

# EXHIBIT E

## DEPARTMENT OF HEALTH, CENTER FOR HEALTH PROTECTION

### SUBJECT: Immunization Requirements

DESCRIPTION: These are immunization requirements for attending daycare, school, or college/university. It is needed to bring immunization requirements more in line with the recommendations of the Advisory Committee on Immunization Practices. Having these requirements improves immunization coverage and reduces vaccine-preventable diseases.

The summary, as revised 01-07-14 follows:

#### Changes for Childcare Facilities:

1. Adding a requirement that school children attending childcare facilities before or after school and during school closings are to meet the childcare immunization requirements according to Table I.
2. Adding instructions for Table 1 to clarify that the age range is to identify what immunizations are required at that age and not a range of time for the child to receive immunizations. Table I is not a recommendation of doses to get, but of doses required to already have at that age.
3. Adding Hep A: 1 dose on or after 1<sup>st</sup> birthday (with 2 doses possible) for ages 19-24 months. 2 doses with one dose on or after 1<sup>st</sup> birthday and at least 6 months from the first dose for ages 25-72 months.
4. Adding the minimum interval for Polio to 6 months between the 3<sup>rd</sup> and 4<sup>th</sup> doses for ages  $\geq 49$  months. Removing the 3-dose option for compliance.
5. Clarifying that children are to meet "age-appropriate" requirements for attendance.
6. Changes age range for Table I from 49-72 months to  $\geq 49$  months.

#### Changes for Kindergarten through 12<sup>th</sup> Grade:

7. For Grades 1-12 only: For Diphtheria, Tetanus and Pertussis disease, changing the vaccine requirement to 4 doses and one dose of Tdap at age 10 years or older **OR** 3 doses for unvaccinated persons 7 years of age and older (including persons who cannot document prior vaccination). One of the three doses (preferably the first) should be administered as Tdap.
8. Increasing the number of doses of Polio from 3 to 4 doses (with 1 dose on or after 4<sup>th</sup> birthday and adding the minimum interval of 6 months between the 3<sup>rd</sup> and 4<sup>th</sup> doses).
9. Adding meningococcal requirements: 1 dose for 7<sup>th</sup> grade and a second dose at age 16 years as of September 1 each year. If first dose is at age 16 or older, no second dose is required. If no prior dose by age 16 years, then 1 dose is required.

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10. Adding a 1-dose requirement of Tdap for ages 10 years as of September 1 each year and older.
11. Adding Hep A: 1 dose on or after 1<sup>st</sup> birthday for Kindergarten. 2 doses with one dose on or after 1<sup>st</sup> birthday and at least 6 months from the first dose for Grade 1.
12. Increasing the number of varicella doses required for grades 1 through 12 to 2 doses.
13. Updating language for 1st through 12th grade Hep B requirements from “an appropriate series” to “two or three doses”.
14. Adding paragraph under Section III.B.3. which states if a child does not meet immunization requirements, refer to a medical authority for immunization or consultation.
15. Identifying the Arkansas Non-public School Accrediting Association (ANSAA) as a partner in cooperating with ADH to ensure compliance with immunization requirements in private schools.

## General Changes:

16. Removing acceptance of parental history of varicella disease. For childcare and schools, a medical professional, defined as medical doctor (MD), advanced practice nurse (APN), doctor of osteopathy (DO), or physician assistant (PA), is allowed to provide history of varicella disease.
17. Removing the availability of the Immunization/Health Record form as was provided by the Arkansas Department of Health. This form is obsolete due to electronic health record systems.
18. Removing the requirement that the Arkansas Department of Health send approval or denial letters for serological testing as proof of immunization to the appropriate facility. Letters will continue to be sent to individuals/parents/guardians.
19. Requiring an approval letter from the Arkansas Department of Health before accepting serology as proof of immunity.
20. Accepting a copy of an immunization record from a provider’s medical record to be placed in the child’s permanent file as proof of immunization.
21. Clarifying that serologic testing only applies to Hepatitis B virus, Measles, Mumps, Rubella, and Varicella as proof of immunity.
22. Clarifying that removal from the facility during an outbreak could last 21 days or longer.
23. Replacing “surveys and audits” with “assessments” to allow flexibility in transitioning from paper documentation to electronic data collection and assessment.
24. Clarifying that the 4-day grace period applies to both minimum age and minimum interval except for the interval between live vaccines which must be 28 days.
25. Making the effective date September 1, 2014.

