

## ILLINOIS REGISTER

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### DEPARTMENT OF PUBLIC HEALTH

#### NOTICE OF PROPOSED AMENDMENTS

1) Heading of the Part: Illinois Home Health Agency Code

2) Code Citation: 77 Ill. Adm. Code 245

3) Section Numbers: Proposed Action:

245.25	Amendment
245.50	Amendment
245.55	New

4) Statutory Authority: Home Health, Home Services, and Home Nursing Agency Licensing Act [210 ILCS 55]

5) A Complete Description of the Subjects and Issues Involved:

The Illinois Home Health Agency Code regulates home health agencies, including staffing, home health aide training, licensure, and violations. The proposed amendments are being undertaken to implement Public Act 94-429, which added a new section to the Home Health, Home Services, and Home Nursing Agency Licensing Act [210 ILCS 55] regulating vaccinations.

Section 245.25 (Incorporated and Referenced Materials) is being amended to update the list of federal regulations, federal guidelines, and state statutes listed in the Section.

Subsection (b) of Section 245.50 (Services) is being amended to conform to amendments adopted November 23, 2005 (29 Ill. Reg. 20003) that extended the time limit for obtaining physicians' or podiatrists' signatures to 30 days after modification of a medical plan of treatment or change in medication. The proposed amendment establishes a 30-day time limit to obtain a physician's signature on a plan of treatment. Other new language in Section 245.50 helps implement P.A. 94-429.

A new Section is being added, Section 245.55 (Vaccinations), which implements the new statutory requirement for annual administration of influenza and pneumococcal vaccinations by home health agencies.

The heading of the Part is being changed to the Illinois Home Health, Home Services, and Home Nursing Agency Code to conform to the Act.

The economic effect of this proposed rulemaking is unknown. Therefore, the Department requests any information that would assist in calculating this effect.

## ILLINOIS REGISTER

---

### DEPARTMENT OF PUBLIC HEALTH

#### NOTICE OF PROPOSED AMENDMENTS

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: None.

7) Will this rulemaking replace an emergency rulemaking currently in effect? No

8) Does this rulemaking contain an automatic repeal date? No

9) Does this rulemaking contain incorporations by reference? Yes

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 a State Mandate.

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 this issue of the *Illinois Register* to:

Susan Meister  
Division of Legal Services  
Illinois Department of Public Health  
535 West Jefferson St., 5<sup>th</sup> Floor  
Springfield, Illinois 62761  
217/782-2043  
e-mail: rules@idph.state.il.us

13) Initial Regulatory Flexibility Analysis:

A) Type of small businesses, small municipalities and not-for-profit corporations affected: home health agencies

B) Reporting, bookkeeping or other procedures required for compliance: The proposed rules require regulated entities to document whether annual influenza and pneumococcal vaccinations were administered to clients and patients or

## ILLINOIS REGISTER

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### DEPARTMENT OF PUBLIC HEALTH

#### NOTICE OF PROPOSED AMENDMENTS

whether the vaccinations were arranged, refused, or medically contraindicated.

C) Types of professional skills necessary for compliance: None

14) Regulatory Agenda on which this rulemaking was summarized: July 2006

The full text of the Proposed Amendment 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 b: HOSPITALS AND AMBULATORY CARE FACILITIES

##### PART 245

##### ILLINOIS HOME HEALTH, HOME SERVICES, AND HOME NURSING AGENCY CODE

##### SUBPART A: GENERAL PROVISIONS

Section	
245.10	Purpose
245.20	Definitions
245.25	Incorporated and Referenced Materials

##### SUBPART B: OPERATIONAL REQUIREMENTS

Section	
245.30	Organization and Administration
245.40	Staffing and Staff Responsibilities
245.50	Services
<u>245.55</u>	<u>Vaccinations</u>
245.60	Annual Financial Statement
245.70	Home Health Aide Training
245.72	Health Care Worker Background Check

##### SUBPART C: LICENSURE PROCEDURES

Section	
245.80	Licensure Required
245.90	License Application
245.100	Provisional License
245.110	Inspections and Investigations
245.120	Violations
245.130	Adverse Licensure Actions
245.140	Penalties and Fines
245.150	Hearings

AUTHORITY: Implementing and authorized by the Home Health, Home Services, and Home Nursing Agency Licensing Act [210 ILCS 55].

