

# ILLINOIS REGISTER

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## DEPARTMENT OF PUBLIC HEALTH

### NOTICE OF PROPOSED AMENDMENT

- 1) Heading of the Part: Immunization Code
- 2) Code Citation: 77 Ill. Adm. Code 695
- 3) 

<u>Section Number:</u> 695.10	<u>Proposed Action:</u> Amend
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- 4) Statutory Authority: Implementing and authorized by the Communicable Disease Prevention Act [410 ILCS 315], Section 27-8.1 of the School Code [105 ILCS 5/27-8.1] and Section 7 of the Child Care Act of 1969 [225 ILCS 10/7].
- 5) A Complete Description of the Subjects and Issues Involved: Existing rules specify required immunizations, physical examinations, and acceptable exemptions for children attending child care facilities, children entering school-operated programs below the kindergarten level and kindergarten through 12<sup>th</sup> grade. Proposed changes in this rulemaking will modify existing requirements to align with current accepted clinical practices as recommended by the Advisory Committee on Immunization Practices (ACIP), the American Academy of Pediatrics (AAP) and the Academy of Family Physicians (AFP). In March 2013, ACIP updated their recommendations for the prevention and control of meningococcal disease. Meningococcal disease can cause severe and devastating illness. The burden of disease is highest among infants aged less than one year, young adults aged 16 through 21 years, and persons aged 65 years or older. The vaccines licensed currently are recommended routinely for adolescents and other persons at increased risk for meningococcal disease. ACIP recommends routine administration of a MenACWY vaccine for all persons aged 11 through 18 years. A single booster dose recommendation is based on age and risk factors.

Public Act 098-0480 was signed into law on August 16, 2013 and provides the Department of Public Health with the authority to prescribe rules requiring students entering the sixth and 12th grade of any public, private, or parochial school, to receive an immunization containing meningococcal conjugate vaccine that meets the standards approved by the U.S. Public Health Service for such biological products and is in accordance with the recommendations of the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices. The immunization shall consist of one dose of the MCV4 vaccine for 6th grade entrance and two doses for 12th grade entrance, unless the first dose was administered to a child who was 16 years of age or older, in which case only one dose is required at 12th grade entrance. Existing Illinois standards for parental or legal guardian objections or medical objections are applicable. The economic effect of this proposed rulemaking is unknown. Therefore, the Department requests any information that would assist in calculating this effect. However, all

ILLINOIS REGISTER

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DEPARTMENT OF PUBLIC HEALTH

NOTICE OF PROPOSED AMENDMENT

vaccines are readily available through the federal Vaccines for Children (VFC) program administered by the Department.

The Department anticipates adoption of this rulemaking approximately six to nine months after publication of the Notice in the *Illinois Register*.

- 6) Published studies or reports, and sources of underlying data used to compose this rulemaking: CDC. Prevention and Control of Meningococcal Disease: Recommendations of the Advisory Committee on Immunization Practices (ACIP); MMWR 2005; 54 (No. RR-7); CDC. Licensure of a Meningococcal Conjugate Vaccine for Children Aged 2 Through 10 Years and Updated Booster Dose Guidance for Adolescents and Other Persons at Increased Risk for Meningococcal Disease - Advisory Committee on Immunization Practices (ACIP); MMWR 2011; 60:1018-1019 CDC. Update Recommendations for use of meningococcal conjugate vaccines - Advisory Committee on Immunization Practices (ACIP); MMWR 2011; 60:72-76 CDC. Prevention and Control of Meningococcal Disease: Recommendations of the Advisory Committee on Immunization Practices (ACIP); MMWR 2013; 62 (No. RR-2);
- 7) Will this rulemaking replace any emergency rulemaking currently in effect? No
- 8) Does this rulemaking contain an automatic repeal date? No
- 9) Does this rulemaking contain incorporations by reference? No
- 10) Are there any other proposed rulemakings pending on this Part? No
- 11) Statement of Statewide Policy Objectives: This rulemaking does not create or expand any state mandates on units of local government.
- 12) Time, Place and Manner in which interested persons may comment on this proposed rulemaking:

