

1 CABINET FOR HEALTH AND FAMILY SERVICES

2 Department for Public Health

3 Division of Epidemiology and Health Planning

4 (Amendment)

5 902 KAR 2:065. Immunization requirements for long-term care facilities.

6 RELATES TO: KRS 209.550, 209.552, [209.554,] 211.090, 211.180, 214.010,

7 216.510, 216.515, 216.530, 42 C.F.R. 483.80

8 STATUTORY AUTHORITY: KRS 209.554(1)

9 NECESSITY, FUNCTION, AND CONFORMITY: KRS 209.554(1) requires the  
10 Cabinet for Health and Family Services, Department for Public Health to promulgate  
11 administrative regulations to implement provisions of KRS 209.550 to KRS 209.554  
12 relating to immunization of residents and employees[~~staff~~] of long-term care facilities  
13 against influenza and pneumococcal disease. This administrative regulation establishes  
14 requirements for long-term care facilities to request that residents and employees agree  
15 to be vaccinated against influenza and pneumococcal disease, to provide vaccine for  
16 the residents and employees or to make a referral for vaccination, [~~to request that~~  
17 ~~residents and employees agree to be vaccinated against influenza and pneumococcal~~  
18 ~~disease,~~] to maintain annual documentation of immunizations, and to report outbreaks  
19 of influenza-like illnesses[~~illness~~].

20 Section 1. Definitions. (1) “Advisory Committee on Immunization Practices” or  
21 “ACIP” means the United States Department of Health and Human Services (HHS)

1 ~~[Public Health Service]~~ Committee that makes national immunization recommendations  
2 to the Secretary of HHS, the Assistant Secretary for Health, and the Director of the  
3 Centers for Disease Control and Prevention (CDC).

4 (2) "Department" is defined by KRS 209.550(2).

5 (3) "Employee" is defined by KRS 209.550(4).

6 (4) ~~["Annual schedule" means the schedule for administering a once-a-year~~  
7 ~~vaccination against influenza, established by ACIP to ensure that in the event of a~~  
8 ~~shortage or delay in production of vaccine, persons at greatest risk are served first.~~

9 (3) "If vaccine is available" means that a sufficient supply of vaccine has been  
10 produced by vaccine manufacturers and is available for purchase and shipment.

11 (5) ~~(4)~~ "Influenza" means an acute viral infection of the respiratory tract:

12 (a) Caused by an influenza virus;[:]

13 (b) Confirmed by:

14 1. Viral [laboratory] culture;

15 2. Polymerase chain reaction (PCR);

16 3. Nucleic acid detection testing; or

17 4. Rapid influenza diagnostic testing (RIDT); and

18 (c) Characterized by the sudden onset of a group of signs and symptoms such as  
19 fever, headache, myalgia, coryza, sore throat, and a dry cough.

20 (6) ~~(5)~~ "Influenza-like illness" or "ILI" means, in the absence of a known cause,  
21 other than influenza, an illness in which a person experiences:

22 (a) Fever greater than or equal to 100 degrees Fahrenheit or thirty seven and eight-  
23 tenths (37.8) degrees Celsius, as confirmed through oral or equivalent methods; and[:]

1 (b) Cough; [ø]

2 (c) Sore throat; or

3 (d) Cough and sore throat.

4 (7)[(6)] "Influenza vaccine" means a vaccine licensed by the Food and Drug  
5 Administration for the prevention of [which produces immunity to] influenza.

6 (8)[(7)] "Immunize" means to vaccinate.

7 (9) "Long-term care facility" is defined by KRS 209.550(6).

8 (10)[(8)] "Medically indicated" means a vaccine is recommended by the ACIP for a  
9 person:

10 (a) Who has not been immunized against a disease; and

11 (b) For whom vaccination is recommended based on:

12 1. The age of the person;

13 2. A preexisting medical condition that may cause the person to be at risk; or

14 3. An occupation of the person that may put others at risk of contracting the disease.

