

DEPARTMENT OF HEALTH, CENTER FOR HEALTH PROTECTION,
IMMUNIZATION SECTION (2536)

SUBJECT: Immunization Requirements

DESCRIPTION: This brings 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.

This changes the requirement for Tdap vaccine at age 10 to 11 years. It also changes the requirement for Kindergarten through Grade 12 from 4 doses to 3 doses of Polio vaccine. It changes the requirement for Grade 1 from 2 to 1 dose of Hepatitis A vaccine. It will also allow students till October 1 to comply with age requirements for Tdap and Meningococcal vaccines.

PUBLIC COMMENT: A public hearing was held May 13, 2014. The public comment period expired May 13, 2014. The Department received the following public comments:

Natalie Mannering, National Vaccine Information Center (NVIC)

COMMENT: The proposal also changes the medical exemption for college students so that only the Dept. of Health can grant them. The current rule allows colleges to accept a medical exemption on a certificate approved by the department and signed by a medical doctor. Medical doctors should be able to write the medical exemption without the approval of the Department of Health. **RESPONSE:** The requirement that medical exemptions for college and university students be granted only by the Department of Health is to assure accurate and uniform assessments of medical contraindications to immunizations. The requirement will remain unchanged.

COMMENT: The proposed new rule also adds that statement that if the Dept. of Health determines that if a possibility of disease transmission exists, an exempt child or individual shall not return to the facility for 21 days or longer. The current rule does not specify the amount of days for exclusion. **RESPONSE:** The vaccine preventable diseases that may occur in childcare facilities/public and private schools/colleges and universities, such as varicella, measles, and pertussis, have incubation periods as long as 21 days. For that reason, when transmission of varicella, measles, or pertussis has occurred, unimmunized persons are excluded to assure that they remain uninfected and cannot also transmit the infection to others. When ongoing transmission occurs, it may take longer than 21 days before unimmunized persons can return to childcare or school. The rule will remain unchanged.

COMMENT: NVIC is opposed to these rules because these vaccines are already available to anyone who wants them and the vaccine exemption process in Arkansas is burdensome and discriminatory. **RESPONSE:** The purpose of these requirements is to control communicable diseases in Arkansas to the extent possible through immunizations. These diseases when not controlled, place a heavy burden on families, communities, health care providers. The requirements will remain unchanged.

COMMENT: Because the current exemption requirements place an extra burden of education on those who want to utilize an exemption as opposed to those who vaccinate with no required education, new mandates significantly negatively impact those utilizing an exemption. **RESPONSE:** The purpose of the required education is to help parents and adult students make informed decisions about vaccination. The currently required education for those who apply for exemptions is to read the one-page Vaccine Information Statement for the relevant vaccines. Immunization providers in Arkansas provide the same Vaccine Information Statements to all parents/adults who receive vaccinations, as required by the federal law. The requirements will remain unchanged.

COMMENT: New mandates raise insurance costs for everyone. **RESPONSE:** Insurance companies are required by law to cover all immunizations recommended by the Advisory Committee for Immunization Practices (ACIP). The proposed requirements fall within the ACIP recommendations and do not require anything more than what insurance companies are already required to cover. The requirements will remain unchanged.

Lisa Lipe, National Vaccine Information Center (NVIC)

COMMENT: The proposal also changes the medical exemption for college students so that only the Dept. of Health can grant them. The current rule allows colleges to accept a medical exemption on a certificate approved by the department and signed by a medical doctor. Medical doctors should be able to write the medical exemption without the approval of the Department of Health. **RESPONSE:** The requirement that medical exemptions for college and university students be granted only by the Department of Health is to assure accurate and uniform assessments of medical contraindications to immunizations. The requirement will remain unchanged.

