**Supplement to the Financial Impact Statement**
**relating to the**
**Proposed Rules and Regulations Pertaining to Immunization Requirements**

**Written findings as required by A.C.A 25-15-204(e)(4)**

1. **A statement of the rule's basis and purpose**

Rules and Regulations Pertaining to Immunization Requirements are duly adopted and promulgated by the Arkansas State Board of Health pursuant to the authority expressly conferred by the laws of the State of Arkansas including, without limitation, Ark. Code Ann. § 20-7-109, Ark. Code Ann. § 6-18-702, Ark. Code Ann. §§ 6-60-501 - 504, and Ark. Code Ann. § 20-78-206.

Immunizations against poliomyelitis, diphtheria, tetanus, pertussis, red (rubeola) measles, mumps, rubella, varicella (chickenpox), *Haemophilus influenzae* type b, hepatitis B, hepatitis A, meningococcal, and pneumococcal, and other communicable diseases have resulted in a dramatic decrease in the incidence of these diseases in Arkansas. However, these diseases continue to occur in childcare facilities, schools, and colleges and universities. A requirement that children and students furnish proof that they have immunity against certain communicable diseases will reduce the potential for an outbreak of those diseases.

2. **The problem the agency seeks to address with the proposed rule, including a statement of whether a rule is required by statute**

Compulsory school vaccinations began in 1916 to prevent the spread of smallpox. Present-day state immunization requirements for attending child care facilities and schools have continued since Act 244 of 1967. Immunizations are proven strategies in reducing communicable diseases.

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3. **A description of the factual evidence that:**

    a. **Justifies the agency's need for the proposed rule**

**Disease remains:**

The following tables and figures depict a significant ongoing burden of vaccine preventable diseases in AR and that large opportunities for improving vaccination coverage exist.

**Reported Pertussis Incidence and Vaccination Status of Cases, Arkansas 2013 Provisional**

| Age groups | # of Pertussis Cases 2013 | Age specific Population | Age specific rate per 100,000 adjusted for partial year | Cases UTD with shots # (%) |
|---|---|---|---|---|
| <1 Year | 50 | 39,844 | 188.23 | 7 (14) |
| 1-4Yrs | 31 | 157,845 | 29.46 | 15 (48) |
| 5-9Yrs | 44 | 196,877 | 33.52 | 35 (80) |
| 10-19Yrs | 86 | 401,364 | 32.14 | 25 (29) |
| 20+ Yrs | 48 | 2,119,988 | 3.40 | 2 (4) |
| TOTAL | 259 | 2,915,918 | 21.32 | |

**Reported Varicella Incidence and Rates**

| | 2006 | 2007 | 2008 | 2009 | 2010 | 2011 | 2012 | 2013 YTD |
|---|---|---|---|---|---|---|---|---|
| Cases | 1213 | 807 | 777 | 496 | 220 | 321 | 236 | 128 |
| Rate per 100,000 | 43.15 | 28.71 | 27.64 | 17.65 | 7.83 | 11.01 | 8.09 | 4.39 |

**Cases of Vaccine-Preventable Diseases 2008-2012**

| Disease | 2008 | 2009 | 2010 | 2011 | 2012 |
|---|---|---|---|---|---|
| H. Influenzae Invasive Disease | 16 | 24 | 22 | 35 | 30 |
| Hepatitis A | 10 | 12 | 2 | 3 | 8 |
| Hepatitis B | 68 | 65 | 66 | 57 | 75 |
| Measles | 2 | 0 | 0 | 0 | 4 |
| Meningococcal Infections | 16 | 9 | 6 | 12 | 8 |
| Mumps | 5 | 4 | 5 | 4 | 1 |
| Pertussis | 197 | 369 | 246 | 80 | 248 |
| Rubella | 0 | 0 | 0 | 0 | 0 |
| S. pneumoniae Invasive Total / < 5 years of age | 152/22 | 221/42 | 194/22 | 230/14 | 188/14 |
| Tetanus | 0 | 0 | 1 | 1 | 0 |
| Varicella | 777 | 501 | 220 | 347 | 237 |