## ILLINOIS REGISTER

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### DEPARTMENT OF PUBLIC HEALTH

#### NOTICE OF PROPOSED AMENDMENTS

SOURCE: Adopted at 2 Ill. Reg. 31, p. 77, effective August 2, 1978; emergency amendment at 3 Ill. Reg. 38, p. 314, effective September 7, 1979, for a maximum of 150 days; amended at 3 Ill. Reg. 40, p. 153, effective October 6, 1979; emergency amendment at 4 Ill. Reg. 18, p. 129, effective April 21, 1980, for a maximum of 150 days; amended at 4 Ill. Reg. 40, p. 56, effective September 23, 1980; emergency amendment at 6 Ill. Reg. 5855, effective April 28, 1982, for a maximum of 150 days; amended at 6 Ill. Reg. 11006, effective August 30, 1982; amended at 7 Ill. Reg. 13665, effective October 4, 1983; codified at 8 Ill. Reg. 16829; amended at 9 Ill. Reg. 4836, effective April 1, 1985; amended at 14 Ill. Reg. 2382, effective February 15, 1990; amended at 15 Ill. Reg. 5376, effective May 1, 1991; amended at 18 Ill. Reg. 2414, effective January 22, 1994; emergency amendments at 20 Ill. Reg. 488, effective January 1, 1996, for a maximum of 150 days; emergency expired May 29, 1996; amended at 20 Ill. Reg. 3273, effective February 15, 1996; amended at 20 Ill. Reg. 10033, effective July 15, 1996; amended at 22 Ill. Reg. 3948, effective February 13, 1998; amended at 22 Ill. Reg. 22050, effective December 10, 1998; amended at 23 Ill. Reg. 1028, effective January 15, 1999; amended at 24 Ill. Reg. 17213, effective November 1, 2000; amended at 25 Ill. Reg. 6379, effective May 1, 2001; amended at 26 Ill. Reg. 11241, effective July 15, 2002; amended at 28 Ill. Reg. 3487, effective February 9, 2004; amended at 28 Ill. Reg. 8094, effective May 26, 2004; amended at 29 Ill. Reg. 20003, effective November 23, 2005; amended at 31 Ill. Reg. \_\_\_\_\_, effective \_\_\_\_\_.

#### SUBPART A: GENERAL PROVISIONS

##### **Section 245.25 Incorporated and Referenced Materials**

- a) The following federal regulations are incorporated by reference in this Part and apply only to Medicare certified agencies:

Department of Health and Human Services, Health Care Financing Administration, Medicare Program Conditions of Participation for Home Health Agencies (42 CFR 484.1 through 484.55484.40), October 1, 2005.59 Federal Register 65482-65498, December 20, 1994.

- b) The following guidelines of a federal agency are incorporated by reference in this Part:

Department of Health and Human Services, Centers for Disease Control and Prevention, Morbidity and Mortality Weekly Report, General Recommendations on Immunization, February 8, 2002.

- c) All incorporations by reference of federal regulations and guidelines and the standards of nationally recognized organizations in this Part refer to the

## ILLINOIS REGISTER

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### DEPARTMENT OF PUBLIC HEALTH

#### NOTICE OF PROPOSED AMENDMENTS

regulations, guidelines, or standards on the date specified and do not include any amendments or editions~~additions or deletions~~ subsequent to the date specified.

**d)e** The following State statutes are referenced in this Part:

- 1) Administrative Review Law [735 ILCS 5/Art. III]
- 2) Business Corporation Act of ~~1983~~<sup>1938</sup> [805 ILCS 5]
- 3) Illinois Administrative Procedure Act [5 ILCS 100]
- 4) Nursing and Advance Practice Nursing Act~~Illinois Nursing Act of 1987~~ [225 ILCS 65]
- 5) Illinois Occupational Therapy Practice Act [225 ILCS 75]
- 6) Illinois Physical Therapy Act [225 ILCS 90]
- 7) Illinois Speech-Language Pathology and Audiology Practice Act [225 ILCS 110]
- 8) Local Records Act [50 ILCS 205]
- 9) Medical Practice Act of 1987 [225 ILCS 60]

**e)d** The following State rules are referenced in this Part:

- 1) Department of Public Health, Certified Local Health Department Code (77 Ill. Adm. Code 600)
- 2) Department of Public Health, Rules of Practice and Procedure in Administrative Hearings (77 Ill. Adm. Code 100).