## **A statement of the rule’s basis and purpose:**

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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.

**1. 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.

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.

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

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

Disease remains:

**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).

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**3. 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.

**4. 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.

**5. 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.

**6. 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.

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**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.

**PUBLIC COMMENT:** A public hearing was held on this rule on December 18, 2014. The public comment period expired December 18, 2014. The Department received no public comments.

Isaac Linam, an attorney with the Bureau of Legislative Research, asked the following questions:

**QUESTION #1:** You state that the purpose of the rule is “[t]o bring immunization requirements more in line with the recommendations of the Advisory Committee on Immunization Practices”. Can you describe who the Advisory Committee on Immunization Practices is? **RESPONSE:** The Advisory Committee on Immunization Practices (ACIP) is a committee made up of independent experts in academia, clinical medicine, and public health who meet quarterly and recommend any revisions of the universal immunization schedules for children or adults to the Director of the CDC. They also make recommendations that apply to high risk individuals who may need additional or different vaccinations than the general population. More information on the committee can be found at <http://www.cdc.gov/vaccines/acip/index.html>

**QUESTION #2:** Are there Advisory Committee recommendations that the Department is not including in this rule? If yes, what are the omitted recommendations and why are they being omitted? **RESPONSE:** The Arkansas Department of Health’s (ADH) recommendations are designed to exactly mirror the ACIP recommendations. The ADH’s regulations, which only apply to preschool and school aged children, closely approximate ACIP recommendations but take into effect when regulations were enacted and which cohorts of people to which they apply. For example, if just last year a vaccine was required for 4 year olds, it is not required for children who are currently 5 years or older.

There are two notable vaccines that are recommended but currently not required for school or daycares. The first is a vaccine for the human papilloma virus which prevents a variety of genitourinary and

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oropharyngeal cancers and genital warts in both boys and girls. The political climate in AR at this time is thought not to be supportive of this requirement due to widely held misconceptions that the vaccine in some way promotes earlier or riskier sexual behavior among adolescents. Numerous studies show the opposite, but due to the sensitivity around the issue, we have not pursued a mandate. The second is the influenza vaccine. This vaccine similarly has associated with it a high number of misconceptions in the general population, the legislature, and even among some medical professionals; among them that it may cause the flu, or is ineffective, or not needed in healthy individuals. Data clearly refute these beliefs, but the political climate and will at this point in time does not seem conducive to a mandate.

Other situations not included in our mandates relate to special populations. We only mandate vaccines that are universally expected among all eligible persons. For example, we don't require a vaccine that only is indicated for a person who is missing a spleen or who has sickle cell disease.

The proposed effective date for the rule is September 1, 2014.

**CONTROVERSY:** This is not expected to be controversial.

**FINANCIAL IMPACT:** Increasing state immunization requirements improves immunization coverage and reduces vaccine-preventable diseases. Prevention of disease reduces costs due to health care and from absenteeism from school and work.

The cost to the state for the next fiscal year is \$717,518. This is not the full cost for the proposed changes. The federal Vaccines for Children Program will cover children eligible through that program which could represent about 70% of children in Arkansas. The proposed \$717,518 cost to the state is an estimated value as 1) vaccine prices change, 2) the impact of the Affordable Care Act may create a shift in where individuals seek immunization services thereby increasing or reducing cost of vaccine provided by local health units, 3) existing state revenue and Medicaid Reimbursement within the Department of Health could support part of the cost, and 4) with the Department of Health implementing the billing of private insurance, costs could be support to the amount available through reimbursement.

