#3146

To Whom it May Concern:

I am writing to discuss concerns over proposed regulations by the Department of Health regarding changes to vaccination requirements (IRRC #3146 & 3147).

First, I would like to address the change of a provisional period from 240 days to 5 days. While I agree that the current 240-day provisional period is excessive and leads to less accurate statistics, a provisional period of 5 days is unnecessarily rigid. A 5-day provisional period does not give parents enough time, especially in the event of child sickness, to catch up on vaccinations. This would cause stress and extra expense to families. No other surrounding states have such a short provisional period. A 60-day provisional period would allow for accurate reporting, and would be accommodating to busy families.

I support the change in the later reporting date, from October 15 to December 31. This gives more time for accurate reporting.

I am concerned about the proposed change for requiring a doctor, physician's assistant, or nurse practitioner to provide proof of natural immunity for chicken pox. First of all, it is irresponsible to require parents to take their child out into public when they are contagious with an infectious illness. Most of the time, chicken pox is a mild illness that does not require medical intervention. Families would also have to bear the financial burden of co-pays and laboratory fees.

Regarding the meningococcal vaccine, no additional doses should be added to the required list. According to the package inserts, "In adolescents 11 through 18 years of age and adults 18 years through 55 years of age, SAEs [Serious Adverse Events] occurred at a rate of 1.0% following Menactra vaccine and at a rate of 1.3% following Menomune – A/C/Y/W-135 vaccine. In adolescents and adults, SAEs occurred at a rate of 1.3% following booster vaccination with Menactra vaccine."
https://www.vaccineshoppe.com/image.cfm?doc_id=12580&image_type=product_pdf. The CDC Pink Book states that, regarding MenACWY-D, "Serious events included headache, fever, vomiting, and nausea. A total of 24 deaths (0.3%) were reported", and for MenACWY-CRM, "One death (0.4%) was reported".
http://www.cdc.gov/vaccines/pubs/pinkbook/mening.html The CDC is stating that .4-.3% of serious adverse events resulted in death for study participants. Again, SAEs occurred in 1-1.3% of study participants. Given that meningococcal disease is very rare, affecting only 0.3-0.5/100,000 (http://www.cdc.gov/vaccines/pubs/surv-manual/chpt08-mening.html), the risk of death from the vaccine is greater than the risk of even contracting the disease. Also, the addition of this dose creates a third reporting burden, resulting in more paperwork and staff hours spent tracking vaccination status of students. Finally, a bill was introduced earlier this session to mandate this vaccine. The legislature chose not to move this bill forward. We can conclude that lawmakers are not in favor of this mandate.

I also have concerns regarding the addition of the pertussis vaccine to the required list. First, the FDA states that the pertussis vaccine does not prevent transmission of pertussis
http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm376937.htm. The theory of herd immunity does not apply in regard to this vaccine, as those who are vaccinated may carry and spread the bacteria, and may do this unknowingly as they are asymptomatic. Despite high levels of vaccination, pertussis outbreaks continue to occur, and vaccinated individuals are quite often affected.
http://www.cdc.gov/pertussis/downloads/pertuss-surv-report-2014.pdf. Furthermore, effectiveness for the pertussis vaccine wanes quickly. One study found results consistent with "a progressive decrease in estimated vaccine effectiveness each year after the final dose of pertussis vaccine."
http://www.ncbi.nlm.nih.gov/pubmed/23188029 Regarding the reported pediatric deaths from pertussis, there

were no reported deaths among school-aged children from 2012-2014. All reported pediatric deaths were in children age 4 years or younger, but primarily in infants under 3 months of age. http://www.cdc.gov/pertussis/downloads/pertuss-surv-report-2013.pdf http://www.cdc.gov/pertussis/downloads/pertuss-surv-report-2012.pdf http://www.cdc.gov/pertussis/downloads/pertuss-surv-report-2014.pdf. We know that the pertussis vaccine (currently DTaP) comes with risks of adverse effects up to and including death. We must weigh these risks with the limited benefit that the pertussis vaccine offers.

I am also concerned about the change to listing antigens as combination vaccines instead of separate antigens. These combinations may change in the future, and keeping them separate is the best way to ensure accuracy of data and prevent confusion in the event of any changes.

There is no requirement for standardized language in communications regarding vaccine requirements, from school districts to parents. Currently, each school district creates its own language regarding vaccine requirements, provisional periods, and reporting. Regulations should be amended to require all schools to use uniform language provided by the DOH which will include the text of 28 PA CODE CH.23 stating the accepted exemptions for PA students.

Thank you for this opportunity for me to provide my comments.

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