(Source: Amended at 31 Ill. Reg. \_\_\_\_\_, effective \_\_\_\_\_)

#### SUBPART B: OPERATIONAL REQUIREMENTS

##### **Section 245.50 Services**

- a) Services Provided

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## ILLINOIS REGISTER

---

### DEPARTMENT OF PUBLIC HEALTH

#### NOTICE OF PROPOSED AMENDMENTS

- 1) Each agency shall provide skilled nursing service and at least one other home health service on a part-time or intermittent basis. The basic skilled nursing service shall be provided directly by agency staff. Other home health services may be provided by agency staff directly or through a contractual purchase of services. Additional skilled specialty nursing services and use of additional nursing staff to meet changes in caseload may be provided by contract. All services shall be provided in accordance with the orders of the patient's physician or podiatrist, under a plan of treatment established by such physician or podiatrist, and under the supervision of agency staff.
- 2) The agency shall state in writing what services will be provided directly and what services will be provided under contractual arrangements.
- 3) Services provided under contractual arrangements shall be through a written agreement that includes but is not limited to the following:
  - A) Services to be provided.
  - B) Provision for adherence to all applicable agency policies and personnel requirements, including requirements for initial health evaluations and employee health policies.
  - C) Designation of full responsibility for agency control over contracted services.
  - D) Procedures for submitting clinical and progress notes.
  - E) Charges for contracted services.
  - F) Statement of responsibility of liability and insurance coverage.
  - G) Period of time in effect.
  - H) Date and signatures of appropriate authorities.
  - I) Provision for termination.

b) Acceptance of Patients. Patient acceptance and discharge policies shall include but not be limited to the following:

## ILLINOIS REGISTER

---

### DEPARTMENT OF PUBLIC HEALTH

#### NOTICE OF PROPOSED AMENDMENTS

- 1) Persons shall be accepted for health service on a part-time or intermittent basis upon a plan of treatment established by the patient's physician or podiatrist. This plan shall be in writing within 14 days after acceptance and signed by the physician within 30 days from the start of care date.
- 2) Prior to acceptance, the person shall be informed of the agency's charges for the various services that it offers.
- 3) No person shall be refused service because of age, race, color, sex, marital status, national origin or source of payment. An agency is not required to accept a patient whose source of payment is less than the cost of the service.
- 4) Patients are accepted for treatment on the basis of a reasonable expectation that the patient's medical, nursing, and social needs can be met adequately by the agency in the patient's place of residence.
- 5) When services are to be terminated by the home health agency, the patient is to be notified three working days in advance of the date of termination, stating the reason for termination. This information shall be documented in the clinical record. When indicated, a plan shall be developed or a referral made for any continuing care.
- 6) Services shall not be terminated until such time as the registered nurse, the appropriate therapist, or both, in consultation with the patient's physician or podiatrist, deem it appropriate or arrangements are made for continuing care.

c) Plan of Treatment

- 1) Skilled nursing and other home health services shall be in accordance with a plan based on the patient's diagnosis and assessment of the patient's immediate and long-range needs and resources. The plan of treatment is established in consultation with the home health services team, which includes the patient's physician or podiatrist, pertinent members of the agency staff, the patient and members of the patient's family. The plan of treatment shall include:
  - A) Diagnoses.
  - B) Functional limitations and rehabilitation potential.

## ILLINOIS REGISTER

---

### DEPARTMENT OF PUBLIC HEALTH

#### NOTICE OF PROPOSED AMENDMENTS

- C) Expected outcomes for the patient.
- D) The patient's physician's or podiatrist's regimen of:
  - i) Medications;
  - ii) Treatments;
  - iii) Activity;
  - iv) Diet;
  - v) Specific procedures deemed essential for the health and safety of the patient;
  - vi) Mental status;
  - vii) Frequency of visits;
  - | viii) Equipment required; **and**
  - | ix) Instructions for timely discharge or referral; **and-**
  - | x) Assessed need for influenza and pneumococcal vaccinations.
- E) The patient's physician's or podiatrist's signature and date.

- 2) Consultation with the patient's physician or podiatrist on any modifications in the plan of treatment deemed necessary shall be documented, and the patient's physician's or podiatrist's signature shall be obtained within 30 days after any modification of the medical plan of treatment.
- 3) The plan shall be reviewed by the home health services team every 62 days or more often should the patient's condition warrant.
- 4) An updated plan of treatment shall be given to the patient's physician or podiatrist for review, for any necessary revisions, and for signature every 62 days or more often as indicated.

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## ILLINOIS REGISTER

### DEPARTMENT OF PUBLIC HEALTH

#### NOTICE OF PROPOSED AMENDMENTS

d) Patient Care Plan

1) Home health services from members of the agency staff as well as those under contractual arrangements shall be given in accordance with the plan of treatment and the patient care plan. The patient care plan shall be written by appropriate members of the home health services team based upon the plan of treatment and an assessment of the patient's needs, resources, family and environment. The initial assessment is to be made by a registered nurse. Assessment by other members of the health services team shall be made on orders of the patient's physician or podiatrist or by request of a registered nurse. In those circumstances where the patient's physician has ordered only therapy services, the appropriate therapist (physical therapist or speech-language pathologist) may perform the initial assessment.