Interested persons may present their comments concerning this rulemaking within 45 days after the publication of this issue of the *Illinois Register* to:

Susan Meister  
Division of Legal Services  
Illinois Department of Public Health  
535 W. Jefferson St., 5<sup>th</sup> floor  
Springfield, Illinois 62761

ILLINOIS REGISTER

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DEPARTMENT OF PUBLIC HEALTH

NOTICE OF PROPOSED AMENDMENT

217/782-2043

e-mail: [dph.rules@illinois.gov](mailto:dph.rules@illinois.gov)

13) Initial Regulatory Flexibility Analysis:

- A) Types of small businesses, small municipalities and not for profit corporations affected: These immunization rules will not have a direct impact on these stated entities. An indirect impact could occur to employer-provided health care coverage for the requirement for additional vaccination protection for children attending kindergarten through 12th grades. However, the Department sponsors a Vaccines For Children (VFC) Plus program, which addresses vaccination needs for under-insured children. This is in addition to the All Kids program, operated by the Department of Healthcare and Family Services.
- B) Reporting, bookkeeping or other procedures required for compliance: Health care providers administering vaccinations are expected to record the following information as documentation for any vaccination provided: the type of vaccine, date administered, vaccine manufacturer, vaccine lot number and the date of the Vaccine Information Statement provided to the patient at the time of the vaccination.

Schools and child care facilities are required to monitor compliance with physical examinations and immunization requirements as noted in Section 27-8.1 of the School Code [105 ILCS 5/27-8.1] and the Child Care Act of 1969 [225 ILCS 10/7]. The proposed amendments revise language to assure consistency with current medical practice, national vaccination scheduling recommendations and alignment with statutory requirements created by P.A. 95-0159.

- C) Types of professional skills necessary for compliance: Only licensed medical professionals can administer vaccinations.

14) Regulatory Agenda on which this rulemaking was summarized: January 2014

The full text of the Proposed Amendment begins on the next page:

ILLINOIS REGISTER

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DEPARTMENT OF PUBLIC HEALTH

NOTICE OF PROPOSED AMENDMENT

TITLE 77: PUBLIC HEALTH

CHAPTER I: DEPARTMENT OF PUBLIC HEALTH

SUBCHAPTER k: COMMUNICABLE DISEASE CONTROL AND IMMUNIZATIONS

PART 695

IMMUNIZATION CODE

Section

695.5	Definitions
695.7	Referenced Materials
695.10	Basic Immunization
695.20	Booster Immunizations
695.30	Exceptions
695.40	List of Non-Immunized Child Care Facility Attendees or Students
695.50	Proof of Immunity
695.APPENDIX A	Vaccination Schedule for Haemophilus influenzae type b Conjugate Vaccines (Hib)
695.APPENDIX B	Vaccination Schedule for Pneumococcal Conjugate Vaccines (PCV13)

**AUTHORITY:** Implementing and authorized by the Communicable Disease Prevention Act [410 ILCS 315], Section 27-8.1 of the School Code [105 ILCS 5/27-8.1], and Section 7 of the Child Care Act of 1969 [225 ILCS 10/7].

**SOURCE:** Emergency amendment effective June 23, 1977; emergency amendment at 3 Ill. Reg. 14, p. 88, effective March 21, 1979, for a maximum of 150 days; amended at 3 Ill. Reg. 52, p. 134, effective December 17, 1979; codified at 8 Ill. Reg. 4512; amended at 11 Ill. Reg. 11799, effective June 29, 1987; emergency amendment at 14 Ill. Reg. 5890, effective March 30, 1990, for a maximum of 150 days; amended at 14 Ill. Reg. 14562, effective August 27, 1990; amended at 15 Ill. Reg. 7712, effective May 1, 1991; amended at 17 Ill. Reg. 2975, effective February 11, 1993; amended at 20 Ill. Reg. 11962, effective August 15, 1996; emergency amendment at 21 Ill. Reg. 11973, effective August 15, 1997, for a maximum of 150 days; emergency expired on January 11, 1998; amended at 26 Ill. Reg. 5930, effective July 1, 2002; amended at 26 Ill. Reg. 10792, effective July 1, 2002; amended at 37 Ill. Reg. 13929, effective August 16, 2013; amended at 38 Ill. Reg. \_\_\_\_\_, effective \_\_\_\_\_.

