

ILLINOIS REGISTER

DEPARTMENT OF PUBLIC HEALTH

NOTICE OF PROPOSED AMENDMENTS

- 1) Heading of the Part: College Immunization Code
- 2) Code Citation: 77 Ill. Adm. Code 694
- 3)

<u>Section Numbers:</u>	<u>Proposed Actions:</u>
694.10	Repealed
694.20	Amendment
694.30	New Section
694.100	Amendment
694.110	Amendment
694.200	Amendment
694.APPENDIX C	Amendment
- 4) Statutory Authority: College Student Immunization Act [110 ILCS 20].
- 5) A Complete Description of the Subjects and Issues Involved: This rulemaking proposes changes to the vaccination requirements for incoming college students at Illinois higher education institutions. Specifically, the rulemakings seeks to add a vaccination requirement for meningococcal disease (one dose of meningococcal vaccine on or after 16th birthday) and for pertussis (students must have received at least one dose of Tdap within previous 10 years) and will require college students to show proof of receipt of two doses of rubella, mumps-containing vaccines. The vaccination requirements will take effect beginning with the 2016-17 Fall term. The proposed amendments seek to align Illinois college vaccination requirements with current accepted clinical practices as recommended by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices (ACIP), the American Academy of Pediatrics (AAP) and the Academy of Family Physicians (AFP).

The economic effect on this proposed rulemaking is unknown. Therefore, the Department requests any information that would assist in calculating this effect. However, all vaccines are readily available through the federal Vaccines for Children (VFC) program administered by the Department.

The Department anticipates adoption of this rulemaking approximately three 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. Updated Recommendations of the Advisory Committee on Immunization Practices (ACIP) for the Control and Elimination of Mumps; MMWR 2006; 55 (No. 22)

ILLINOIS REGISTER

DEPARTMENT OF PUBLIC HEALTH

NOTICE OF PROPOSED AMENDMENTS

CDC. Vaccine Use and Strategies for Elimination of Measles, Rubella, and Congenital Rubella Syndrome and Control of Mumps: Recommendations of the Advisory Committee on Immunization Practices (ACIP); MMWR 1998; 47 (No. RR-8)

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 neither creates nor expands 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:

Elizabeth Paton
Assistant General Counsel
Division of Legal Services
Illinois Department of Public Health
535 W. Jefferson St., 5th floor
Springfield, Illinois 62761

ILLINOIS REGISTER

DEPARTMENT OF PUBLIC HEALTH

NOTICE OF PROPOSED AMENDMENTS

(217) 782-2043

e-mail: 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 students attending college. However, the Department sponsors a Vaccines For Children (VFC) program, which addresses vaccination needs for under-insured children through age 18 years and a Vaccines For Adults (VFA) program for adults to address the needs of under-insured and uninsured adults.
- 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.

Colleges and universities with on-campus student housing are required to monitor compliance with immunization requirements as noted in the College Student Immunization. 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. 86-1324 and 85-1315.

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

14) Regulatory Agenda on which this rulemaking was summarized: July 2015

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

ILLINOIS REGISTER

DEPARTMENT OF PUBLIC HEALTH

NOTICE OF PROPOSED AMENDMENTS

TITLE 77: PUBLIC HEALTH

CHAPTER I: DEPARTMENT OF PUBLIC HEALTH

SUBCHAPTER k: COMMUNICABLE DISEASE CONTROL AND IMMUNIZATIONS

PART 694

COLLEGE IMMUNIZATION CODE

SUBPART A: GENERAL PROVISIONS

Section

694.10	Purpose (Repealed)
694.20	Definitions
694.30	Referenced Materials

SUBPART B: IMMUNIZATION REQUIREMENTS

Section

694.100	Proof of Immunity
694.110	Record Keeping
694.120	Completion and Submission of the Summary Report

SUBPART C: EXEMPTIONS

Section

694.200	Medical Exemption
694.210	Religious Exemption
694.220	Classification Exemption

694.APPENDIX A	Certificate of Immunity Form (Repealed)
694.APPENDIX B	Summary Report of the Immunization Status of College/University Students (Repealed)
694.APPENDIX C	Required Elements of Health Record

AUTHORITY: Implementing and authorized by the College Student Immunization Act [110 ILCS 20].