The department also provided the following information concerning the financial impact.

**LEGAL AUTHORIZATION:** Ark. Code Ann. § 20-7-109 provides that the Department of Health shall promulgate reasonable rules to protect

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public health and safety and to suppress and prevent infectious, contagious, and communicable diseases.

Ark. Code Ann. § 6-18-702 provides that children must be immunized from “poliomyelitis, diphtheria, tetanus, pertussis, red (rubeola) measles, rubella, and other diseases as designated by the State Board of Health, as evidenced by a certificate of a licensed physician or a public health department acknowledging the immunization” before being admitted to a public or private school or child care facility. That section also provides that the State Board of Health must promulgate rules to enforce the immunization requirement.

Ark. Code Ann. § 6-60-502 provides that students who attend a public or private institution of higher education must furnish proof “by way of an official record from another educational institution in Arkansas or a certificate from a licensed medical doctor or an authorized public health department representative, that he or she has immunity against measles, rubella, and such other diseases as delineated by the State Board of Health”. Ark. Code Ann. § 6-60-503 empowers the State Board of Health to promulgate rules to enforce this immunization requirement.

Ark. Code Ann. § 20-78-206 provides that a child care facility is prohibited from admitting a child unless the child has “been age-appropriately immunized from poliomyelitis, diphtheria, tetanus, pertussis, red (rubeola) measles, rubella, and any other diseases as designated by the State Board of Health”, and that the “immunization shall be evidenced by a certificate of a licensed physician or a public health department acknowledging the immunization”.

Ark. Code Ann. §§ 6-18-702, 6-60-504, and 20-78-206 all provide that the Department of Health must promulgate regulations concerning the application for exemptions to the immunization requirements for “medical, religious, and philosophical” reasons.





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## QUESTIONNAIRE FOR FILING PROPOSED RULES AND REGULATIONS WITH THE ARKANSAS LEGISLATIVE COUNCIL AND JOINT INTERIM COMMITTEE

DEPARTMENT/AGENCY Arkansas Department of Health  
DIVISION Center for Health Protection - Immunization Section  
DIVISION DIRECTOR Donnie Smith  
CONTACT PERSON Hilda Douglas  
ADDRESS 4815 West Markham, MS-48, Little Rock, AR 72205  
PHONE NO. 501-661-2493 FAX NO. 501-661-2300 E-MAIL Hilda.Douglas@Arkansas.gov  
NAME OF PRESENTER AT COMMITTEE MEETING \_\_\_\_\_  
PRESENTER E-MAIL Dirk.Haselow@Arkansas.gov

### INSTRUCTIONS

- A. Please make copies of this form for future use.
- B. Please answer each question completely using layman terms. You may use additional sheets, if necessary.
- C. If you have a method of indexing your rules, please give the proposed citation after "Short Title of this Rule" below.
- D. Submit two (2) copies of this questionnaire and financial impact statement attached to the front of two (2) copies of the proposed rule and required documents. Mail or deliver to:

Donna K. Davis  
Administrative Rules Review Section  
Arkansas Legislative Council  
Bureau of Legislative Research  
One Capitol Mall, 5<sup>th</sup> Floor  
Little Rock, AR 72201

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1. What is the short title of this rule? Immunization Requirements
2. What is the subject of the proposed rule? Immunization Requirements for attending daycare, school, or college/university
3. Is this rule required to comply with a federal statute, rule, or regulation? Yes  No   
If yes, please provide the federal rule, regulation, and/or statute citation. \_\_\_\_\_
4. Was this rule filed under the emergency provisions of the Administrative Procedure Act? Yes  No   
If yes, what is the effective date of the emergency rule? \_\_\_\_\_

When does the emergency rule expire? \_\_\_\_\_

Will this emergency rule be promulgated under the permanent provisions of the Administrative Procedure Act?