**Section 695.10 Basic Immunization**

- a) The optimum starting ages for the specified immunizing procedures are as

# ILLINOIS REGISTER

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## DEPARTMENT OF PUBLIC HEALTH

### NOTICE OF PROPOSED AMENDMENT

follows:

- 1) Diphtheria – two to four months
  - 2) Pertussis – two to four months, combined with tetanus toxoid
  - 3) Tetanus – two to four months
  - 4) Poliomyelitis – two to four months
  - 5) Measles – 12 to 15 months
  - 6) Rubella – 12 to 15 months
  - 7) Mumps – 12 to 15 months
  - 8) Haemophilus – two to four months influenzae type b
  - 9) Hepatitis B – birth ~~Birth~~ to two months
  - 10) Varicella – 12 to 18 months
  - 11) Invasive Pneumococcal disease (except as noted in subsection (1)) – two to four months
  - 12) Meningococcal Disease – six months to two years
- b) Upon first entering a child care facility, all children two months of age and older shall show proof that the child has been immunized, or is in the process of being immunized, according to the recommended schedule, against diphtheria, pertussis, tetanus, polio, measles, mumps, rubella, Haemophilus influenzae type b, hepatitis B, varicella, and invasive pneumococcal disease.
- c) All children entering school programs in Illinois for the first time shall show proof of immunity against:
- 1) Diphtheria

ILLINOIS REGISTER

---

DEPARTMENT OF PUBLIC HEALTH

NOTICE OF PROPOSED AMENDMENT

- 2) Pertussis (except as noted in subsection (d))
  - 3) Tetanus
  - 4) Poliomyelitis
  - 5) Measles (except as noted in subsection (f))
  - 6) Rubella
  - 7) Mumps
  - 8) Haemophilus influenzae type b (except as noted in subsection (i))
  - 9) Hepatitis B (except as noted in subsection (j))
  - 10) Varicella (except as noted in subsection (k))
  - 11) Invasive pneumococcal disease (except as noted in subsection (l))
  - 12) Meningococcal Disease (except as noted in subsection (m))
- d) Diphtheria, Tetanus, Pertussis
- 1) Any child entering a child care facility or school program below the kindergarten level shall show proof of having received three doses of Diphtheria, Tetanus, Pertussis (DTP or DTaP) vaccine by one year of age and one additional dose by the second birthday. The first three doses in the series shall have been received no less than four weeks (28 days) apart. The interval between the third and fourth doses shall be at least six months. Any child 24 months of age or older shall show proof of four doses of DTP or DTaP vaccine, appropriately spaced.
  - 2) Any child entering school (kindergarten or first grade) for the first time shall show proof of having received four or more doses of Diphtheria, Tetanus, Pertussis (DTP or DTaP) vaccine, with the last dose being a booster and having been received on or after the fourth birthday. The first three doses in the series shall have been received no less than four weeks

# ILLINOIS REGISTER

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## DEPARTMENT OF PUBLIC HEALTH

### NOTICE OF PROPOSED AMENDMENT

(28 days) apart. The interval between the third and fourth doses shall be at least six months. Children six years of age or older may receive adult Tetanus, Diphtheria (Td) vaccine in lieu of DTP or DTaP vaccine.

- 3) Any child entering school at a grade level not included in subsection (d)(1) or (2) shall show proof of having received three or more doses of DTP, DTaP, pediatric DT or adult Tetanus, Diphtheria (Td), with the last dose being a booster and having been received on or after the fourth birthday. The first two doses in the series shall have been received no less than four weeks (28 days) apart. The interval between the second and third doses shall be at least 6 months.
  - 4) Receipt of pediatric Diphtheria, Tetanus (DT) vaccine in lieu of DTP or DTaP is acceptable only if the pertussis component of the vaccine is medically contraindicated. Documentation of the medical contraindication shall be verified as specified in Section 695.30.
  - 5) Beginning with school year 2011-2012, any child entering sixth grade shall show proof of receiving one dose of Tdap (defined as tetanus, diphtheria, acellular pertussis) vaccine regardless of the interval since the last DTaP, DT or Td dose.
  - 6) Students entering grades seven through 12 who have not already received Tdap are required to receive only one Tdap dose regardless of the interval since the last DTaP, DT or Td dose.
  - 7) For students attending school programs in which grade levels (kindergarten through 12) are not assigned, including special education programs, proof of one dose of Tdap vaccine as described in subsection (d)(5) shall be submitted prior to the school years in which the child reaches the ages of 11 and 15.
  - 8) School-age children entering a child care facility shall comply with the immunization requirements in subsections (d)(2), (3), (4) and (5).
- e) Polio
- 1) Any child entering a child care facility or school program below the

