

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

DEPARTMENT/AGENCY Department of Health  
DIVISION Immunization Section  
DIVISION DIRECTOR Dirk Haselow, M.D.  
CONTACT PERSON Hilda Douglas  
ADDRESS 4815 West Markham, Slot 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 James Phillips, M.D.  
PRESENTER E-MAIL james.phillips@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  
Room 315, State Capitol  
Little Rock, AR 72201

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1. What is the short title of this rule? Rules and Regulations Pertaining to Immunization Reporting  
Amending the rules pursuant to Act 179 of 2011 which expands reporting to the Immunization Registry to better protect the citizens of Arkansas.
2. What is the subject of the proposed rule? \_\_\_\_\_
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.

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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 Yes  No

of the Administrative Procedure Act?

5. Is this a new rule? Yes  No

If yes, please provide a brief summary explaining the regulation.

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- 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If yes, a copy of the repealed rule is to be included with your completed questionnaire.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.

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- 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."**

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6. Cite the state law that grants the authority for this proposed rule?

If codified, please give Arkansas Code citation.

Ark. Code Ann. § 20-15-1201-1203

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7. What is the purpose of this proposed rule? Why is it necessary?

To comply with Act 179 of 2011 which expands the Immunization Registry to allow reporting the administration of adult immunizations to the Department of Health after receiving consent from the adult.

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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/Pages/RulesRegulations.aspx>

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

If yes, please complete the following:

Date: 12/7/2011

Time: 9:30 a.m.

Place: Room 2508, Arkansas Department of Health, 4815 West Markham, Little Rock, AR

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10. When does the public comment period expire for permanent promulgation? (Must provide a date.)

12/7/2011

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

03/01/2012

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

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

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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 (For); Arkansas Advocates for Children and Families (For); Arkansas Pharmacists Association; Arkansas Medical Society

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**FINANCIAL IMPACT STATEMENT**

**PLEASE ANSWER ALL QUESTIONS COMPLETELY**

**DEPARTMENT** Department of Health  
**DIVISION** 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 Act 1104 of 1995, please complete the following Financial Impact Statement and file two copies with the questionnaire and proposed rules.

**SHORT TITLE OF THIS RULE** Rules and Regulations Pertaining to Immunization Reporting

1. Does this proposed, amended, or repealed rule have a financial impact? Yes  No
2. Does this proposed, amended, or repealed rule affect small businesses? Yes  No   
If yes, please attach a copy of the economic impact statement required to be filed with the Arkansas Economic Development Commission under Arkansas Code § 25-15-301 et seq.

3. If you believe that the development of a financial impact statement is so speculative as to be cost prohibited, please explain.

4. If the purpose of this rule is to implement a federal rule or regulation, please give the incremental cost for implementing the rule. Please indicate if the cost provided is the cost of the program.

**Current Fiscal Year**

General Revenue NA  
Federal Funds \_\_\_\_\_  
Cash Funds \_\_\_\_\_  
Special Revenue \_\_\_\_\_  
Other (Identify) \_\_\_\_\_  
Total \_\_\_\_\_

**Next Fiscal Year**

General Revenue NA  
Federal Funds \_\_\_\_\_  
Cash Funds \_\_\_\_\_  
Special Revenue \_\_\_\_\_  
Other (Identify) \_\_\_\_\_  
Total \_\_\_\_\_

5. What is the total estimated cost by fiscal year to any party subject to the proposed, amended, or repealed rule? Identify the party subject to the proposed rule and explain how they are affected.

**Current Fiscal Year**

\$ NA

**Next Fiscal Year**

\$ N/A

The Act and regulations permit reporting of immunizations administered to adults, but does not require reporting. Reporting will be through a web-based system currently used for children.

6. What is the total estimated cost by fiscal year to the agency to implement this rule? Is this the cost of the program or grant? Please explain.

**Current Fiscal Year**

\$ NA

**Next Fiscal Year**

\$ NA

The electronic reporting system exists for children. Allowing adult reporting will be a minimal cost.