2) The patient care plan shall be updated as often as the patient's condition indicates. The plan shall be maintained as a permanent part of the patient's record. The patient care plan shall indicate:

- A) Patient problems.
- B) Patient's goals, family's goals, service goals.
- C) Service approaches to modify or eliminate problems.
- D) The staff responsible for a given element of service.
- E) Anticipated outcome of service approach with an estimated time frame for completion.
- F) Potential for discharge from service.

e) Clinical Records. Each patient shall have a clinical record, identifiable for home health services and maintained by the agency in accordance with accepted professional standards. Clinical records shall contain:

- 1) Appropriate identifying information for the patient, household members and caretakers, medical history and current findings.
- 2) A plan of treatment signed by the patient's physician or podiatrist.

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## ILLINOIS REGISTER

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### DEPARTMENT OF PUBLIC HEALTH

#### NOTICE OF PROPOSED AMENDMENTS

- 3) A patient care plan developed by the home health services team, that is in accord with the patient's physician's or podiatrist's plan of treatment.
- 4) A medication list with dates reviewed, revised and date sent to the patient's physician or podiatrist.
- 5) Initial and periodic patient assessments by the registered nurse, which include documentation of the patient's functional status and eligibility for service.
- 6) Assessments made by other members of the home health services team.
- 7) Signed and dated clinical notes for each contact, which are written the day of service and incorporated into the patient's clinical record at least weekly.
- 8) Reports on all patient home health care conferences.
- 9) Reports of contacts with the patient's physician or podiatrist by patient and staff.
- 10) Indication of supervision of home health services by the supervising nurse, a registered nurse, or other members of the home health services team.
- 11) Written summary reports sent to the patient's physician or podiatrist every 62 days containing home health services provided, the patient's status, recommendations for revision of the plan of treatment and the need for continuation or termination of services noted.
- 12) Written and signed confirmation of the patient's physician's or podiatrist's interim verbal orders.
- 13) A discharge summary giving a brief review of service, patient status, reason or reasons for discharge and plans for post discharge needs of the patient. A discharge summary may suffice as documentation to close the patient record for one-time visits and short-term or event-focused or diagnosis-focused interventions. The discharge summary need not be a separate piece of paper and may be incorporated into the routine summary reports already furnished to the physician.

## ILLINOIS REGISTER

---

### DEPARTMENT OF PUBLIC HEALTH

#### NOTICE OF PROPOSED AMENDMENTS

- 14) A copy of appropriate patient transfer information, when requested, if the patient is transferred to another health facility or health agency.
- 15) Each agency shall have a written policy on records procedures and shall retain records for a minimum of five years beyond the last date of service provided. These procedures may include that the agency will utilize and maintain faxed copies of records from licensed professionals, rather than original records, provided that the faxed copies will be maintained on nonthermal paper and that the original records will be maintained for a period of five years by the professional who originated the records. If that professional is providing services through a contract with the agency, then the contract must include that the original records must be maintained for a period of five years by the professional.
- 16) Those agencies which are subject to the Local Records Act should note that *except as otherwise provided by law, no public record shall be disposed of by any officer or agency unless the written approval of the appropriate Local Records Commission is first obtained.* (Section 7 of the Local Records Act [50 ILCS 205/7])
- 17) Each agency shall have a written policy and procedure for the protection of confidentiality of patient records, which explains the use of records, removal of records and release of information.

f) Drugs and Biologicals. The agency shall have written policies governing the supervision and administration of drugs and biologicals, which shall include but not be limited to the following:

- 1) All orders for medications to be given shall be dated and signed by the patient's physician or podiatrist.
- 2) Drugs and treatments are administered by agency staff only as ordered by the physician, with the exception of influenza and pneumococcal polysaccharide vaccines, which may be administered per agency policy developed in consultation with a physician, and after an assessment of the patient.
- 3) 2) All orders for medications shall contain the name of the drug, dosage, frequency, method or site of injection and permission from the patient's physician or podiatrist if the patient, the patient's family, or both are to be taught to give medications.