Yes

No

5. Is this a new rule? Yes  No   
If yes, please provide a brief summary explaining the regulation. \_\_\_\_\_

Does this repeal an existing rule? Yes  No

If yes, a copy of the repealed rule is to be included with your completed questionnaire. If it is being replaced with a new rule, please provide a summary of the rule giving an explanation of what the rule does.  
\_\_\_\_\_

Is this an amendment to an existing rule? Yes  No

If yes, please attach a mark-up showing the changes in the existing rule and a summary of the substantive changes. **Note: The summary should explain what the amendment does, and the mark-up copy should be clearly labeled "mark-up."**

6. Cite the state law that grants the authority for this proposed rule? If codified, please give the Arkansas Code citation. A.C.A 20-7-109, 6-18-702, 6-60-501-504 and 20-78-206

7. What is the purpose of this proposed rule? Why is it necessary? To bring immunization requirements more in line with the recommendations of the Advisory Committee on Immunization Practices. Having state requirements improves immunization coverage and reduces vaccine-preventable diseases.

8. Please provide the address where this rule is publicly accessible in electronic form via the Internet as required by Arkansas Code § 25-19-108(b).  
<http://www.healthy.arkansas.gov/aboutADH/RulesRegs/IMMRulesandRegsProposed.pdf>

9. Will a public hearing be held on this proposed rule? Yes  No

If yes, please complete the following:

Date: 12/18/2013

Time: 1:00

Place: Arkansas Department of Health, Room 2508

10. When does the public comment period expire for permanent promulgation? (Must provide a date.)  
8:00 a.m. 12/18/2013

11. What is the proposed effective date of this proposed rule? (Must provide a date.)  
September 1, 2014

12. Do you expect this rule to be controversial? Yes  No

If yes, please explain.  
\_\_\_\_\_

13. Please give the names of persons, groups, or organizations that you expect to comment on these rules?

Please provide their position (for or against) if known.

Arkansas Department of Human Services, Childcare Division - For

Arkansas Department of Education - For

Arkansas Department of Higher Education - For

Arkansas Chapter of the American Academy of Pediatricians - For

Arkansas Academy of Family Physicians - For

Anti-vaccine groups - Against

Arkansas Family Council - Against

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**FINANCIAL IMPACT STATEMENT**

**PLEASE ANSWER ALL QUESTIONS COMPLETELY**

**DEPARTMENT** Arkansas Department of Health  
**DIVISION** Center for Health Protection - Immunization Section  
**PERSON COMPLETING THIS STATEMENT** Hilda Douglas  
**TELEPHONE NO.** 501-661-2493 **FAX NO.** 501-661-2300 **EMAIL:** Hilda.Douglas@Arkansas.gov

To comply with Ark. Code Ann. § 25-15-204(e), please complete the following Financial Impact Statement and file two copies with the questionnaire and proposed rules.

**SHORT TITLE OF THIS RULE** Immunization Requirements

1. Does this proposed, amended, or repealed rule have a financial impact?      Yes       No
2. Is the rule based on the best reasonably obtainable scientific, technical, economic, or other evidence and information available concerning the need for, consequences of, and alternatives to the rule?      Yes       No
3. In consideration of the alternatives to this rule, was this rule determined by the agency to be the least costly rule considered?      Yes       No

If an agency is proposing a more costly rule, please state the following:

(a) How the additional benefits of the more costly rule justify its additional cost; Prevention of disease reduces costs due to health care and from absenteeism from school and work

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(b) The reason for adoption of the more costly rule; To bring immunization requirements more in line with the recommendations of the Advisory Committee on Immunization Practices. Having state requirements improve immunization coverage and reduces vaccine-preventable diseases.

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(c) Whether the more costly rule is based on the interests of public health, safety, or welfare, and if so, please explain; and; Increasing state immunization requirements improves immunization coverage and reduces vaccine-preventable diseases. Prevention of disease reduces costs due to health care and from absenteeism from school and work.

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(d) Whether the reason is within the scope of the agency's statutory authority; and if so, please explain. The Arkansas Department of Health and the Board of Health have the public health responsibility.