## Arkansas Department of Health

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4815 West Markham Street • Little Rock, Arkansas 72205-3867 • Telephone (501) 661-2000  
Governor Mike Beebe  
Paul K. Halverson, DrPH, FACHE, Director and State Health Officer

### **Summary of Proposed Changes to Rules and Regulations Pertaining to Immunization Reporting**

It is proposed to revise the Rules and Regulations Pertaining to Immunization Reporting pursuant to the procedures of the Administrative Procedures Act process, as amended by the authority of Act 434 of 1967 as amended. These rules are adopted by the Arkansas Board of Health pursuant to the authority expressly conferred by the laws of the State of Arkansas including, without limitation Ark. Code Ann. §§ 20-15-1201 – 1203.

These rules are being revised pursuant to Act 179 of 2011 which expands the Immunization Registry to better protect the citizens of Arkansas. The Act allows providers to report the administration of adult immunizations to the Department of Health after receiving consent from the adult.

#### Proposed Changes

- Correct references from the Division of Health to the Department of Health.
- Delete the word “childhood” from references to the immunization registry.
- Clarify the minimum data element reporting for insurance status and previous immunizations.
- Permit providers who immunize persons age 22 years or older to register with the Department.
- Add that data regarding persons age 22 years or older may be reported by the provider to the registry upon receiving consent from the individual.
  - A Department-approved format shall be used for reporting the data.
  - Providers should submit the information within two weeks of administration.
  - Previously unreported doses, if available, should also be reported to provide a complete immunization history to the registry.
- Specify that an individual may request a copy of his/her immunization record from the Department.
- Permit electronic requests for information from the registry.
- Update the HIPAA form number from DHHS Form 4000 to AS Form 4000.
- Allow licensed daycare facilities responsible for ensuring compliance with immunization requirements read-only access to registry information upon the submission of a signed user agreement.

- Clarify penalties:
  - A provider who administers an immunization to a person under 22 years of age without fulfilling reporting requirements shall be fined \$25.
  - Any wrongful disclosure of individually identifiable health information may be considered a violation of HIPAA and may result in fines administered by the Office for Civil Rights of the U.S. Department of Health and Human Services of up to \$250,000, or imprisonment of not more than 10 years, or both. Wrongful disclosures may also result in state criminal sanctions of fines up to \$500 or imprisonment not exceeding one month, or both. In addition, civil penalties may be administered by the Board of Health of fines up to \$1,000 per violation.

MARK-UP 7-6-2011

**RULES AND REGULATIONS  
PERTAINING TO  
IMMUNIZATION REPORTING**

**Promulgated Under the Authority of  
Ark. Code Ann. §§ 20-15-1201 - 1203**

**ARKANSAS STATE BOARD OF HEALTH**

**Effective  
January 2008** MARK-UP 7/6/2011

**Arkansas Department of Health  
Little Rock, Arkansas  
(~~Dr.~~ Paul Halverson, DrPH, FACHE, Director)**

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**RULES AND REGULATIONS  
PERTAINING TO IMMUNIZATION REPORTING**

**SECTION I. AUTHORITY**

The following Rules and Regulations Pertaining to Immunization Registration are duly adopted and promulgated by the Arkansas Board of Health pursuant to the authority expressly conferred by the laws of the State of Arkansas including, without limitation, Ark. Code Ann. §§ 20-15-1201 – 1203.

**SECTION II. PURPOSE**

To protect the health of the citizens of Arkansas, these rules and regulations are necessary to establish and maintain a statewide ~~childhood~~ immunization registry and provide for the collection of data, enrollment of and reporting by Providers, and the release of immunization information. The immunization registry will serve as a repository of immunization information that may be available to an individual requesting a copy of his/her immunization record, parents or guardians of a child, Providers who report the immunization status of ~~children~~ individuals in their care, and such other persons or organizations designated by rule or regulation of the Board.

