



## 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.

**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.

~~D~~E. 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