COMMENT: I firmly believe that vaccination should be a decision made by parents or of-age individuals with advice from their medical providers. As a teacher of students with various learning disabilities, I am quite concerned about the current number of vaccines being given, especially those being given to very young children and multiple vaccines being given in one dose. I believe there is enough medical evidence of risks, that these procedures should be strictly voluntary. Individuals should have a right to their own bodies and to decide what medical procedures they will undergo and what risks (either way) they are willing to take. Parents should have a right to make this decision with regard to their own children. I do not believe mandating vaccines is the responsibility of state agencies, and I respectfully ask that you do not encourage any more of them to be mandated. All the proposed vaccines are available to those who want them. **RESPONSE:** Current scientific information shows that simultaneous vaccination with multiple vaccines has no adverse effect on children's immune systems. A number of studies have been conducted to examine the effects of giving various combinations of vaccines simultaneously. These studies have shown that the recommended vaccines are as effective in combination as they are individually, and that such combinations carry no greater risk for adverse side effects. Consequently, both the ACIP and the American Academy of Pediatrics recommend simultaneous administration of all routine childhood vaccines when appropriate. An infant's immune system is more than ready to respond to the very small number of weakened and killed infectious agents (antigens) in vaccines. From the time they are born, babies are exposed to thousands of germs and other antigens

in the environment and their immune systems are readily able to respond to these large numbers of antigens. The requirements will remain unchanged.

rirccasey

COMMENT: First, I would like to applaud your efforts to propose rules and regulations to further immunize our children against preventable disease.

I do have some questions pertaining to the proposal:

1. Will there be enough vaccine and available appointments for children to be immunized in the timeline required?
2. Why is hepatitis A changed to one dose when it is a two dose series.
3. In a school setting management of students is much more effective by grade--why are their ages required versus grade? I understand the CDC guideline recommendations; but success of its implementation should be considered by grade. If a student were to "fail" a grade--they would receive the immunization the next year....Example: 10 year old=4th grade; 16 year old=10th grade. There is a "range of recommended ages for catch-up immunization".
4. MCV4 will be difficult for a parent to understand in the way the 1 is required or 2 is required.....If children were required to have it in 10th grade versus an age; success in its implementation (number of students who are compliant) might be greater.

Thank-you for efforts to ensure our children are adequately immunized.

- RESPONSE:**
1. The Arkansas Department of Health local health units are working with providers, schools and communities to assure that sufficient vaccine and flexible clinic times are available for the temporary increase in the number of doses needed to meet the proposed requirements.
 2. The Arkansas Department of Health encourages parents to follow the ACIP recommendations for all childhood immunizations. In the case of Hepatitis A, the ACIP recommendation is to initiate the 2-dose Hepatitis A vaccine series at 12 through 23 months and separate the 2 doses by 6 to 18 months. For any person aged 2 years and older who has not already received the Hepatitis A vaccine series, the recommendation is for 2 doses of Hepatitis A vaccine separated by 6 to 18 months. If a first-grade student has not previously been vaccinated, the second dose could be received after first grade is completed, and still fall within the ACIP recommendations. In this case, a requirement for 2 doses during first grade would be stricter than the ACIP recommendations. For that reason, only 1 dose is required, but 2 doses are recommended.
 3. The age-based requirement was made because of the increased diversity of ages that are present in middle and high school grades. Fortunately, school nurses are now able to obtain immunization reports by age or by grade through the Arkansas Public School Computer Network (APSCN) which will ease the burden on them for tracking student compliance.
 4. There is indeed a potential for confusion related to the MCV4 (meningococcal) vaccine. It may be helpful for providers and parents to keep in mind that the proposed requirements are based on the ACIP recommendations. Students who follow the ACIP

schedule for persons their age, regardless of their grade, will meet the school requirements. The requirements will remain unchanged.

Bob Hoskings, MD, UAMS

COMMENT: The proposed requirements will bring the Arkansas school immunization requirements into accord with the ACIP recommendations and current science of childhood immunizations. I endorse these requirements as good public health and medical practice in accord with scientific evidence. **RESPONSE:** It is important to note that the proposed requirements do not include all of the immunizations that are recommended for children by the Advisory Committee for Immunization Practices (ACIP). For information about all of the recommended vaccines, we encourage all parents talk to their doctor or nurse. Information about all of the recommended childhood vaccinations is available from the Centers for Disease Control and Prevention at this link: <http://www.cdc.gov/vaccines/schedules/index.html>. The requirements will remain unchanged.

Chris Barr

COMMENT: 1. Cases of Hep A does not justify adding a HepA vaccine requirement to schedule every child in Arkansas at more than \$3,000,000 (annual cost times 5 years).