**Immunization coverage is low:**

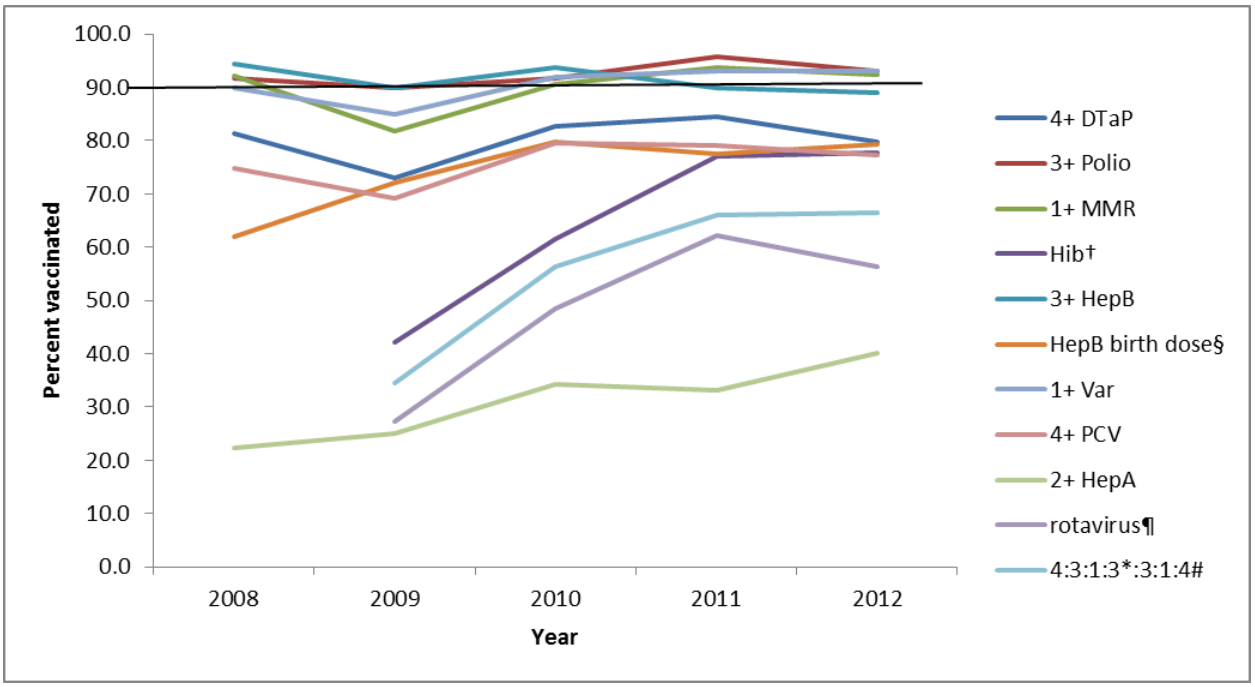
Estimated Vaccination Coverage, Age 13-17 and Arkansas Ranking in 2012 per the National Teen Immunization Survey conducted by the Centers for Disease Control and Prevention. A rank of 1 reflects the highest vaccination coverage in the nation and a rank of 50 reflects the lowest.