15 (11)[(9)] "Outbreak" means two (2) or more cases of influenza, or ILI, occurring in a  
16 single long-term care facility during a seventy-two (72) hour period[~~one (1) week~~].

17 (12)[(10)] "Pneumococcal disease" means a bacterial infection usually involving the  
18 lungs producing inflammation caused by Streptococcus pneumoniae, the bacteria  
19 commonly referred to as "pneumococcus".

20 (13)[(11)] "Pneumococcal vaccine" means a vaccine licensed by the Food and Drug  
21 Administration for the prevention of pneumococcus[~~, also known as "PPV" means the~~  
22 ~~FDA licensed twenty-three (23) valent pneumococcal polysaccharide vaccine].~~

1 Section 2. Vaccine Availability. (1) If vaccine is available, a long-term care facility  
2 shall:

3 (a) Obtain a sufficient quantity of influenza and pneumococcal vaccine to immunize  
4 each employee and[or] resident of a facility for whom the vaccine is medically indicated;  
5 or

6 (b) Enter into an agreement with a local health department or other health care  
7 provider to obtain or[and] administer influenza and pneumococcal vaccine to each  
8 employee and[or] resident of a facility for whom the vaccine is medically indicated and  
9 age-appropriate.

10 (2) A long-term care facility may charge a third party, a resident, or an employee for  
11 the cost of the:

12 (a) Vaccine; and

13 (b) Administration of the vaccine.

14 Section 3. Immunization Schedule for Residents. (1) A long-term care facility shall  
15 have an infection prevention and control plan in compliance with 42 C.F.R. 483.80.

16 (2) Influenza immunization shall be offered to each resident in compliance with 42.  
17 C.F.R. 483.80(d)(1).

18 (3) Pneumococcal immunization shall be offered to each resident in compliance with  
19 42 C.F.R. 483.80(d)(2).

20 Section 4. Immunization for Employees. (1) A long-term care facility shall request  
21 that each [current] employee [or resident] agree to be vaccinated on an annual schedule  
22 against influenza when the vaccine is:

23 (a) Available;[-and]

1 (b) Medically indicated; and

2 (c) Age-appropriate.

3 (2) A long-term care facility shall request that each [~~current~~] employee [~~or resident~~]  
4 agree to be vaccinated against pneumococcal disease if the vaccine is:

5 (a) Available; [~~and~~]

6 (b) Medically indicated; and

7 (c) Age-appropriate.

8 (~~3~~) [~~Upon admission or employment, a long-term care facility shall request that each~~  
9 ~~new employee or resident agree to be vaccinated on an annual schedule against~~  
10 ~~influenza when the vaccine is:~~

11 (~~a~~) Available; and

12 (~~b~~) Medically indicated.

13 (~~4~~) [~~Upon admission or employment, a long-term care facility shall request that each~~  
14 ~~new employee or resident agree to be vaccinated against pneumococcal disease if the~~  
15 ~~vaccine is:~~

16 (~~a~~) Available; and

17 (~~b~~) Medically indicated.

18 (~~5~~) If a long-term care facility is located within a larger facility, such as a hospital,  
19 the provisions of this administrative regulation shall apply to every employee of the  
20 larger facility who may also work in the long-term care facility on a full-time, part-time, or  
21 contractual basis.

22 Section 5[4]. Health Records. (1) A long-term care facility shall maintain an  
23 immunization health record for each employee and[~~or~~] resident that shall document:

1 (a) The immunization status of the employee or resident for influenza virus and  
2 pneumococcal disease;

3 (b) The date that the employee or resident received counseling on the risks and  
4 benefits of the vaccines;

5 (c) The date the employee or resident was requested to be immunized against  
6 influenza virus and pneumococcal disease; and

7 (d) The date the employee or resident was vaccinated against each disease.

