunity appears to be long-lasting. Breakthrough infection (after vaccination), is significantly milder than infection among unvaccinated persons, with fewer lesions, generally fewer than 50 and without a fever present. References Hamborsky, J., Kroger, A., & Wolfe, C. (S. (2015). *Epidemiology and prevention of vaccine-preventable diseases*. United States: U.S. Dept. of Health & Human Services, Centers for Disease Control and Prevention. Varicella Chapter. Kimberlin D.W., Brady M.T., Jackson M. A., Long S. Sl, eds. *Red Book:2018 Report of the Committee on Infectious Diseases.* 31st ed. Itasca, IL: American Academy of Pediatrics, 2018: Varicella 869-893.
general	DHS received 107 comments that broadly stated injecting foreign materials (e.g., chemicals, preservatives, vaccinations) into the body is wrong/dangerous/ineffective/expensive/not trustworthy.	There is solid medical and scientific evidence that the benefits of vaccines far outweigh the risks. Vaccines go through extensive, rigorous testing to ensure safety and efficacy prior to licensure. Monitoring for side effects continues post-licensure through a number of different systems, including the Vaccine Adverse Event Reporting system (VAERS), the Vaccine Safety Datalink, the Post-Licensure Rapid Immunization Safety Monitoring, and the Clinical Immunization Safety Assessment. Additionally, an article published in *Seminars in Pediatric Infectious Diseases,* discusses that since vaccines are administered to children, they are held to a higher safety standard than medications given to treat people who are ill. References Vaccines: Vac-Gen/Side Effects. (n.d.). Retrieved from https://www.cdc.gov/vaccines/vac-gen/side-effects.htm Ensuring the Safety of Vaccines in the United States. Retrieved from https://www.cdc.gov/vaccines/hcp/patient-

		ed/conversations/downloads/vacsafe-ensuring-bw-office.pdf Halsey, N. A. (2002). The science of evaluation of adverse events associated with vaccination. *Seminars in Pediatric Infectious Diseases*, *13*(3), 205–214. doi: 10.1053/spid.2002.125864
general	DHS received 28 comments expressing general opposition to the rule changes (i.e., no specific rationales were provided).	Per the Wisconsin Legislative Council, state agencies promulgate administrative rules to implement or interpret provisions of the statutes enforced or administered by the agency or to establish agency procedures for administering programs. Administrative rules have the force and effect of law. Administrative Rule 144 has not been updated since 2009 and is not current with ACIP recommendations (meningococcal vaccination), it contains outdated language when Tdap and varicella were included as recommendations, it allows for parenteral report of varicella disease, and other minor changes are being proposed. Reference Administrative Rules. (n.d.). Retrieved from https://lc.legis.wisconsin.gov/administrative-rules/
144.03 (20) (g)	DHS received 13 comments stating varicella infection does not need to be diagnosed by providers, it can be diagnosed by parents.	To limit the number of false-positive reports and ensure immunity, the national Advisory Committee on Immunization Practices (ACIP) recommends that evidence of immunity should be either a diagnosis of varicella by a health care provider or a health care provider verification of a history of disease rather than parental or self-reporting. In the past, the predictive value of a self-reported positive disease victory for varicella was extremely high in adults in the pre-vaccine era for their children. As disease incidence decreases and the proportion of vaccinated persons with varicella having mild cases increases, varicella will be less readily recognized clinically. A recent study demonstrated that only 75% of unvaccinated children aged 12 months through 4 years who reported a positive history of varicella were in fact immune (confirmed by serological testing), compared with 89% of children aged 5 through 9 and 10 through 14 years. References Perella, D., Fiks, A. G., Jumaan, A., Robinson, D., Gargiullo, P., Pletcher, J., … Spain, C. V. (2009). Validity of Reported Varicella History as

		a Marker for Varicella Zoster Virus Immunity Among Unvaccinated Children, Adolescents, and Young Adults in the Post-Vaccine Licensure Era. *Pediatrics*, *123*(5). doi: 10.1542/peds.2008-3310 Davis, M. M. (2004). Decline in Varicella-Related Hospitalizations and Expenditures for Children and Adults After Introduction of Varicella Vaccine in the United States. *Pediatrics*, *114*(3), 786–792. doi: 10.1542/peds.2004-0012
general	DHS received 1 comment stating the vaccine mandates proposed do not follow international trends.	Per the World Health Organization (WHO), immunization has proven the test of time as one of public health's most cost-effective interventions. In 2017, the number of children immunized – 116.2 million – was the highest ever reported. Since 2010, 113 countries have introduced new vaccines, and more than 20 million additional children have been vaccinated. A journal article published in 2018 reported that all 31 European countries recommended vaccines and 11 have compulsory immunization policies. Ten leading medical organizations, including American Academy of Pediatrics to the American Nurses Association to the Infectious Diseases Society of American all endorse strong school and childcare vaccination requirements as a primary way to ensure high vaccination rate. https://www.immunize.org/catg.d/p2071.pdf Mandatory vaccinations in European countries, undocumented information, false news and the impact on vaccination uptake: the position of the Italian pediatric society Elena Bozzola, Giulia Spina, Rocco Russo, Mauro Bozzola, Giovanni Corsello, Alberto Villani. Ital J Pediatr. 2018; 44: 67 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6001041/
144.03 (10) (a)	DHS received 4 comments stating vaccine reporting infringes on health privacy. For example, providers should not share children's' vaccination information with schools, daycares, and other providers without written or verbal permission from an adult. One respondent suggested, "the language be changed to require signed written consent from a student, age 18 or older, or a parent in order for this information to be released to a school or daycare center, or among vaccine providers."	Wisconsin Statute, Chapter 252.04 (2) states that "Any student admitted to any elementary, middle, junior, or senior high school or into any child care center or nursery school shall, within 30 school days after the date on which the student is admitted, present written evidence to the school, child care center, or nursery school of having completed the first immunization for each vaccine requirement for the student's grade and being on schedule for the remainder of the basic and recall (booster) immunization series for mumps, measles, rubella (German