**SECTION III. DEFINITIONS**

For the purposes of these rules and regulations, the following words and phrases when used herein shall be construed as follows:

- A. “Board” means the Arkansas Board of Health;
- B. “Department” means the Arkansas Department of Health;
- C. “Section” means the Communicable Disease/Immunization Section of the Arkansas Department of Health;
- D. “Provider” means any health care professional who has direct or supervisory responsibility for the delivery of immunizations. NOTE: A school nurse or other

health official who has direct or supervisory responsibility for the delivery of immunizations falls within the definition of "health care professional"; and

- E. "Other persons or organizations" means any non-Providers who have direct or supervisory responsibility of ~~children~~ an individual whose immunization history could have a direct impact upon their admission policy as outlined by state requirements. A child care facility licensed by the state of Arkansas falls within the definition of "Other persons or organizations".

#### **SECTION IV. GENERAL REQUIREMENTS**

- A. A statewide ~~childhood~~ immunization registry shall be established and include data as specified by the Department.

1. All persons under 22 years of age receiving immunizations shall be enrolled into the registry. (As of January 1993, all newborns to Arkansas residents have been automatically enrolled.)

2. Persons age 22 years or older may be enrolled into the registry upon granting consent to the Provider.

23. The minimum data elements to be furnished by the Provider in an immunization record in the immunization registry are:

Clinic Name

Clinic Code

Name

Date of Birth

Address

Mother's Name (Maiden name preferred)

Gender

Race

Shot Type

Date Immunization Given

Provider Number

Lot Number

Insurance Status for persons under 22 years of age

~~All previous immunization if not given by the reporting Provider~~

~~Vaccine Manufacturer~~

In addition to current immunizations being reported, also report any previous immunizations even if not given by the reporting Provider.

- B. All Providers who provide immunizations to persons under 22 years of age shall register with the Department ~~if they provide immunizations to persons under twenty-~~



~~two years of age.~~ Providers who provide immunizations to persons age 22 years or older may register with the Department.

1. Enrollment:

- a. The Section shall maintain a current listing of Providers.
- b. The Section shall respond to Providers by assigning a clinic code and supplying the Provider agreement (See Section IV.B.2.) for signature by a physician or administrator.
- c. The Section's response shall also include instructions for the Provider to submit reports of doses given and make requests for immunization records.

2. Department/Provider Agreement:

A signed agreement shall be kept on file by the Section and the Provider. It shall specify the purpose for the information and outline required security/confidentiality measures. Statements on disclosure of information specifying what and how information is to be released shall be included. Providers signing the agreement will specifically certify that information will be accessed only on persons for whom they have medical responsibility.

C. All Providers shall report to the Department the administration of any childhood immunization to any person under twenty-two years of age.

1. A Department approved format for the reporting of data shall be used by all Providers to report immunizations given.
2. Providers shall submit information on immunizations provided within two weeks of administration.
3. When reporting immunizations, previous unreported doses shall also be reported to provide a complete immunization history to the registry.
4. Failure to report shall result in the Department contacting the Provider to encourage compliance. Continued non-compliance may result in sanctions not to exceed \$25.00 and/or removal from the Vaccine For Children (VFC) program.

D. Providers may report immunizations given to individuals age 22 years or older to the registry after receiving consent from the individual.

1. A Department approved format for the reporting of data shall be used by all Providers to report immunizations given.
2. Providers should submit information on immunizations provided within two weeks of administration.
3. When reporting immunizations, previous unreported doses, if available, should also be reported to provide a complete immunization history to the registry.

~~DE.~~ The Department shall upon request make information regarding the immunization status of ~~children~~ individuals in the registry available to an individual requesting a copy of his/her immunization record, the parents or legal guardians of the child, ~~to~~ Providers who report on the immunization status of ~~children~~ individuals in their care and such other persons or organizations authorized by the Board. The Section will

evaluate the written documentation requesting access to information from the registry. If the request is authorized within these regulations and criteria approved by the Board, the Section will grant access to the information.