SOURCE: Adopted at 14 Ill. Reg. 1609, effective January 19, 1990; emergency amendment at 14 Ill. Reg. 5882, effective March 30, 1990, for a maximum of 150 days; amended at 14 Ill. Reg. 14551, effective August 27, 1990; amended at 16 Ill. Reg. 5916, effective March 31, 1992; amended at 17 Ill. Reg. 2306, effective February 11, 1993; amended at 19 Ill. Reg. 3584,

ILLINOIS REGISTER

DEPARTMENT OF PUBLIC HEALTH

NOTICE OF PROPOSED AMENDMENTS

effective February 10, 1996; amended at 26 Ill. Reg. 10784, effective July 1, 2002; amended at 40 Ill. Reg. _____, effective _____.

SUBPART A: GENERAL PROVISIONS

Section 694.10 Purpose (Repealed)

~~The purpose of immunization requirements for public and private colleges and universities is to prevent the introduction and spread of vaccine-preventable diseases among students and the secondary spread of such diseases into the surrounding community. This Part specifies the circumstances under which proof of immunization shall be required for enrollment in a public or private college or university.~~

(Source: Repealed at 40 Ill. Reg. _____, effective _____)

Section 694.20 Definitions

"Act" means the College Student Immunization Act ~~[110 ILCS 20]~~.

"Advanced practice nurse" means a person who is licensed as an advanced practice nurse under the Nurse Practice Act.

"Certificate of immunity" means a form acceptable to a post-secondary educational institution signed by a health care provider who has administered an immunizing agent to a student (or has reviewed health records evidencing such administration), specifying the vaccine administered and the date of administration.

"Department" means the Illinois Department of Public Health. (Section 1(a) of the Act)

"Designated recordkeeping office" means the office designated by a post-secondary educational institution as responsible for maintaining student immunization records. In institutions with health services, that office shall be the designated office of record.

"Enroll" means the student is a bona fide member of the post-secondary educational institution's student body receiving academic credit for on-campus instruction.

ILLINOIS REGISTER

DEPARTMENT OF PUBLIC HEALTH

NOTICE OF PROPOSED AMENDMENTS

"Health care provider" means a physician licensed to practice medicine in all of its branches (M.D. or D.O.), advanced practice nurse, physician assistant, pharmacist, local health authority, registered nurse employed by a school, college or university, or a Department recognized vaccine provider.

"Pharmacist" means a person who is licensed to practice pharmacy under the Pharmacy Practice Act.

"Physician" means a physician licensed to practice medicine in all of its branches (M.D. or D.O.).

"Physician assistant" means a person who is licensed as a physician assistant under the Physician Assistant Practice Act of 1987.

"Post-secondary educational institution" means a public or private college or university offering degrees and instruction above the high school level, and shall include, but not be limited to,

Any and all private colleges and universities; the University of Illinois; Southern Illinois University; Chicago State University; Eastern Illinois University; Governors State University; Illinois State University; Northeastern Illinois University; Northern Illinois University; Western Illinois University; and any other public university now or hereafter established or authorized by the General Assembly; except that a post-secondary educational institution does not mean or include any public college or university that does not provide on-campus housing for its students in dormitories or equivalent facilities that are owned, operated, and maintained by the public college or university.

The term shall not include any public or private junior or community college (i.e., any public or private degree-granting institution at which the highest degree offered is an associate degree or an undergraduate certificate of two years or less), or any post-secondary educational institution at which the highest award offered is a diploma or certificate of two years or less, or any institution offering degrees and instruction which utilizes correspondence as its primary mode of student instruction.
(Section 1(b) of the Act)

"Proof of immunity" means evidence of appropriate immunization, ~~physician diagnosed disease,~~ or laboratory evidence of immunity~~immunization~~ documented

ILLINOIS REGISTER

DEPARTMENT OF PUBLIC HEALTH

NOTICE OF PROPOSED AMENDMENTS

in writing by a health care provider in accordance with the requirements of this Part. Laboratory evidence applies to measles, mumps and rubella only. The content of the immunization record form ~~used~~utilized by an institution shall include, as a minimum, the basic elements listed in Appendix C.

"Student health record" means a record containing the immunization status of a student relating to the vaccine-preventable diseases covered by this Part. The content of the immunization record form ~~used~~utilized by an institution shall include, as a minimum, the basic elements listed in Appendix C.

"Summary report" means a form developed by the Department for gathering statistical information on the number of students enrolled at a post-secondary educational institution, the number with proof of immunity, the number with medical or religious exemptions, and the number without proof of immunity or such exemptions.