# ILLINOIS REGISTER

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## DEPARTMENT OF PUBLIC HEALTH

### NOTICE OF PROPOSED AMENDMENT

kindergarten level shall show proof of having received two doses of polio vaccine (defined as oral poliovirus vaccine (OPV) or inactivated poliovirus vaccine (IPV)) by one year of age and a third dose by the second birthday. Doses in the series shall have been received no less than four weeks (28 days) apart. Any child 24 months of age or older shall show proof of at least three doses of polio vaccine, appropriately spaced.

- 2) Any child entering school at any grade level, kindergarten through 12, shall show proof of having received three or more doses of polio vaccine (defined as oral poliovirus vaccine (OPV) or inactivated poliovirus vaccine (IPV)). A child who received any combination of IPV and OPV shall show proof of having received at least four doses, with the last dose having been received on or after the fourth birthday. Doses in the series shall have been received no less than four weeks (28 days) apart. A child who received IPV exclusively or OPV exclusively shall show proof of having received at least three doses, with the last dose having been received on or after the fourth birthday. Doses in the series shall have been received no less than four weeks (28 days) apart.
- 3) School-age children entering a child care facility shall comply with the immunization requirements in subsection (e)(2).

f) Measles

- 1) Any child entering a child care facility or school program below the kindergarten level shall show proof of having received one dose of live measles virus vaccine by the second birthday. The measles vaccine shall have been received on or after the first birthday.
- 2) The child shall:
  - A) Show proof that he or she has been age-appropriately immunized against measles prior to entering a child care facility or school, including school programs below the kindergarten level, for the first time; or
  - B) Present a statement from the physician that he or she has had measles as noted in Section 695.50(c); or



ILLINOIS REGISTER

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DEPARTMENT OF PUBLIC HEALTH

NOTICE OF PROPOSED AMENDMENT

- C) Present laboratory evidence of measles immunity.
  - 3) Children entering school at any grade level, kindergarten through-12, shall show proof of having received two doses of live measles virus vaccine, the first dose on or after the first birthday and the second dose no less than four weeks (28 days) after the first dose, or other proof of immunity as described in this Part.
  - 4) For students attending school programs where grade levels (kindergarten through 12) are not assigned, including special education programs, proof of two doses of live measles virus vaccine as described in subsection (f)(3) shall be submitted prior to the school years in which the child reaches the ages of five, 11 and 15.
  - 5) School-age children entering a child care facility shall comply with the immunization requirements in subsections (f)(2), (3) and (4).
- g) Mumps
- 1) Any child entering a child care facility or school program below the kindergarten level shall show proof of having received one dose of live mumps virus vaccine by the second birthday. The mumps vaccine shall have been received on or after the first birthday.
  - 2) The child shall:
    - A) Show proof that he or she has been age-appropriately immunized against mumps prior to entering a child care facility or school, including school programs below the kindergarten level, for the first time; or
    - B) Present a statement from the physician that he or she has had mumps as noted in Section 695.50(e); or
    - C) Present laboratory evidence of mumps immunity (see Section 695.50(e)).
  - 3) Beginning with the school year 2014-2015, children entering school at any

# ILLINOIS REGISTER

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## DEPARTMENT OF PUBLIC HEALTH

### NOTICE OF PROPOSED AMENDMENT

grade level, kindergarten through 12, shall show proof of having received two doses of live mumps virus vaccine, the first dose on or after the first birthday and the second dose no less than four weeks (28 days) after the first dose, or other proof of immunity as described in this Part.