Hep A -- side effects and adverse events

Hep A – made from human fetal diploid (lung) cells to propagate the virus

Hep A vaccine – contents contains preservatives.

“Both Havrix and Vaqta manufacturer package inserts say they have ‘not been evaluated for its carcinogenic or mutagenic potential, or its potential to impair fertility.’”

Hep A – no long-term studies that evaluated associations between specific chronic illness or disability.

2. Pertussis incidence was reduced before vaccine was used. Incidence of disease is higher in vaccinated persons vs. unvaccinated persons.

3. No reason/benefit to change exemption rules for college students.

4. No reason to have a set amount of days for excluding exempted children from school during an outbreak.

5. The doctors and health professionals in attendance gave very general comments with few or no specifics. Fear was a common component. It is not a matter of vaccinate or do nothing. It is a matter of, to quote the World Health Organization (below) "consider alternative or additional prevention methods, such as better sanitation and health education for improved hygiene." I raised 8 children without vaccinations and none of the allegedly "vaccine preventable" illnesses occurred. I have assisted thousands of others through 5 decades. There are other options that are both safer and more effective.

Very rarely have I ever encountered the alleged "vaccine preventable illnesses" in these people and never was it deadly, life threatening, or any great discomfort, long term or with long lasting side effects. Better E-D-U-C-A-T-I-O-N about better options should be the goal and not just the same ol' same ol'. Again, it is not a matter of vaccinate or do nothing, suffer and die. The facts from numerous sources that I cited in the meeting (CDC, WHO, PubMed/Medline/National Library of Medicine) indicate vaccination is not the end all and be all it is made out to be. Those who want vaccination -- have at it. Just don't mandate it for those of us who know better -- and do something about it and NOT doing nothing about it. I visited with a family just last night that had a 13-month old child

with medically diagnosed pertussis more than 5 years ago. The doctor gave an injection of steroids that made no initially discernible difference and gave a prescription for oral steroid medication. The parents filled the prescription, went home, looked up the side effects and were frightened by what they read. They then called me and I gave them a short history on the herb lobelia in a tincture form and how to use it. The first administration gave noticeable relief. By end of day the baby slept through the night.

After 2 days there was no more cough at all. That was not the only pertussis instance of which I have personal knowledge with successful relief and elimination in a short time with lobelia.

RESPONSE: 1. The incidence of locally acquired hepatitis A is low in Arkansas and the United States. In contrast the infection is very common in Mexico, South America, Africa, the Middle East, and other locations around the world. Hepatitis A is primarily a food or water-borne infection. The virus is shed in stool at very high levels and can contaminate uncooked food items through poor food handling or preparation or via human feces contamination of fruits or vegetables at the level of the agricultural producer. This is relevant because we eat food that is imported from around the world. A study in 2011 by the US Department of Agricultural Research Service and the Food and Drug Administration showed that 62% of fish and shell fish, 38% of fruits, and 11% of vegetables consumed in the US come from other countries. The increasing globalization of our food supply necessitates that we take active steps to prevent hepatitis A. Many of the countries that provide our food are in areas with high rates of hepatitis A. A recent outbreak affecting over 600 US citizens, was traced back to salsa made with onions grown in Mexico. Hepatitis A immunization when given as part of the routine childhood immunizations saves more money than it costs. These costs are shouldered by the federal Vaccine for Children programs as well as by private insurance.

2. Vaccinated children with pertussis infections experience reduced illness severity and duration.

3. Medical exemptions for college and university students shall be granted only by the Department of Health to provide accurate and uniform assessment of medical contraindications to immunizations and to ease the burden on health care providers.

4. The vaccine preventable diseases that may occur in schools, such as varicella, measles, and pertussis, have incubation periods as long as 21 days. For that reason, when transmission of varicella, measles, or pertussis has occurred, unimmunized persons are excluded to assure that they remain uninfected and cannot also transmit the infection to others. When ongoing transmission occurs, it may take longer than 21 days before unimmunized persons can return to childcare or school.