"Term" means any period of on-campus instruction offered by a post-secondary educational institution. Students enrolling for the first time during a special term of less than the traditional duration (Summer Session, Interim, Intersession, etc.) may be permitted to enroll in an immediate following term of traditional length before providing proof of immunity in accordance with this Part.

(Source: Amended at 40 Ill. Reg. _____, effective _____)

Section 694.30 Referenced Materials

The following materials are referenced in this Part:

- a) Nurse Practice Act [225 ILCS 65]
- b) Pharmacy Practice Act [225 ILCS 85]
- c) Physician Assistant Practice Act of 1987 [225 ILCS 95]
- d) Family Educational Rights and Privacy Act of 1974 (20 USC 1232g) and 34 CFR 99.36.

(Source: Added at 40 Ill. Reg. _____, effective _____)

SUBPART B: IMMUNIZATION REQUIREMENTS

ILLINOIS REGISTER

DEPARTMENT OF PUBLIC HEALTH

NOTICE OF PROPOSED AMENDMENTS

Section 694.100 Proof of Immunity

- a) Beginning with the Fall term 2016-2017, students who enroll at a post-secondary educational institution shall present to the designated recordkeeping office proof of immunity evidencing the following immunizations:

1) Diphtheria, Tetanus, Pertussis

~~A)~~ ~~Students not considered international students, pursuant to subsection (b), are required to provide proof of at least one dose of Tetanus and Diphtheria (Td) vaccine having been received within 10 years of the term of current enrollment. (It is recommended that the student provide dates of at least 2 previous doses of any combination of Diphtheria, Tetanus, and Pertussis (DTP or DTaP), pediatric Diphtheria and Tetanus (DT) or adult Tetanus and Diphtheria (Td) vaccine.)~~

AB) ~~Students shall~~ ~~International students are required to~~ provide dates of any combination of three or more doses of Diphtheria, Tetanus, and Pertussis containing vaccine. One dose must be Tdap vaccine. The last dose must have been ~~(DTP or DTaP), pediatric Diphtheria and Tetanus (DT) or adult Tetanus and Diphtheria (Td) vaccine, with the most recent dose having been~~ received within 10 years prior to the term of current enrollment.

BC) The minimum time interval between the first and second dose must have been at least four~~4~~ weeks (28 days), with the third dose having been received at least six~~6~~ months after the second or last dose of the basic series.

CD) Receipt of Tetanus Toxoid (T.T.) vaccine is not acceptable in fulfilling this requirement.

2) Measles

A) Students ~~shall~~must provide documentation of receipt of two~~2~~ doses of live measles virus vaccine on or after the first birthday. The minimum time interval between each dose must have been at least four~~4~~ weeks (28 days). If either dose was received prior to 1968,

ILLINOIS REGISTER

DEPARTMENT OF PUBLIC HEALTH

NOTICE OF PROPOSED AMENDMENTS

proof must be provided that a live virus vaccine, without gamma globulin, was administered.

~~B) Those students attending a post-secondary educational institution prior to the Fall 1990 term, who have had at least one dose of live measles virus vaccine on or after the first birthday, may be considered protected and in compliance.~~

~~B) Students who cannot provide proof of immunization may provide laboratory (serologic) evidence of measles immunity; or a physician's signed confirmation of disease history and date of conclusive diagnosis. A diagnosis of measles disease made by a physician on or after July 1, 2002 must be confirmed by laboratory evidence.~~

3) Rubella

~~A) Students shall provide documentation of receipt of two doses of live rubella virus vaccine on or after the first birthday. The minimum time interval between each dose must have been at least four weeks (28 days). Immunization with rubella vaccine on or after the first birthday;~~

~~B) Students who cannot provide proof of immunization may provide laboratory Laboratory (serologic) evidence of rubella immunity; or~~

~~C) History of disease is not acceptable as proof of immunity.~~

4) Mumps

~~A) Students shall provide documentation of receipt of two doses of live mumps virus vaccine on or after the first birthday. The minimum time interval between each dose must have been at least four weeks (28 days). Immunization with live mumps vaccine on or after the first birthday; or~~

~~B) A physician's signed confirmation of disease history and date of conclusive diagnosis; or~~

~~B) Students who cannot provide proof of immunization may provide~~

ILLINOIS REGISTER

DEPARTMENT OF PUBLIC HEALTH

NOTICE OF PROPOSED AMENDMENTS

~~laboratory~~Laboratory (serologic) evidence of mumps immunity.