- 4) Only those children who have been immunized with live mumps virus vaccine on or after the first birthday, have had physician diagnosed mumps disease, or show laboratory evidence of immunity shall be considered to be immune.
- 5) For students attending school programs where grade levels (kindergarten through 12) are not assigned, including special education programs, proof of two doses of live mumps virus vaccine as described in subsection (f)(3) shall be submitted prior to the school years in which the child reaches the ages of five, 11 and 15.
- 6) School-age children entering a child care facility shall comply with the immunization requirements in subsections (g)(2), (3) and (4).

#### h) Rubella

- 1) Any child entering a child care facility or school program below the kindergarten level shall show proof of having received one dose of live rubella virus vaccine by the second birthday. The rubella vaccine shall have been received on or after the first birthday.
- 2) The child shall:
  - A) Show proof that he or she has been age-appropriately immunized against rubella prior to entering a child care facility or school, including school programs below the kindergarten level, for the first time; or
  - B) Present ~~present~~ laboratory evidence of immunity to rubella.
- 3) Beginning with the school year 2014-2015, children entering school at any grade level, kindergarten through 12, shall show proof of having received two doses of live rubella virus vaccine, the first dose on or after the first

ILLINOIS REGISTER

---

DEPARTMENT OF PUBLIC HEALTH

NOTICE OF PROPOSED AMENDMENT

birthday and the second dose no less than four weeks (28 days) after the first dose, or other proof of immunity as described in this Part.

- 4) Only those children who have been immunized with rubella vaccine on or after the first birthday, or have a laboratory (serologic) evidence of immunity to rubella, shall be considered to be immune.
  - 5) For students attending school programs where grade levels (kindergarten through 12) are not assigned, including special education programs, proof of two doses of live rubella virus vaccine as described in subsection (f)(3) shall be submitted prior to the school years in which the child reaches the ages of five, 11 and 15.
  - 6) School-age children entering a child care facility shall comply with the immunization requirements in subsections (h)(2), (3) and (4).
- i) Haemophilus influenzae type b (Hib)
- 1) Any child under five years of age entering a child care facility or school program below the kindergarten level shall show proof of immunization that complies with the Hib vaccination schedule in Appendix A of this Part.
  - 2) Children 24 to 59 months of age who have not received the primary series of Hib vaccine, according to the Hib vaccination schedule, shall show proof of receiving one dose of Hib vaccine at 15 months of age or older.
  - 3) Any child who has reached his or her fifth birthday shall not be required to provide proof of immunization with Hib vaccine.
- j) Hepatitis B
- 1) Any child two years of age or older enrolling in a child care facility or school program below the kindergarten level shall show proof of having received three doses of hepatitis B vaccine. The first two doses shall have been received no less than four weeks (28 days) apart. The interval between the second and third doses shall be at least two months. The interval between the first and the third doses shall be at least four months.

## ILLINOIS REGISTER

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### DEPARTMENT OF PUBLIC HEALTH

#### NOTICE OF PROPOSED AMENDMENT

The third dose shall have been administered on or after six months of age.  
The child shall:

- A) Show proof that he or she has been age-appropriately immunized against hepatitis B prior to enrolling in a child care facility or school program below the kindergarten level for the first time; or
  - B) Present laboratory evidence of prior or current hepatitis B infection.
- 2) Children entering the sixth grade shall show proof of having received three doses of hepatitis B vaccine. The first two doses shall have been received no less than four weeks (28 days) apart. The interval between the second and third dose must be at least 2 months. The interval between the first dose and the third shall be at least four months. Proof of prior or current infection, if verified by laboratory evidence, may be substituted for proof of vaccination (see Section 695.50(f)).
  - 3) The third dose of hepatitis B vaccine is not required if it can be documented that the child received two doses of adult formulation Recombivax-HB vaccine (10 mcg), the child was 11 to 15 years of age at the time of vaccine administration, and the interval between receipt of the two doses was at least four months.
  - 4) Only those children who have been immunized with hepatitis B vaccine in accordance with subsections (j)(1), (2) and (3) or have laboratory evidence of prior or current hepatitis B infection shall be considered immune.
  - 5) School-age children entering a child care facility shall comply with the immunization requirements in this subsection (j).
- k) Varicella
- 1) Any child two years of age or older entering a child care facility or school program below the kindergarten level shall show proof of having received one dose of varicella vaccine or other proof of immunity as specified in Section 695.50(g). The varicella vaccine shall have been received on or after the first birthday.