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4. If the purpose of this rule is to implement a federal rule or regulation, please state the following:

(a) What is the cost to implement the federal rule or regulation?

**Current Fiscal Year**

**Next Fiscal Year**

General Revenue \_\_\_\_\_

General Revenue \_\_\_\_\_

Federal Funds \_\_\_\_\_  
Cash Funds \_\_\_\_\_  
Special Revenue \_\_\_\_\_  
Other (Identify) \_\_\_\_\_

Federal Funds \_\_\_\_\_  
Cash Funds \_\_\_\_\_  
Special Revenue \_\_\_\_\_  
Other (Identify) \_\_\_\_\_

Total \_\_\_\_\_

Total \_\_\_\_\_

(b) What is the additional cost of the state rule?

**Current Fiscal Year**

**Next Fiscal Year**

General Revenue \_\_\_\_\_

General Revenue \_\_\_\_\_

Federal Funds \_\_\_\_\_

Federal Funds \_\_\_\_\_

Cash Funds \_\_\_\_\_

Cash Funds \_\_\_\_\_

Special Revenue \_\_\_\_\_

Special Revenue \_\_\_\_\_

Other (Identify) \_\_\_\_\_

Other (Identify) \_\_\_\_\_

Total \_\_\_\_\_

Total \_\_\_\_\_

5. What is the total estimated cost by fiscal year to any private individual, entity and business subject to the proposed, amended, or repealed rule? Identify the entity(ies) subject to the proposed rule and explain how they are affected.

**Current Fiscal Year**

**Next Fiscal Year**

\$ \_\_\_\_\_

\$ \_\_\_\_\_

6. What is the total estimated cost by fiscal year to state, county, and municipal government to implement this rule? Is this the cost of the program or grant? Please explain how the government is affected.

**Current Fiscal Year**

**Next Fiscal Year**

\$ \_\_\_\_\_

\$ 717,518

This is not the full cost for the proposed changes. The federal Vaccines For Children Program will cover children eligible through that program which could represent about 70% of children in Arkansas. The proposed \$717,518 cost to the State is an estimated value as 1) vaccine prices change, 2) the impact of the Affordable Care Act may create a shift in where individuals seek immunization services thereby increasing or reducing cost of vaccine provided by Local Health Units, 3) existing state revenue and Medicaid Reimbursement within the Arkansas Department of Health could support part of the cost and 4) with the Arkansas Department of Health implementing the billing of private insurance, costs could be supported to the amount available through reimbursement.

7. With respect to the agency's answers to Questions #5 and #6 above, is there a new or increased cost or obligation of at least one hundred thousand dollars (\$100,000) per year to a private individual, private entity, private business, state government, county government, municipal government, or to two (2) or more of those entities combined?

Yes  No

If YES, the agency is required by Ark. Code Ann. § 25-15-204(e)(4) to file written findings at the time of filing the financial impact statement. The written findings shall be filed simultaneously with the financial impact statement and shall include, without limitation, the following:

(1) a statement of the rule's basis and purpose;

- (2) the problem the agency seeks to address with the proposed rule, including a statement of whether a rule is required by statute;
- (3) a description of the factual evidence that:
  - (a) justifies the agency's need for the proposed rule; and
  - (b) describes how the benefits of the rule meet the relevant statutory objectives and justify the rule's costs;
- (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;
- (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;
- (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; and
- (7) an agency plan for review of the rule no less than every ten (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;
  - (b) the benefits of the rule continue to justify its costs; and
  - (c) the rule can be amended or repealed to reduce costs while continuing to achieve the statutory objectives.

**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.

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.