1. Providers

- a. When written requests are used, they shall be made on letterhead and include the Provider's clinic code (if applicable), patient name, and date of birth.
- b. Phone requests shall be accepted, but only if the clinic code (if applicable) is provided along with patient name and date of birth.
- c. Faxed requests shall be submitted on letterhead and include the Provider's clinic code (if applicable), patient name and date of birth. The information shall be faxed or phoned to the numbers on file only.
- d. Electronic requests shall be accepted if they include the Provider's clinic code (if applicable), patient name and date of birth.

2. Parents/Legal Guardians of Children/Self

Parents/Legal Guardians of children/Self shall receive immunization information from the registry without providing consent for the release of information. Requests may be made in writing, in person, electronically, or by fax with requested qualifying the information.

3. Other Persons or Organizations

- a. If accompanied by a HIPAA compliant authorization to disclose on ~~DHHS Form 4000~~ AS Form 4000 signed by a parent or guardian, written requests shall be granted. The request shall include the patient name and date of birth. Information shall include the requesting party's name, mailing address, and phone number.
- b. Phone requests shall not be granted.
- c. Faxed and electronic requests shall be accompanied by a signed and dated authorization to disclose and include the patient name and date of birth. Information shall include the requesting party's name, email or mailing address, phone number, and fax number. ~~The original consent shall be mailed in following the faxed request.~~
- d. Any licensed daycare facility responsible for ensuring compliance with immunization requirements may have read-only access after the submission of a signed user agreement.
- ~~d. If a request is made by a party which does not have signed authorization to disclose for the release of records, written documentation must be submitted to the Section and satisfy the following requirements:~~
  - ~~1) HIPAA requirements for research Re. 4.512(A)~~
    - a) ~~Must demonstrate that this is a Public Health Activity as recognized by the HIPAA Privacy Regulations and approved by the DHHS HIPAA Privacy Officer.~~

7)4. Granting access to the registry does not commit the Department ~~division~~ to any expense.

~~D. Any Provider who administers an immunization to a person under 22 years of age without fulfilling the requirements of Section IV-B 1, 2 and Section IV-C 1-4 shall be fined twenty-five dollars (\$25). (See Section IV-C 4.)~~

F. Confidentiality of medical information shall be observed. The patient's name, date of birth, and immunization information shall be the only information released from the registry. No further identifying or contact information shall be disclosed.

#### **SECTION V. PENALTIES**

A. Any Provider who administers an immunization to a person under 22 years of age without fulfilling the requirements of Section IV-B 1, 2 and Section IV-C 1-4 shall be fined twenty-five dollars (\$25). (See Section IV-C 4.)

B. Any wrongful disclosure of individually identifiable health information may be considered a violation of HIPAA (42 USC 1320d-6) and may result in fines administered by the Office for Civil Rights of the U.S. Department of Health and Human Services of up to \$250,000, or imprisonment of not more than 10 years, or both. Wrongful disclosures may also result in state criminal sanctions of fines up to \$500.00 or imprisonment not exceeding one (1) month, or both. In addition, civil penalties may be administered by the State Board of Health of fines up to \$1, 000 per violation.

#### **SECTION ~~V~~ VI. SEVERABILITY**

If any provision of these rules and regulations, or the application thereof to any person or circumstances is held invalid, such invalidity shall not affect other provisions or applications of these rules and regulations which can give effect without the invalid provisions or applications, and to this end the provisions hereto are declared to be severable.

#### **SECTION ~~VI~~ VII. REPEAL**

All regulations in conflict herewith are hereby repealed.

#### **CERTIFICATION**

This will certify that the foregoing Rules and Regulations for immunization reporting were adopted by the Arkansas Board of Health at a regular session of the Board held in Little Rock, Arkansas on the 1<sup>st</sup> day of November, 2007.

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Paul Halverson, DrPH, FACHE, Secretary  
Arkansas State Board of Health

MARK-UP 7/6/2011

~~A copy of the foregoing Rules and Regulations, copy having been filed in my the appropriate state office, are hereby approved on this \_\_\_ day of \_\_\_\_\_, 2007.~~

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~~Mike Beebe  
Governor~~