ILLINOIS REGISTER

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DEPARTMENT OF PUBLIC HEALTH

NOTICE OF PROPOSED AMENDMENT

- 2) The child shall:
  - A) Show proof that he or she has been age-appropriately immunized against varicella prior to entering a child care facility or school program below the kindergarten level for the first time, or
  - B) Present a statement from a physician verifying that the child has had varicella, or
  - C) Present a statement from a health care provider (as defined in Section 695.50(a)) verifying that a parent's or legal guardian's description of varicella disease history is indicative of past infection, or
  - D) Present laboratory evidence of immunity to varicella.
- 3) Children who entered kindergarten for the first time on or after July 1, 2002 shall show proof of having received one dose of varicella vaccine on or after the first birthday or other proof of immunity as specified in Section 695.50(g).
- 4) Beginning with the school year 2014-2015, any child entering kindergarten, sixth grade or ninth grade for the first time shall show proof of having received two doses of varicella vaccine, the first dose on or after the first birthday and the second dose no less than four weeks (28 days) after the first, or other proof of immunity as specified in Section 695.50(g).
- 5) Only those children who have been immunized with varicella vaccine in accordance with subsections (k)(1), (2)(A), (3) and (4), have had physician diagnosed varicella disease, have a health care provider's interpretation that a parent's or legal guardian's description of varicella disease history is indicative of past infection, or have laboratory evidence of immunity shall be considered to be immune.
- 6) For students attending school programs where grade levels (kindergarten through 12) are not assigned, including special education programs, proof of two doses of varicella vaccine as described in subsections (k)(3) and (4)

# ILLINOIS REGISTER

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## DEPARTMENT OF PUBLIC HEALTH

### NOTICE OF PROPOSED AMENDMENT

shall be submitted prior to the school years in which the child reaches the ages of five, 11 and 15.

- 7) School-age children entering a child care facility shall comply with the immunization requirements in subsections (k)(2), (3) and (4).

#### l) Invasive Pneumococcal Disease

- 1) Any child under two years of age entering a child care facility or school program below the kindergarten level shall show proof of immunization that complies with the pneumococcal vaccination schedule in Appendix B.
- 2) Children 24 to 59 months of age who have not received the primary series of pneumococcal conjugate vaccine, according to the recommended vaccination schedule, shall show proof of receiving one dose of pneumococcal vaccine.
- 3) Any child who has reached his or her fifth birthday shall not be required to provide proof of immunization with pneumococcal conjugate vaccine.

#### m) Meningococcal Disease

- 1) Beginning with the school year 2015-2016, any child entering the sixth grade shall show proof of having received one dose of meningococcal conjugate vaccine on or after the 11<sup>th</sup> birthday.
- 2) Beginning with the school year 2015-2016, any child entering the 12<sup>th</sup> grade shall show proof of receiving two doses of meningococcal conjugate vaccine prior to entering the 12<sup>th</sup> grade. The first dose shall have been received on or after the 11<sup>th</sup> birthday, and the second dose shall have been received at least eight weeks after the first dose. If the first dose is administered when the child is 16 years of age or older, only one dose is required.
- 3) For students attending school programs where grade levels (kindergarten through 12) are not assigned, including special education programs, proof of having received one dose of meningococcal conjugate vaccine shall be submitted prior to the school year in which the child reaches age 11

ILLINOIS REGISTER

---

DEPARTMENT OF PUBLIC HEALTH

NOTICE OF PROPOSED AMENDMENT

and a second dose prior to the school year in which the child reaches age 15.

n)m The requirements of this Section also apply to children who transfer into Illinois child care facilities, school programs, and schools from other states, regardless of the age or grade level at which the child transfers.

(Source: Amended at 38 Ill. Reg. \_\_\_\_\_, effective \_\_\_\_\_)