| | ≥2 MMR¶ | ≥ 3 HepB** | History of varicella disease†† | var ≥ 1 doses vaccine if had no history of disease | var ≥ 2 doses vaccine if had no history of disease | History of disease or received ≥ 2 doses varicella vaccine |
|---|---|---|---|---|---|---|
| **US National** | 91.4(±0.8) | 92.8(±0.7) | 30.6(±1.2) | 94.7(±0.8) | 74.9(±1.4) | 82.6(±1.0) |
| **Arkansas** | 89.5(±4.5) | 92.6(±3.3) | 31.0(±6.7) | 91.8(±4.9) | 53.3(±8.4) | 67.8(±6.6) |
| **AR Rank** | **36** | **31** | **31** | **40** | **48** | **50** |

| | ≥ 1 Td or Tdap¶ | ≥ 1 Tdap** | ≥ 1 MenACWY†† | ≥ 1 HPV§§ | ≥ 2 doses HPV¶¶ | ≥ 3 doses HPV*** |
|---|---|---|---|---|---|---|
| **US National** | 88.5(±0.8) | 84.6(±0.9) | 74.0(±1.1) | 53.8(±1.9) | 43.4(±1.9) | 33.4(±1.7) |
| **Arkansas** | 69.8(±6.4) | 64.4(±6.8) | 37.5(±7.0) | 41.2(±10.7) | 32.4(±10.0) | 18.3(±7.2) |
| **AR Rank** | 47 | 49 | 50 | 48 | 47 | 49 |

| | HPV 3 dose series completion††† | ≥ 1 HPV§§ | ≥ 2 doses HPV¶¶ | ≥ 3 doses HPV*** | HPV 3 dose series completion††† |
|---|---|---|---|---|---|
| **US National** | 66.7(±2.6) | 20.8(±1.5) | 12.7(±1.3) | 6.8(±1.0) | 45.1(±5.0) |
| **Arkansas** | 48.0(±17.8) | 12.7(±6.6) | NA | NA | NA |
| **AR Rank** | 49 | 45 | NA | NA | NA |