5. The purpose of the hearing and comment period was to gather input regarding the proposed requirements. The science behind immunizations was not the focus. The Arkansas Department of Health supports the importance of good sanitation and health education. In addition, the Health Department recognizes the contribution of immunizations in controlling vaccine-preventable diseases that once sickened and killed thousands of children in Arkansas. The requirements will remain unchanged.

Maria Jacob

COMMENT: Opposed changes due to:

1. These vaccines were already available for those who choose to vaccinate

2. Additional requirements are MORE burdensome for exempted children and families.
3. Safety of multiple doses of vaccinations given at a time and its long-term effects are not studied
4. There are no studies comparing the health outcomes of fully vaccinated versus unvaccinated children
5. The effectiveness of vaccines are questionable including the 'herd immunity' theory

RESPONSE: 1. It is important to note that the proposed requirements do not include all of the immunizations that are recommended for children by the Advisory Committee for Immunization Practices. For information about all of the recommended vaccines, we encourage all parents to talk to their doctor or nurse. Information about all of the recommended childhood vaccinations is available from the Centers for Disease Control and Prevention at this link: <http://www.cdc.gov/vaccines/schedules/index.html>. Students who follow the ACIP schedule for persons their age will meet the school requirements.

2. The purpose of these requirements is to control communicable diseases in Arkansas to the extent possible through immunizations. These diseases when not controlled, place a heavy burden on families, communities, health care providers.

3., 4., & 5. A recent study published in Pediatrics showed that vaccinating children as recommended prevents 17,685,495 cases of disease and 42,032 deaths yearly. This study also showed that childhood vaccines saved \$13.5 billion in medical costs and \$68.8 billion in societal costs. The requirements will remain unchanged.

Michele Meissner

COMMENT: I urge you to please fight the latest addition of vaccinations.

RESPONSE: The requirements will remain unchanged.

Wendy

COMMENT: 1. Vaccine injuries exist.

2. My child, my choice.

3. More education, studies, and awareness should be the priority.

RESPONSE: 1. The National Childhood Vaccine Injury Act (NCVIA) requires health care providers to report adverse events (possible side effects) that occur following vaccination, so the Food and Drug Administration (FDA) and Centers for Disease Control and Prevention (CDC) established the Vaccine Adverse Events Reporting System (VAERS) in 1990. VAERS is a national reporting system that accepts reports from the public on adverse events associated with vaccines licensed in the United States. Approximately 30,000 VAERS reports are filed annually, with 10-15% classified as serious (resulting in permanent disability, hospitalization, life-threatening illnesses or death). Anyone can file a VAERS report, including health care providers, manufacturers, and vaccine recipients or their parents or guardians.

2. The Arkansas Department of Health acknowledges the tension between individual freedom and the public health's related to immunization requirements.

3. The Arkansas Department of Health agrees that increased education and awareness, as well as studies, are needed to address immunizations in Arkansas.

The requirements will remain unchanged.

Pamela Ungerank

COMMENT: Opposed to more governmental influence and believe that educated informed choice should be maintained. **RESPONSE:** The requirements will remain unchanged.

Kathy Dickey

COMMENT: In support of new immunization rules and regs. **RESPONSE:** The requirements will remain unchanged.

mksterling

COMMENT: I do not believe (nor does the constitution back you up) you have the right to mandate or force medicate the population. I am against more vaccines and against making it mandatory to for students and or the public. I do not think you should make it harder for students to opt out of vaccines to attend public schools. Science is not on your side. Stop forcing this on the public it is as bad Nazi Germany. **RESPONSE:** The U.S. Supreme Court has affirmed states' right to mandate immunizations. The requirements will remain unchanged.

John

COMMENT: I am not ok with any means a forcible medication on the Arkansas public. Including vaccines. I find it to be highly offensive and intrusive that a gov. Organization even believes they can force this on the people of a state. If passed I will use my spare time to fight it and bring to light the injustice through every form of media at my disposal. I don't believe this to be a public health concern on your part, but a power grab. Ball's in your court. Is it worth it? **RESPONSE:** The U.S. Supreme Court has affirmed states' right to mandate immunizations. The requirements will remain unchanged.