		measles), diphtheria, pertussis (whooping cough), poliomyelitis, tetanus and other diseases that the department specifies by rule or shall present a written waiver under sub. (3)." Chapter 252.04 (4) states "The student, if an adult, or the student's parent, guardian, or legal custodian shall keep the school, child care center, or nursery school informed of the s student's compliance with the immunization schedule." The proposed changes do not affect Wisconsin Statute, Chapter 252. Reference Wisconsin State Legislature ch. 118.125, Stats. http://docs.legis.wisconsin.gov/statutes/statutes/118/125
general	DHS received 2 comments stating vaccinated individuals should tolerate others' decisions not to get vaccinated because they are protected. There is no risk to those not vaccinated.	While vaccines significantly reduce the possibility of contracting a disease, there are rare instances where vaccinated individuals may still become ill (but the illness is likely not to be as severe). However, the greater risk is to those individuals in the community who cannot be vaccinated due to medical reasons (e.g. undergoing chemotherapy). Therefore, those who choose not be vaccinated place these vulnerable at higher risk by decreasing herd immunity, and increasing likelihood of a disease circulating. This results in a greater chance that the vulnerable individual will be exposed and contract the disease.
144.02 (21) (h) 144.03 (20) (g)	DHS received 2 comments stating the recommended change about varicella outbreaks is against the 14th amendment because it segregates/discriminates students' based on their medical history.	Under Wisconsin Statute Chapter 252.04 (1), "The department shall carry out a statewide immunization program to eliminate mumps, measles, rubella (German measles), diphtheria, pertussis (whooping cough), poliomyelitis and other diseases that the department specifies by rule, and to protect against tetanus." Vaccination is the primary mechanism recommended by national and international boards to reduce or eliminate the spread of diseases for which a vaccine is licensed and available. According to the report "Childhood Immunization Schedule and Safety: Stakeholder Concerns, Scientific Evidence, and Future Studies" from the Health and Medicine Division of the National Academies of Science, Engineering and Medicine (formerly the Institutes of Medicine),", released in 2013, it states that "Vaccines are among the most safe and effective public health interventions to prevent serious disease and death.".

		As overall disease incidence declines, the risk for exposure to varicella-zoster virus (VZV) decreases, leading to susceptible (unvaccinated and vaccinated) children aging into adolescence and adulthood. Although the total number of varicella cases is declining, a shift of the remaining varicella disease burden to middle school years is being observed. In 1995, the median age of varicella infection ranged from 3-5 years in vaccinated persons and from 5-6 years in unvaccinated persons. By 2005, the median age increased to 6–8 years in vaccinated persons and 13–19 years in unvaccinated persons. Investigations of varicella outbreaks in schools and other settings in the vaccine era will improve our knowledge of the epidemiology of varicella, assess virus transmission patterns, describe disease burden and risk factors for severe varicella, provide estimates of varicella vaccine effectiveness for two versus one dose of vaccine, and identify risk factors for vaccine failure. In addition, monitoring the number and size of varicella outbreaks will help to assess impact of the second-dose recommendation. These data will facilitate the development and refinement of appropriate public health interventions to control and prevent future varicella outbreaks and further reduce varicella morbidity and mortality. References Guris, D., Jumaan, A. O., Mascola, L., Watson, B. M., Zhang, J. X., Chaves, S. S., Seward, J. F. (2008). Changing Varicella Epidemiology in Active Surveillance Sites—United States, 1995–2005. *The Journal of Infectious Diseases*, *197*(s2). doi: 10.1086/522156 Institute of Medicine. 2013. *The Childhood Immunization Schedule and Safety: Stakeholder Concerns, Scientific Evidence, and Future Studies*. Washington, DC: The National Academies Press.https://doi.org/10.17226/13563.
general	DHS received 1 comment stating the advisory Committee on Immunization Practices (ACIP) has conflicts of interest/bias.	Per CDC, vaccine recommendations are developed using an explicit evidence-based method on the Grading of Recommendations, Assessment, Development and Evaluation (GRADE) approach. Key factors considered in development of recommendations include balance of benefits and harms, type or quality of