**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)
<b>TOTAL</b>	<b>259</b>	<b>2,915,918</b>	<b>21.32</b>	

Reported Varicella Incidence and Rates

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

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:**

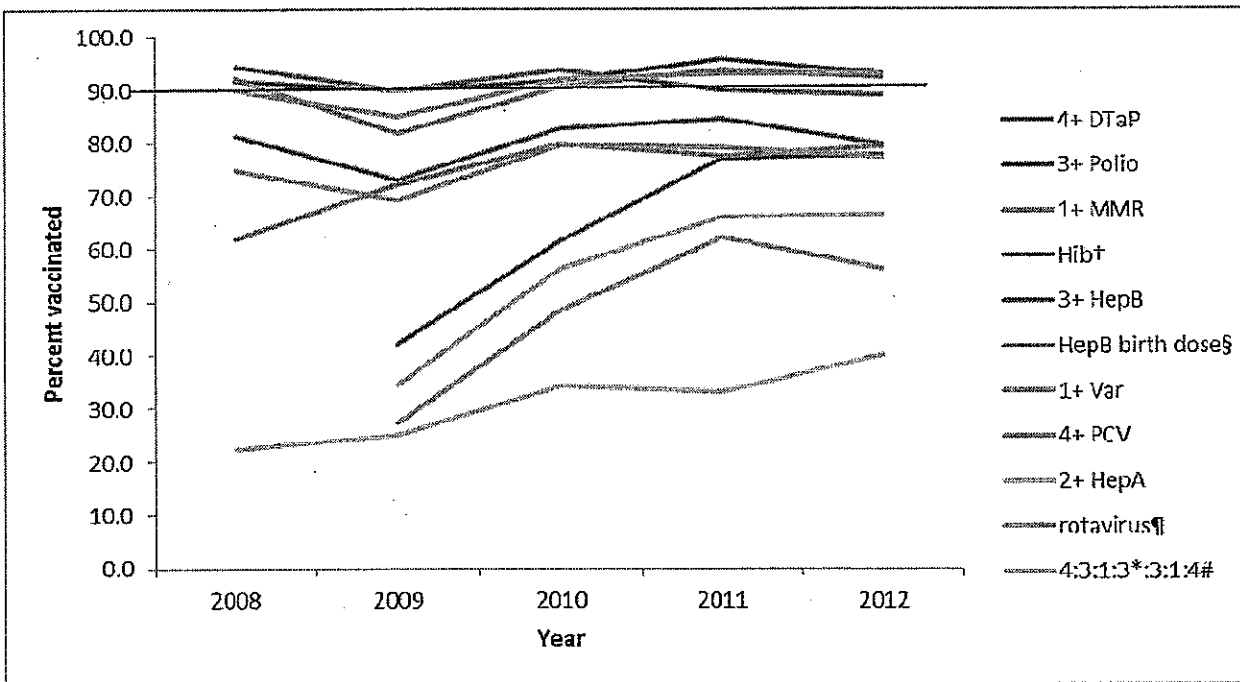
Estimated Vaccination Coverage, Age 13-17 and Arkansas Ranking in 2012 per the National Teen Immunization Survey conducted by the Centers for Disease Control and Prevention. A rank of 1 reflects the highest vaccination coverage in the nation and a rank of 50 reflects the lowest.

	≥2 MMR <sup>††</sup>	≥ 3 HepB <sup>**</sup>	History of varicella disease <sup>††</sup>	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 <sup>†</sup>	≥ 1 Tdap <sup>**</sup>	≥ 1 MenACWY <sup>††</sup>	≥ 1 HPV <sup>§§</sup>	≥ 2 doses HPV <sup>†††</sup>	≥ 3 doses HPV <sup>***</sup>
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 <sup>†††</sup>	≥ 1 HPV <sup>§§</sup>	≥ 2 doses HPV <sup>†††</sup>	≥ 3 doses HPV <sup>***</sup>	HPV 3 dose series completion <sup>†††</sup>
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:**