Katheren Richardson

COMMENT: 1. As a school nurse for 17 years, of her 750 students all will need 1 to 3 shots each.
2. Parents don't take children to doctor for varicella disease. Doctors don't want these children in their offices. A parent's note should be accepted.
3. This is an enormous task for schools, local health units, and parents for all these changes being made at one time. Not to mention the expense for the state of Arkansas with the burden on tax payers.

RESPONSE: 1. For students who follow ACIP recommendations for childhood immunizations, no new immunizations are required beyond the vaccines they would normally receive.
2. Clinical studies show that a history of varicella disease given by parents is often inaccurate.
3. It is the goal of the Arkansas Department of Health and health care professionals around the state to increase the number of children who receive all of the ACIP-recommended immunizations by increasing the number of immunizations we provide in our clinics. All children not covered by private insurance are covered by the federal Vaccines for Children program that provides vaccines at no cost to patients. In addition,

federal law requires that private insurance cover all ACIP-recommended vaccines at no cost to patients. The requirements will remain unchanged.

Orrin Davis, MD, and 18 pediatricians in Northwest Arkansas Pediatric Clinic

COMMENT: Supports new vaccine changes. **RESPONSE:** The requirements will remain unchanged.

Chad Rogers, MD, Little Rock Pediatric Clinic

COMMENT: Very supportive of the new vaccine regulations and requirements for school entry. **RESPONSE:** The requirements will remain unchanged.

Keyur Vyas, MD

COMMENT: I am an infectious disease physician. I support the proposed changes. In my opinion as an infectious disease specialist, there is extensive science on the subject of vaccines that it is well shown to prevent illness and to improve the quality of life as well as illness in the community and as well as the individual patient. I agree with the proposed changes. **RESPONSE:** The requirements will remain unchanged.

Ryan Bariola, MD

COMMENT: As an infectious disease physician, I have seen people die from vaccine preventable illnesses, and feel these regulations are appropriate, lifesaving and I strongly support it. **RESPONSE:** The requirements will remain unchanged.

Dennis Kuo, MD

COMMENT: I am a general pediatrician and the vice president of Arkansas Chapter of the American Academy of Pediatrics. I am speaking on behalf of our executive committee. We strongly support the changes. We think these are excellent long term recommendations for the schools and are consistent with the recommended vaccine schedule. It is not a burden to our providers. It is a part of our routine vaccine schedule. To have an additional mechanism to protect the health of our children is an important one for the state of Arkansas. **RESPONSE:** The requirements will remain unchanged.

Margo Bushmaier

COMMENT: I'm a school nurse and I'm speaking in favor of these vaccines. I too have seen children die from these diseases and will never forget that. The Hep-A rate is lower in Arkansas. But in surrounding states they are much higher and we have a highly mobile population in that a lot of people come in to Arkansas and that poses a risk for our children. Of Pertussis, I've known of several cases in our schools and some have transmitted to infants of teenage mothers, and the infants became severely ill because they were not able to be fully protected. As for Varicella, I have seen the cases go down significantly with the protection of the vaccine that was implemented several years ago. So it's true it has improved the quality of life with the vaccines that we have. So these proposed regulations and changes would improve the compliance and protect our children. **RESPONSE:** The requirements will remain unchanged.

Jean Paul Hammel

COMMENT: I represent me. My people are destroyed for lack of knowledge is well documented. I hope ya'll know the book. Also, well documented are the words "science falsely so called". I hope you know the book. Coughing is increased by aerosol crimes. Aerosol crimes. I hope ya'll catch a clue. **RESPONSE:** The requirements will remain unchanged.

Jose Romero, MD

COMMENT: I'm chief of pediatrics of infectious disease at Arkansas Children's Hospital. I have been involved with vaccine related issues for several decades; locally, regionally and nationally. I'm in favor of the proposed recommendations. I, like many of my colleagues have seen deaths occur due to these diseases. I recently treated a child with Tetanus disease we rarely ever see in this country because the decision was made not to vaccinate the child. I can tell you that the economic cost and the cost to that family are significant. These diseases exist and they exist in our communities. They have to be controlled by immunization. There is no better way of controlling them or preventing these diseases. The main reason we don't see them in florid numbers that we saw 50 years ago is because of vaccines. So I think it is important that we maintain the immunization levels in our communities and that we expand the vaccines to address the deficiencies that we are discovering in the prolonged immunity for some of the vaccines. **RESPONSE:** The requirements will remain unchanged.