8 (2) If after being advised of the risks and benefits of the vaccine, an employee,  
9 resident, or legal guardian of a resident refuses to be vaccinated, as provided in KRS  
10 209.552(5), a long-term care facility shall document in the health record:

11 (a) The date each vaccine was offered;

12 (b) Each vaccine that was not administered; and

13 (c) The reason each vaccine was refused.

14 Section ~~6~~[5]. Reporting. (1) Upon recognition of an outbreak of ILI, a long-term care  
15 facility shall report the outbreak within twenty four (24) hours, by telephone, facsimile, or  
16 e-mail to ~~the~~:

17 (a) The local health department having~~[serving the]~~ jurisdiction ~~[in which the long-~~  
18 ~~term care facility is located]~~; or

19 (b) The department ~~[for public health]~~.

20 (2) Upon receipt of a report of an outbreak from a long-term care facility, a local  
21 health department shall:

22 (a) Immediately notify the department ~~[for Public Health, Division of Epidemiology]~~;

23 and

1 (b) Assist the department in carrying out a public health response as instructed.

2 (3) Within one (1) week of reporting an outbreak of ILI, a long-term care facility shall  
3 submit a completed EPID 200, Kentucky Reportable Disease Form, incorporated by  
4 reference in 902 KAR 2:020, for each affected employee or resident to:

5 (a) The local [county] health department having[~~servicing the~~] jurisdiction [~~in which the~~  
6 ~~long-term care facility is located~~]; or

7 (b) The department [~~for Public Health, Division of Epidemiology~~].

8 (4) Upon notification of an outbreak of ILI, the local health department having  
9 jurisdiction or the department [~~for Public Health~~] shall contact the long-term care facility  
10 to make recommendations for appropriate confirmation of the etiology of illness and  
11 intervention.

12 (5) The department [~~for Public Health~~] shall maintain a database[~~data-base~~] of  
13 confirmed occurrences of influenza [~~and of pneumococcal disease~~] occurring in long-  
14 term care facilities.

15 (6) All long-term care facilities shall report the seasonal immunization survey  
16 utilizing an electronic reporting system provided by the department[~~The Department for~~  
17 ~~Public Health shall maintain a data system to report the number of long-term care~~  
18 ~~residents diagnosed with influenza or pneumococcal disease, and associated~~  
19 ~~complications, and the number of hospitalizations of long-term care facility residents~~  
20 ~~each year due to influenza virus, pneumococcal disease, and associated complications,~~  
21 ~~pursuant to the requirements of KRS 209.554(4)].~~

22 Section 7[6]. Educational Literature. [~~Within ninety (90) days of publication by the~~  
23 ~~CDC,~~] The department [~~for Public Health~~] shall provide each licensed long-term care

1 facility with access to [~~a camera-ready copy of~~] the most current vaccine information  
2 statements for influenza and pneumococcal disease as published by the CDC.

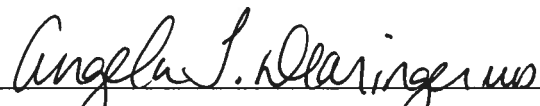
3 [~~Section 7. Incorporation by Reference. (1) "Kentucky Reportable Disease Form,~~  
4 ~~EPID-200 (Rev. Jan/01)" is incorporated by reference.~~

5 (~~2) This material may be inspected, copied, or obtained, subject to applicable~~  
6 ~~copyright law, at the Department for Public Health, 275 East Main Street, Frankfort,~~  
7 ~~Kentucky 40621, Monday through Friday, 8 a.m. to 4:30 p.m.]~~




902 KAR 2:065

REVIEWED:

 12/18/19  
\_\_\_\_\_  
Angela T. Dearing, M.D., MPH Date  
Commissioner, Department for Public Health

APPROVED:

 1/10/20  
\_\_\_\_\_  
Eric C. Friedlander Date  
Acting Secretary, Cabinet for Health and Family Services