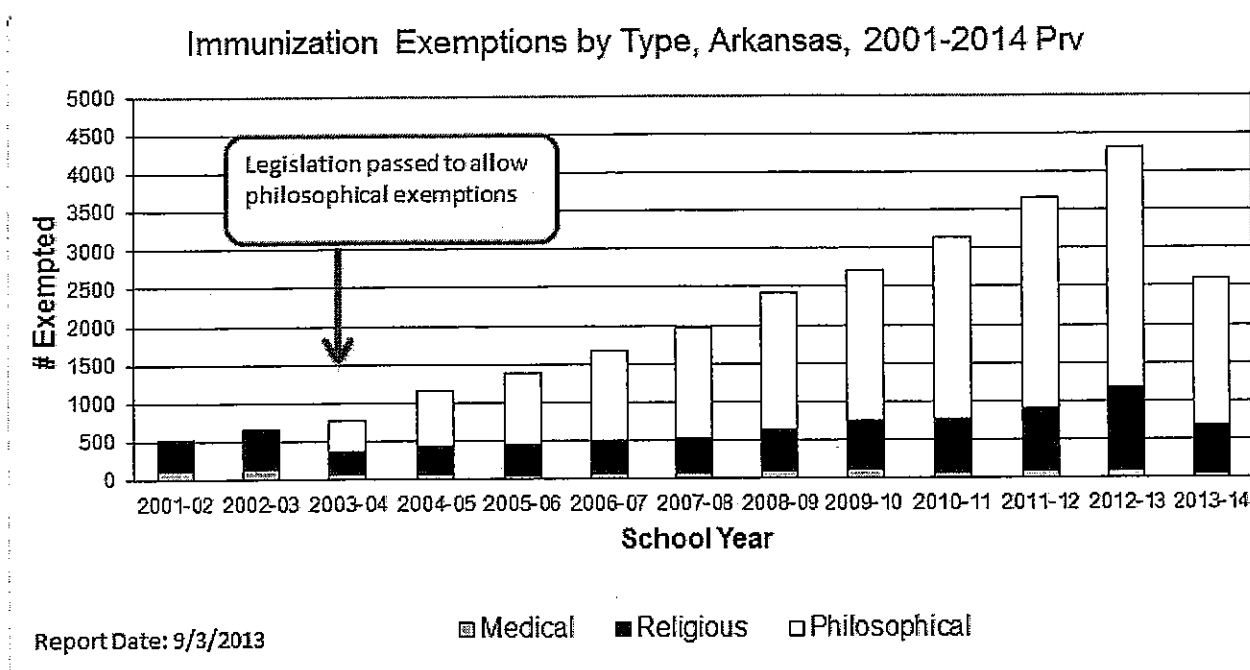
\* HP2020 target for HepA and the birth dose of HepB is 85%. Target for rotavirus and the 4:3:1:3\*:3:1:4 series is 80%.

† 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.

## RULEMAKING TRACKING FORM

*Please track completion of each rulemaking activity on this form to ensure that the process is completed in a timely fashion. Remember, this is an internal document and does not go to any party outside of the Department.*

Work Unit: Immunization Section		Primary Contact: Hilda Douglas Phone #: 501-661-2493	
Name of Rule: Rules and Regulations Pertaining to Immunization Requirements		Authorizing Statute: <b>Ark. Code Ann. §§ 20-7-109, 6-18-702, 6-60-501 - 504, and 20-78-206</b>	
Step	Action	Date	Notes
1	Prepare the rule packet, to include: <ul style="list-style-type: none"> <li>the draft rule or rule change</li> <li>the cover page</li> <li>the questionnaire</li> <li>the financial impact statement</li> <li>the cover summary</li> <li>the fiscal impact statement (if needed)</li> </ul>	11/08/13 09/17/12 03/26/13	Repeat process for public hearing and filing with Secretary of State Revised after July attempt Revised again after January 9, 2013 Public Hearing
2	Will the financial impact of this rule be greater than \$100,000 on a particular group or groups? <u> X </u> Yes <u> </u> No <ul style="list-style-type: none"> <li>If yes, prepare the Written Findings</li> </ul>	09/18/13	See Financial Impact Statement
4	Have Center Director and the Agency Attorney review your rule	09/17/12 03/26/13	Completed
5	Place Item on agenda of the next Executive Staff Meeting		Completed
	Get Executive Staff approval to present Rule/Reg to the Board		Completed
6	Place Item on agenda of the next Board Meeting	10/09/12 06/26/13	
	Appear before the Board to obtain approval to proceed with the public hearing	11/8-09/12 04/25/13	
7	Does this rule/reg impact schools? <u> X </u> Yes <u> </u> no <ul style="list-style-type: none"> <li>If yes, obtain approval from appropriate school rep</li> <li>If yes, prepare the fiscal impact statement</li> </ul>	10/29/13 03/26/13 09/17/12	Obtained support of the Arkansas Department of Education representative Paula Smith There is no financial impact to schools, colleges, universities, or daycares.
	Are any other groups impacted? If so have they been contacted <u> X </u> Yes <u> </u> no <ul style="list-style-type: none"> <li>Any problems or issues that need to be resolved?</li> </ul>	06/08/12  06/18/13	Dept. of Ed. Dept. of Higher Ed. DHS ANSAA (Private school assn.) VMAC DHS, Dept. of Ed., Higher Ed.,