Terry Yamauchi, MD

COMMENT: I just returned from the WHO meeting in Geneva. I understand the concerns about 35 million dollars for Hep-A saving one life in 30 years. These diseases are preventable or the effects of these diseases that can be lessened are still major problems around the world, and granted what you said about hygiene still the number one problem for health in the whole world is clean water is a major problem. But it's still a problem. We still see outbreaks of measles that kill people; children and adults. We can see the advantages that vaccines have made in that it virtually eliminated Smallpox, which is a vaccine preventable disease. We know that there are outbreaks now of Polio again is trying to come up even though we've made major, major strides in prevention of Polio with vaccine.

But I would urge that we continue to both educate our public and our health professionals on the importance of using these vaccines. They are still the best weapon we have for prevention of many of these infectious diseases that we have seen controlled with the advent whether its the association of the vaccine with the education of hygiene and some of these other things, one thing we do know, they play an important role in making these decisions. **RESPONSE:** The requirements will remain unchanged.

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

QUESTION: Is this proposed rule based on ACIP recommendations that were not available in November? If these recommendations were available in November but were not promulgated then, why are they only being promulgated now rather than with the November promulgation? **RESPONSE:** The proposed changes to the rules bring the

requirements into alignment with ACIP recommendations that were available in November. The requirement for Tdap vaccine, which protects against tetanus, diphtheria and pertussis, changes the required age from 10 to 11 years of age to align it with the ACIP recommended age of 11 years for routine Tdap vaccination. This change is based on concerns voiced by health care providers regarding age 10 as being outside of the ACIP recommendations, even though children in Arkansas have high rates of pertussis at age 10. The changes to Polio vaccine and Hepatitis A vaccine requirements reduce the number of required doses so that the requirement would not be more stringent than the ACIP recommendations for those persons who are behind in their immunization schedules for these vaccines. The requirements will remain unchanged.

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

CONTROVERSY: This is not expected to be controversial.

FINANCIAL IMPACT: The agency indicates that the cost to implement the rule is \$653,610; however, 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 \$653,610 cost to the state is an estimated value as 1) vaccine prices change and 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.

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

PIL 05/22/14

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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

(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.

(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.

(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.

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 _____
Federal Funds _____
Cash Funds _____
Special Revenue _____
Other (Identify) _____

General Revenue _____
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

\$ 0

\$ 653,610

The amount listed 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 \$653,610 cost to the State is an estimated value as 1) vaccine prices change and 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.

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 rate per 100,000	Cases UTD with Shots (%)
<1 Year	79	198.27	57 (72)
1-4Yrs	58	36.74	27 (47)
5-9Yrs	88	44.70	68 (77)
10-19Yrs	156	38.87	55 (35)
20+ Yrs	85	4.01	18 (21)
TOTAL	466	15.98	236 (49)

Reported Varicella Incidence and Rates

	2006	2007	2008	2009	2010	2011	2012	2013
Cases	1213	807	777	496	220	321	237	249
Rate per 100,000	43.15	28.71	27.64	17.65	7.83	11.01	8.13	8.54

Cases of Vaccine-Preventable Diseases 2008-2013

Disease	2008	2009	2010	2011	2012	2013
H. Influenzae Invasive Disease	16	24	22	35	30	25
Hepatitis A	10	12	2	3	8	9
Hepatitis B	68	65	66	57	75	49
Measles	2	0	0	0	4	0
Meningococcal Infections	16	9	6	12	8	7
Mumps	5	4	5	4	1	3
Pertussis	197	369	246	80	248	466
Rubella	0	0	0	0	0	0
S. pneumoniae Invasive Total / < 5 years of age	152/22	221/42	194/22	230/14	188/14	252/11
Tetanus	0	0	1	1	0	0
Varicella	777	501	220	347	237	249

Immunization coverage is low:

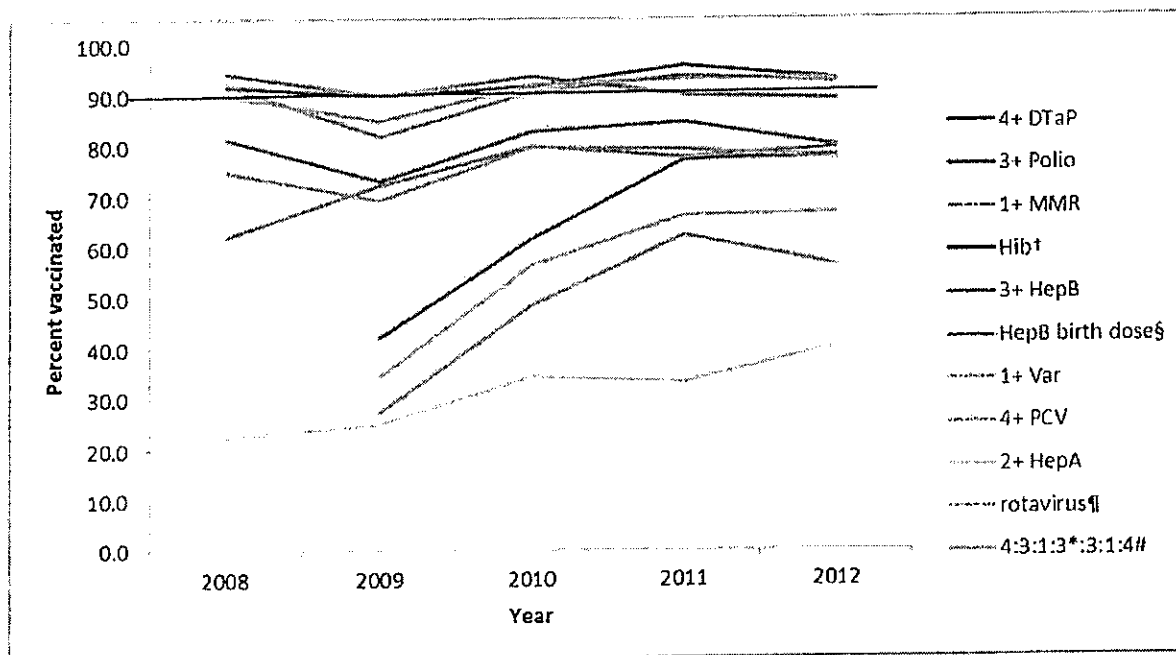
Estimated Vaccination Coverage, Age 13-17 and Arkansas Ranking in 2012 per the National Teen Immunization Survey conducted by the Centers for Disease Control and Prevention. A rank of 1 reflects the highest vaccination coverage in the nation and a rank of 50 reflects the lowest.

	≥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%.

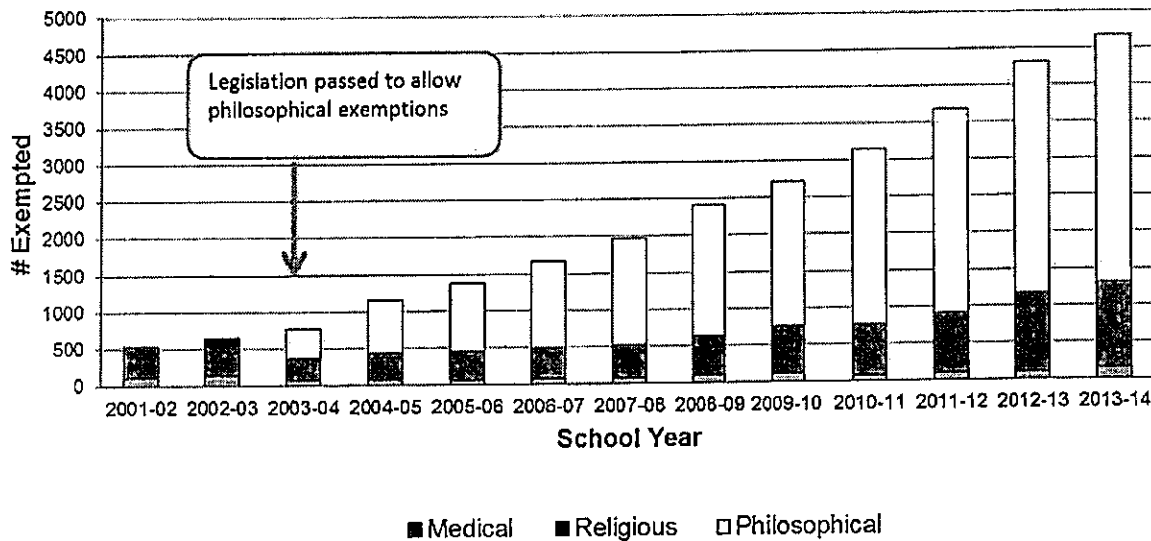
† 3 or 4 doses of *Haemophilus influenzae* type B vaccine, depending on vaccine type