5) Meningococcal vaccine. Beginning Fall term 2016-2017, all incoming students shall show proof of having at least one dose of meningococcal conjugate vaccine on or after 16 years of age.

b) ~~Proof of immunity may be provided by a certificate of immunity containing the following information:~~

1) ~~The month, day and year of vaccine receipt for measles, mumps, and rubella. Whole year dates (e.g., 1969) are acceptable only when it is clear that the student was at least one year of age when the vaccine was received.~~

2) ~~The month, day and year of vaccine receipt for diphtheria and tetanus.~~

c) ~~Proof of immunity may also be provided by one of the following:~~

1) ~~A copy of the student's Illinois high school health record which complies with the immunization requirements of this Part;~~

b2) For measles, mumps and rubella vaccines only, in~~In~~ lieu of proof of immunity as defined in this Part, evidence of birth on or before January 1, 1957, such as a birth certificate, drivers license, or personal identification card issued by the Secretary of State.

cd) Additional immunization entries made in a student health record by a post-secondary educational institution shall be based upon a certificate of immunity which complies with the requirements of this Part.

de) A student who enrolls at a post-secondary educational institution without providing proof of immunity shall be precluded from enrolling at that institution in a subsequent term unless the student provides proof of immunity acceptable to the designated recordkeeping office or is granted a medical or religious exemption by the institution.

ef) Students shall provide proof of immunity each time they transfer to another post-secondary educational institution.

(Source: Amended at 40 Ill. Reg. _____, effective _____)

ILLINOIS REGISTER

DEPARTMENT OF PUBLIC HEALTH

NOTICE OF PROPOSED AMENDMENTS

Section 694.110 Record Keeping

- a) The designated recordkeeping office shall maintain records containing the required elements (as in Appendix C) of the immunization status of each student. The student health records shall be maintained by the post-secondary educational institution.
- b) If an exemption has been granted for medical or religious reasons, or if laboratory evidence of immunity has been submitted, a copy of the request for exemption or the laboratory report must be kept with the student health record.
- c) A post-secondary educational institution shall keep susceptibility lists by disease category indicating the names of all students who are granted medical or religious exemptions by the institution or who have not provided proof of immunity. Those~~Such~~ lists shall be disclosed to the Department in health and safety emergencies in accordance with the Family Educational Rights and Privacy Act of 1974 (20 USC 1232g) and 34 CFR 99.36.

(Source: Amended at 40 Ill. Reg. _____, effective _____)

SUBPART C: EXEMPTIONS

Section 694.200 Medical Exemption

- a) A student may be exempted from one or more of the specific immunization requirements specified in this Part upon acceptance by the designated record keeping office of a written statement by a physician indicating the nature and probable duration of the medical condition or circumstances that contraindicates those immunizations~~such immunization(s)~~, identifying the specific vaccines ~~that vaccine(s) which~~ could be detrimental to the student's health.
- b) Female students may be granted temporary exemption from immunization against measles, mumps, and rubella under subsection (a) ~~above~~ if pregnancy or suspected pregnancy is certified by a written physician's statement.
- c) If a student is on an approved schedule of receipt for any required~~of all necessary doses of Td~~ vaccine, the student will be granted temporary medical exemption for the duration of the approved schedule.

ILLINOIS REGISTER

DEPARTMENT OF PUBLIC HEALTH

NOTICE OF PROPOSED AMENDMENTS

- d) If a student's medical condition or circumstances later permit immunization, the ~~exemption~~exemption(s) granted under subsection (a), (b) or (c) ~~above~~ shall ~~thereupon~~ terminate and the student shall be required to obtain the ~~immunizations~~immunization(s) from which the student has been exempted.

(Source: Amended at 40 Ill. Reg. _____, effective _____)

Section 694. APPENDIX C Required Elements of Health Record

1. Name
2. Student Identification Number
3. Month, Day, and Year of Birth
4. ~~Gender~~Sex
5. Term and Year of First Entry
6. Dates to Establish Immunity to Measles (Rubeola)
7. Dates to Establish Immunity to Rubella
8. Dates to Establish Immunity to Mumps
9. Dates to Establish Immunity to Tetanus/Diphtheria
10. Date of Most Recent Tetanus/Diphtheria/Pertussis Booster (Tdap)
11. Date of Most Recent Meningococcal Vaccine
1241. Phone Number of Certifying Health Care Provider
1342. Name and Signature of Health Care Provider

(Source: Amended at 40 Ill. Reg. _____, effective _____)