## **PUBLIC HEARING AND PUBLIC COMMENT PERIOD:**

A public hearing on this administrative regulation shall, if requested, be held on March 23, 2020, at 9:00 a.m. in Suites A & B, Health Services Building, First Floor, 275 East Main Street, Frankfort, Kentucky, 40621. Individuals interested in attending this hearing shall notify this agency in writing by March 16, 2020, five (5) workdays prior to the hearing, of their intent to attend. If no notification of intent to attend the hearing is received by that date, the hearing may be canceled. This hearing is open to the public. Any person who attends will be given an opportunity to comment on the proposed administrative regulation. A transcript of the public hearing will not be made unless a written request for a transcript is made. If you do not wish to be heard at the public hearing, you may submit written comments on this proposed administrative regulation until March 31, 2020. Send written notification of intent to attend the public hearing or written comments on the proposed administrative regulation to the contact person. Pursuant to KRS 13A.280(8), copies of the statement of consideration and, if applicable, the amended after comments version of the administrative regulation shall be made available upon request.

**CONTACT PERSON:** Donna Little, Deputy Executive Director, Office of Legislative and Regulatory Affairs, 275 East Main Street 5 W-A, Frankfort, KY 40621; Phone: 502-564-6746; Fax: 502-564-7091; CHFSregs@ky.gov.

## REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

Administrative Regulation: 902 KAR 2:065

Agency Contact: Julie Brooks, (502) 564-3970, julied.brooks@ky.gov or Donna Little, (502) 564-6746, CHFSregs@ky.gov

(1) Provide a brief summary of:

(a) What this administrative regulation does: This administrative regulation establishes requirements for long-term care facilities to request that residents and employees agree to be vaccinated against influenza and pneumococcal disease, to provide vaccine for the residents and employees or to make a referral for vaccination, to maintain annual documentation of immunizations, and to report outbreaks of influenza-like illnesses to the local health department having jurisdiction or the department for public health.

(b) The necessity of this administrative regulation: This administrative regulation is necessary to ensure all residents and employees of long-term care facilities are properly protected from influenza and pneumococcal disease.

(c) How this administrative regulation conforms to the content of the authorizing statutes: KRS 209.552 requires every long-term care facility to require residents and employees to be immunized against pneumococcal disease and influenza. KRS 209.554 authorizes the department for public health to implement the provisions outlined in the statute through the promulgation of administrative regulations.

(d) How this administrative regulation currently assists or will assist in the effective administration of the statutes: This administrative regulation provides details implementing vaccinations against influenza and pneumococcal disease of employees and residents in long-term care facilities.

(2) If this is an amendment to an existing administrative regulation, provide a brief summary of:

(a) How the amendment will change this existing administrative regulation: The amendment to this administrative regulation defines department and employee, and revises other defined terms for clarity, adds that a long-term care facility shall have an infection prevention and control plan in compliance with 42 C.F.R. 483.80, adds that all residents shall be offered immunization against influenza and pneumococcal disease in compliance with 42 C.F.R. 483.80, adds that all employees, regardless of employment status, should be offered immunization against influenza and pneumococcal disease, and clarifies the outbreak data reporting requirements for long-term care facilities.

(b) The necessity of the amendment to this administrative regulation: The amendment to this administrative regulation is necessary to ensure residents and employees of long-term care facilities are properly immunized against influenza and pneumococcal disease. Proper immunization of residents and employees will reduce the potential for a disease outbreak in the facility.

(c) How the amendment conforms to the content of the authorizing statutes: KRS 290.554 authorizes the department to implement the provisions outlined in the statute through the promulgation of administrative regulations.

(d) How the amendment will assist in the effective administration of the statutes: This amendment assists in the clarity and the implementation of the regulatory requirements.

(3) List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation: Currently there are 316 long-term care facilities registered with the Office of Inspector General. The amendment to this administrative regulation will affect all employees and residents of these registered facilities.

(4) Provide an analysis of how the entities identified in question (3) will be impacted by either the implementation of this administrative regulation, if new, or by the change, if it is an amendment, including:

(a) List the actions that each of the regulated entities identified in questions (3) will have to take to comply with this administrative regulation or amendment: The long-term care facilities will have to offer and administer influenza and pneumococcal vaccines to all employees and residents.