		06/26/13	ANSAA, AR Pharmacists Assn., AAFP and AAP
8	Place Notice for Public Hearing Name of Publication: <u>Arkansas Democrat Gazette</u> Date Sent: <u>11/07/13</u> Date Appeared: 11/21-23/12 1 <sup>st</sup> time, 06/13-15/13 2 <sup>nd</sup> time, 11/10-12/13 3 <sup>rd</sup> time. Notice sent to any other publications: Name of Publication: _____ Date Sent: _____ Date Appeared: _____		See Notice
9	E-Mail public hearing notice & draft rule to Secretary of State		
10	Place notice & draft rule on the Department's Website		
11	Send draft rule and public hearing notice to Interested Parties Interested Parties are: • _____ • _____ • _____	06/08/12 11/13/13  06/18/13 11/13/13 06/26/13 11/13/13	Dept. of Ed. Dept. of Higher Ed. DHS ANSAA (Private school assn.) VMAC DHS, Dept. of Ed., Higher Ed., ANSAA, AR Pharmacists Assn., AAFP and AAP
12	Submit draft rule, questionnaire, and financial impact statement to the Bureau and the Joint Committee		
13	File draft rule and financial impact statement with the Arkansas State Library		
14	Place Notice of hearing on <u>www.arkansas.gov</u> at least <b>3 days before hearing</b>		
15	Hold Public Hearing • Did Major changes result from public hearing? <u>X</u> Yes first time <u>X</u> No second time • If yes send notice to Governor's office, Bureau, and Joint Committee	12/18/13 07/17/13	
16	Obtain agency attorney review/approval of changes resulting from public hearing. • Do any steps need to be repeated? ____ Yes ____ No	02/22/13  08/02/13	Agency Attorney determined changes were substantive and that process would need to start over. Therefore, current process stopped. Plans to re-start process with all changes after receiving Board of Health approval in April 2013.  Minutes sent to Agency Attorney to rule on if further revisions are

			needed.
17	Appear before the Leg. Council and Joint Interim Committees		
18	Place item on agenda for next full Board Meeting		
	Appear Before the full Board for rule adoption		
19	Prepare final rule packet for certification, to include: <ul style="list-style-type: none"> <li>• The final rule and Cover Sheet</li> <li>• Letter Requesting Director's Signature</li> <li>• Summary of Comments and Responses</li> <li>• Financial Impact Statement</li> </ul>		
	Obtain Agency Director's signature for certification of final rule		
	Prepare copies of the final certified rule		
20	Obtain "Authorized Officer" signature on final rule		
21	File final certified rule copies with the Secretary of State & State Library		
	Return agency copies to your office and the agency attorney		
22	Send copies of the adopted rule to: <ul style="list-style-type: none"> <li>• Bureau, if there are rule changes</li> <li>• Gov. Office, if there are rule changes</li> <li>• Interested Parties</li> <li>• Those affected by the rule</li> </ul>		
23	Post final rule and summaries of comments and responses on the Department's website		