**National Immunization Survey, reflecting immunization coverage rates for ages 19-35 months during 2008-2012:**



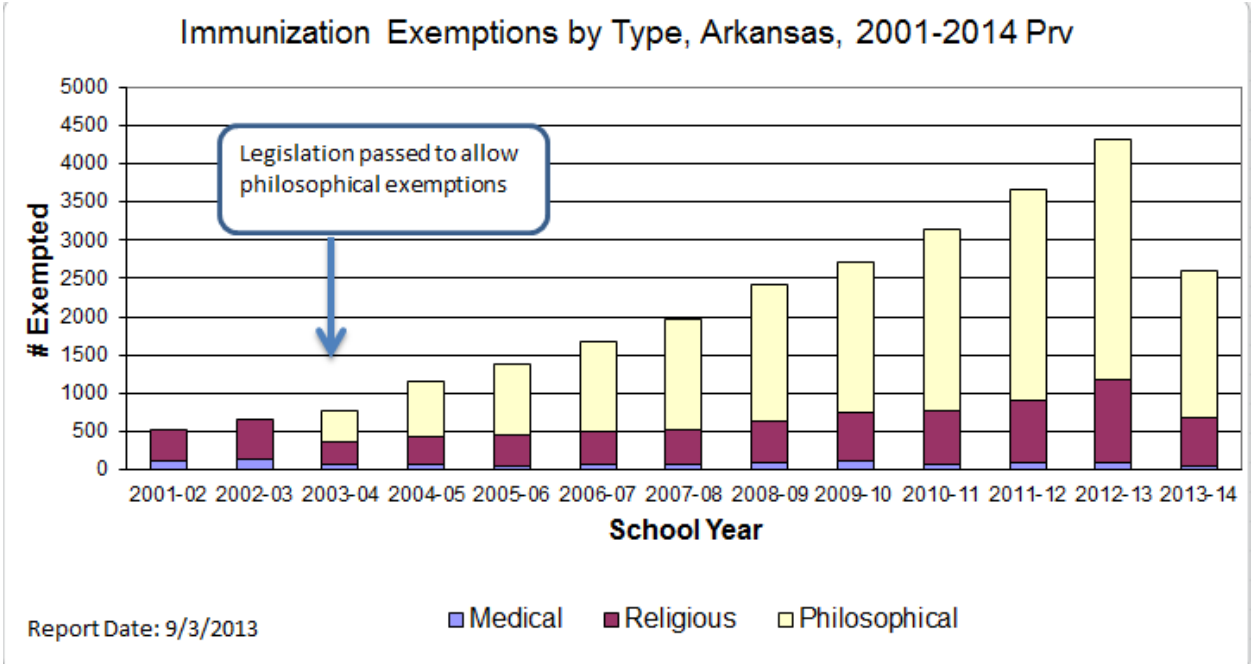

* HP2020 target for HepA and the birth dose of HepB is 85%. Target for rotavirus and the 4:3:1:3*:3:1:4 series is 80%.

† 3 or 4 doses of *Haemophilus influenzae* type B vaccine, depending on vaccine type

§ Coverage estimates by birth cohort. Estimates presented are for children born in 2005, 2006, 2007, 2008, and 2009.

# 4+ DTaP, 3+ polio, 1+ MMR, 3 or 4 doses Hib, depending on vaccine type, 3+ HepB, 1+ varicella, and 4+ PCV.

**Potential for increased disease is the ever-increasing number of exemptions:**




Please note that 2013-2014 data are provisional and are not expected to be different from the previous increasing trend

**b. Describes how the benefits of the rule meet the relevant statutory objectives and justify the rule's costs**

Immunization is essential to the prevention of disease, reduction in costs to treat disease, reduced absenteeism from school and work, and reduced morbidity and mortality as proven by various national studies conducted by the Institute of Medicine and the Centers for Disease Control and Prevention (CDC).

**4. A list of less costly alternatives to the proposed rule and the reasons why the alternatives do not adequately address the problem to be solved by the proposed rule**

Immunization requirements can be met without proof of immunization through the application for exemptions. However, exemptions do not prevent disease nor increase the number of individuals protected by immunization.

**5. A list of alternatives to the proposed rule that were suggested as a result of public comment and the reasons why the alternatives do not adequately address the problem to be solved by the proposed rule**

There were no substantive comments relating to alternatives raised during the public comment period nor during the public hearing.

6. **A statement of whether existing rules have created or contributed to the problem the agency seeks to address with the proposed rule and, if existing rules have created or contributed to the problem, an explanation of why amendment or repeal of the rule creating or contributing to the problem is not a sufficient response**

   The only existing rule that could negatively impact increased immunization rates is the addition of the philosophical exemption since 2003 within this current statute and rule. (See Table in Question 3 for the increase in exemptions that are not Medical.) Another problem with the philosophical exemption is that it is an easier process than the Medical exemption which requires a doctor's letter to support the medical contraindication. This results in parents taking the easier process and then there is no record within the daycare or school indicating that the vaccine may be actually contraindicated.

7. **An agency plan for review of the rule no less than every 10 years to determine whether, based upon the evidence, there remains a need for the rule including, without limitation, whether:**
   a. **The rule is achieving the statutory objectives**

      Immunization coverage is monitored annually through child care and school/college assessments conducted by the Arkansas Department of Health. In addition, there are annual national monitors conducted through the Behavioral Risk Factor Surveillance System and the National Immunization Surveys for ages 19-35 months and for teens.

   b. **The benefits of the rule continue to justify its costs and**

      The Arkansas Department of Health Immunization Section will continue to monitor immunization coverage and the incidence of disease to determine if additional changes are required to reduce vaccine-preventable diseases in Arkansas.

   c. **The rule can be amended or repealed to reduce costs while continuing to achieve the statutory objectives.**

      The Advisory Committee on Immunization Practices meets three times a year to review the incidence of disease, the impact of vaccines to reduce disease, and introduction of new vaccines. Changes to their recommendations are scientifically based. The Arkansas Department of Health Immunization Section adopts ACIP recommendations by updating internal policy for implementing changes within Local Health Units across the state. The Arkansas Department of Health will also review the ACIP changes to determine if the current rules and regulations should be amended or repealed.