(b) In complying with this administrative regulation or amendment, how much will it cost each of the identities identified in question (3): The cost to the long-term care facilities will be the cost of the vaccines and any additional costs required to administer the vaccines. Long-term care facilities can charge a fee to employees and residents for the vaccines.

(c) As a result of compliance, what benefits will accrue to the entities identified in question (3): The long-term care facilities will benefit by having healthier employees and residents, allowing for less hospitalizations due to influenza or pneumococcal disease for residents and less sick days incurred by employees.

(5) Provide an estimate of how much it will cost the administrative body to implement this administrative regulation:

(a) Initially: There will be no additional cost to the Department for Public Health to implement this change.

(b) On a continuing basis: There will be no additional cost on an ongoing basis.

(6) What is the source of the funding to be used for the implementation and enforcement of this administrative regulation: Agency funds are used for the implementation and enforcement of this administrative regulation.

(7) Provide an assessment of whether an increase in fees or funding will be necessary to implement this administrative regulation, if new or by the change, if it is an

amendment: This amendment does not require an increase in fees or funding for implementation.

(8) State whether or not this administrative regulation established any fees or directly or indirectly increased any fees. There is no increase in fees associated with this amendment.

(9) TIERING: Is tiering applied? (Explain why or why not.) Tiering is not applied. This administrative regulation impacts all affected entities equally.

## FISCAL NOTE ON STATE OR LOCAL GOVERNMENT

Administrative Regulation: 902 KAR 2:065

Agency Contact: Julie Brooks, (502) 564-3970, julied.brooks@ky.gov or Donna Little, (502) 564-6746, CHFSregs@ky.gov

1. What units, parts or divisions of state or local government (including cities, counties, fire departments, or school districts) will be impacted by this administrative regulation? This administrative regulation impacts local health departments and the Division of Epidemiology and Health Planning within the Department for Public Health.

2. Identify each state or federal statute or federal regulation that requires or authorizes the action taken by the administrative regulation. KRS 209.550, 209.552 and 209.554.

3. Estimate the effect of this administrative regulation on the expenditures and revenues of a state or local government agency (including cities, counties, fire departments, or school districts) for the first full year the administrative regulation is to be in effect.

(a) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for the first year? This administrative regulation does not generate revenue.

(b) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for subsequent years? This administrative regulation does not generate revenue.

(c) How much will it cost to administer this program for the first year? There are no additional cost to administer this program.

(d) How much will it cost to administer this program for subsequent years? There are no additional cost to administer this program.

Note: If specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation.

Revenues (+/-):

Expenditures (+/-):

Other Explanation:

## FEDERAL MANDATE ANALYSIS COMPARISON

Administrative Regulation: 902 KAR 2:065

Agency Contact: Julie Brooks

Phone Number: 564-3970

Email: julied.brooks@ky.gov

1. Federal statute or regulation constituting the federal mandate. 42 C.F.R. 483 Subpart B
2. State compliance standards. This regulation adopts the federal standards for a long-term care facility to provide an infection prevention and control program, and to provide influenza and pneumococcal immunizations for each resident.
3. Minimum or uniform standards contained in the federal mandate. The scope of 42 C.F.R. 483 Subpart B contains the requirements that institutions must meet in order to qualify to participate as a Skilled Nursing Facility in the Medicare program, and as a nursing facility in the Medicaid program.
4. Will this administrative regulation impose stricter requirements, or additional or different responsibilities or requirements, than those required by the federal mandate? No. This administrative regulation adopts the federal requirements for an infection prevention and control program, and for influenza and pneumococcal immunizations for each resident of a long-term care facility.
5. Justification for the imposition of the stricter standard, or additional or different responsibilities or requirements. There are no different, stricter, or additional responsibilities or requirements.