		evidence, values and preferences of the people affected, and health economic analyses. An article in *Pediatrics,* describes fully how ACIP assures avoidance of conflicts of interest and bias with stringent measures in place and rigorous screening of committee members. References About ACIP Evidence-Based Recommendation Method (GRADE) | CDC. (n.d.). Retrieved from https://www.cdc.gov/vaccines/acip/recs/grade/about-grade.html Smith, J. C. (2010). The structure, role, and procedures of the U.S. Advisory Committee on Immunization Practices (ACIP). *Vaccine*, *28*. doi: 10.1016/j.vaccine.2010.02.037
general	DHS received 1 comment stating the use of the word "outbreak" in the proposed rules is a "fear mongering" tactic.	This is common terminology for epidemiologic events. Per CDC, epidemic refers to an increase, often sudden, in the number of cases of a disease above what is normally expected in that population in that area. Outbreak carries the same definition of epidemic, but is often used for a more limited geographic area. Cluster refers to an aggregation of cases grouped in place and time that are suspected to be greater than the number expected, even though the expected number may not be known. Pandemic refers to an epidemic that has spread over several countries or continents, usually affecting a large number of people. Reference Principles of Epidemiology | Lesson 1 - Section 11. (n.d.). Retrieved from https://www.cdc.gov/csels/dsepd/ss1978/lesson1/section11.html
144.02 (21) (h) 144.03 (20) (g)	DHS received 2 comments stating the varicella vaccination requirement update is unwarranted because there is insufficient supporting research.	The proposed changes do not include any changes to the varicella vaccination requirement. The proposed change is for a health care provider to document varicella disease and remove parental or adult student report of varicella disease as an acceptable exception.
	DHS received 1 comment stating the measles, mumps, and rubella (MMR) vaccine is dangerous.	The measles-mumps-rubella (MMR) vaccine that is in current use today was licensed in 1968 and has a long record of vaccine safety and is used in many parts of the world. Vaccines are rigorously monitored pre and post-licensure, including MMR, and include systems such as the Vaccine Adverse Event Reporting system

		and the Vaccine Safety Datalink to identify safety issues after licensure. The national Advisory Committee on Immunization Practices periodically reviews safety and efficacy data and continue to include the MMR vaccine as part of the routinely recommended vaccines for both children and susceptible adults. Reference Understanding MMR Vaccine Safety retrieved from CDC. https://www.cdc.gov/vaccines/hcp/patient-ed/conversations/downloads/vacsafe-mmr-color-office.pdf Ensuring the Safety of Vaccines in the United States . Accessed at: https://www.cdc.gov/vaccines/hcp/patient-ed/conversations/downloads/vacsafe-ensuring-bw-office.pdf
144.02 (21) (h) 144.03 (20) (g)	DHS received 2 comments stating the varicella vaccination requirement update is unwarranted because the varicella vaccine is dangerous.	Varicella vaccine, like all vaccines has undergone significant study before and after licensure and has been shown to be safe and well tolerated, with the most common side effects after vaccination being soreness or swelling where the shot was given, fever and a mild rash. The proposed changes do not alter the requirement for varicella vaccination, but rather update the reporting options for those who have had the disease. Reference Chickenpox (Varicella) Vaccine Safety, CDC. Accessed at: https://www.cdc.gov/vaccinesafety/vaccines/varicella-vaccine.html Perella, D., Fiks, A. G., Jumaan, A., Robinson, D., Gargiullo, P., Pletcher, J., … Spain, C. V. (2009). Validity of Reported Varicella History as a Marker for Varicella Zoster Virus Immunity Among Unvaccinated Children, Adolescents, and Young Adults in the Post-Vaccine Licensure Era. *Pediatrics*, *123*(5). doi: 10.1542/peds.2008-3310

Summary of Items Submitted with this Report to the Legislature

Below is a checklist of the items that are attached to or included in this report to the legislature under s. 227.19 (3), Stats.

Documents/Information	Included in Report	Attached	Not Applicable
Final proposed rule -- Rule Summary and Rule Text		X	
Department response to Rules Clearinghouse recommendations	X		
Final Regulatory Flexibility Analysis			X
Changes to the Analysis or Fiscal Estimate/Economic Impact Analysis			X
Public Hearing Summary	X		
List of Public Hearing Attendees and Commenters	X		
Summary of Public Comments and Department Responses	X		
Fiscal Estimate/Economic Impact Analysis		X	
Revised Fiscal Estimate/Economic Impact Analysis			X
Small Business Regulatory Review Board (SBRRB) statement, suggested changes, or other material, and reports made under s. 227.14 (2g), Stats. and Department's response			X
Department of Administration (DOA) report under s. 227.115 (2), Stats., on rules affecting housing			X
DOA report under s. 227.137 (6), Stats., on rules with economic impact of $20 MM or more			X
Public Safety Commission (PSC) energy impact report under s. 227.117 (2), Stats. and the Department's response, including a description of changes made to the rule			X