§ 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:

Immunization Exemptions by Type, Arkansas, 2001-2014*



* 2013-14 data provisional as of 4/1/2014

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.

Notice of Public Hearing for Immunization Requirements

The Arkansas Department of Health will hold a public hearing Tuesday, May 13, 2014, at 1:00 p.m. in Room L137 (the Engineering Conference Room) of the Department of Health building at 4815 West Markham, Little Rock, Arkansas, to allow interested persons to comment on proposed changes to the Rules and Regulations Pertaining to Immunization Requirements pursuant to ACA §§ 20-7-109, 6-18-702, 6-60-501 - 504, and 20-78-206.

Copies of the proposed Rules and Regulations are available at www.healthy.arkansas.gov and at the Immunization Section, Room 260, at the Arkansas Department of Health.

The public may submit written comments no later than 8:00 a.m. on May 13, 2014. Comments may be sent by email to Hilda.Douglas@Arkansas.gov or by mail to:

Hilda Douglas, Assistant Section Chief
Immunization Section
Arkansas Department of Health
4815 West Markham, Slot 48
Little Rock, AR 72205



Arkansas Department of Health

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Governor Mike Beebe

Nathaniel Smith, MD, MPH, Director and State Health Officer

Summary of Proposed Rules and Regulations Pertaining to Immunization Requirements Revised 04-02-14

It is proposed to revise the Rules and Regulations Pertaining to Immunization Requirements pursuant to the procedures of the Administrative Procedures Act process, as amended, by the authority of Act 434 of 1967 as amended. These requirements apply to the childcare, kindergarten through grade 12, and college/university immunization requirements under the authority of Ark. Code Ann. §§ 20-7-109, 6-18-702, 6-60-501-504, and 20-78-206.

In summary, the proposed changes include:

Changes for Childcare Facilities:

No changes.

Changes for Kindergarten through Grade 12:

1. For Grades 1-12 only: For Diphtheria, Tetanus and Pertussis vaccine, changing the requirement to 4 doses and 1 dose of Tdap at age 11 years or older or 3 doses for students age 7 years of age and older who have not been fully immunized (including persons who cannot document prior vaccination). One of the 3 doses should be administered as Tdap.
2. For students age 11 years and older: Require 1-dose of Tdap vaccine for students age 11 years as of September 1 each year and older. Students who have reached age 11 by September 1 have until October 1 to comply.
3. For Kindergarten through Grade 12: Require 3 doses of Polio vaccine with 1 dose on or after 4th birthday and adding the minimum interval of 6 months between the 2nd and 3rd doses OR 4 doses with 1 dose on or after 4th birthday and a minimum interval of 6 months between the 3rd and 4th doses.
4. For Kindergarten and Grade 1: For Hepatitis A vaccine, require 1 dose on or after 1st birthday.
5. For students age 16 years: Require a dose of Meningococcal (MCV4) vaccine for students who turn 16 on or before September 1. If they received a dose of MCV4 vaccine at Grade 7, they will still need a dose at age 16. Clarification is added so that if the student was not vaccinated prior to age 16 only one dose is required. Students who have reached age 16 by September 1 have until October 1 to comply.
6. Clarify that a facility may temporarily admit a child provided that the child becomes appropriately immunized, is in-process of receiving the needed doses of vaccine, or shows proof that they have applied for an exemption for those vaccines he/she has not received

within thirty (30) calendar days after the child's original admission or by October 1 for Tdap and MCV4 vaccines at age 11 and 16 years, respectively.

Changes for College or University:

No changes.