## ILLINOIS REGISTER

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### DEPARTMENT OF PUBLIC HEALTH

#### NOTICE OF PROPOSED AMENDMENTS

- | **4)3)** The agency's physician or podiatrist or registered nurse shall check all medicines a patient may be taking to identify possible ineffective drug therapy or adverse reactions, significant side effects, drug allergies, and contraindicated medications and shall promptly report any problem to the patient's physician or podiatrist.
- | **5)4)** All verbal orders for medication or change in medication orders shall be taken by the registered nurse, written, and signed by the patient's physician or podiatrist within 30 days.
- | **6)5)** When any experimental drug, sera, allergenic desensitizing agent, penicillin or any other potentially hazardous drug is administered, the registered nurse administering such drugs shall have an emergency plan and any drugs and devices that may be necessary in the event of a drug reaction.
- g) Evaluation. The home health agency shall have written policies and shall make an overall evaluation of the agency's total program at least once a year. This evaluation shall be made by the Professional Advisory Group (or a committee of this group), home health agency staff, consumers, or representation from professional disciplines that are participating in the provision of home health services. The evaluation shall consist of an overall policy and administrative review and a clinical record review. The evaluation shall assess the extent to which the agency's program is appropriate, adequate, effective and efficient. Results of the evaluation shall be reported to and acted upon by those responsible for the operation of the agency and maintained separately as administrative records.
- h) Policy and Administrative Review. As a part of the evaluation process, the policies and administrative practices of the agency shall be reviewed to determine the extent to which they promote patient care that is appropriate, adequate, effective and efficient. Mechanisms shall be established in writing for the collection of pertinent data to assist in evaluation. The data to be considered may include but are not limited to: number of patients receiving each service offered, number of patient visits, reasons for discharge, breakdown by diagnosis, sources of referral, number of patients not accepted with reasons and total staff days for each service offered.
- i) Clinical Record Review

## ILLINOIS REGISTER

---

### DEPARTMENT OF PUBLIC HEALTH

#### NOTICE OF PROPOSED AMENDMENTS

- 1) At least quarterly, members of professional disciplines representing at least the scope of the agency's programs, shall review a sample of both active and closed clinical records to assure that established policies are followed in providing services (direct, as well as those under contractual arrangement). This review shall include, but not be limited to:
  - A) Whether the patient care plan was directly related to the stated diagnosis and plan of treatment;
  - B) Whether the frequency of visits was consistent with the plan of treatment;
  - C) Whether the services could have been provided in a shorter span of time.
- 2) Clinical records shall be reviewed continually for each 62 day period that a patient received home health services to determine the adequacy of the plan of treatment and the appropriateness of continuing home health care.

(Source: Amended at 31 Ill. Reg. \_\_\_\_\_, effective \_\_\_\_\_)

#### Section 245.55 Vaccinations

- a) Influenza
  - 1) A home health agency shall annually administer or arrange for administration of a vaccination against influenza to each client/patient, in accordance with the recommendations of the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention titled Morbidity and Mortality Weekly Report, General Recommendations on Immunization (see Section 245.25), unless the vaccination is medically contraindicated or the client/patient has refused the vaccine. (Section 6.5 of the Act)
  - 2) The following activities by home health agencies shall be considered to be “arranging for” a home health client/patient to receive an influenza vaccination:
    - A) Referring a client/patient to the physician who is supervising the client/patient’s home care, or to his/her primary care physician; or

## ILLINOIS REGISTER

---

### DEPARTMENT OF PUBLIC HEALTH

#### NOTICE OF PROPOSED AMENDMENTS

- B) Referring a client/patient to the hospital affiliated with the home health agency; or
- C) Referring a client/patient to the local health department or other community location (e.g., local pharmacy, influenza vaccine clinic, hospital) where influenza vaccinations are available; or
- D) Arranging for the local health department or other private or community health organization to provide the vaccination in the client/patient's home.

3) When a referral or arrangement is made, home health agency staff shall assist the client/patient in developing a plan for implementing the referral or arrangement and shall assess implementation of the plan and document the outcome.

4) Influenza vaccination for all clients/patients age 65 or over shall be completed by November 30 of each year or as soon as practicable if vaccine supplies are not available before November 1. Home health clients/patients whose services start after November 30, during the flu season, and until February 1 shall, as medically appropriate, receive an influenza vaccination prior to or upon service initiation or as soon as practicable if vaccine supplies are not available at the time of the service initiation, unless the vaccine is medically contraindicated or the client/patient has refused the vaccine. (Section 6.5(a) of the Act)

5) For all clients/patients who are provided services between November 1 and February 28, the home health agency shall document in the client/patient's medical record that an annual vaccination against influenza was administered, arranged, refused, or medically contraindicated or that the client/patient is not a member of a vaccination priority population. (Section 6.5(a) of the Act)

6) The following shall be considered to be documentation approaches that meet the requirements of Section 6.5 of the Act:

- A) Individual client/patient record entries identifying the assessment for the need of vaccination; date of offer or referral; client/patient response; administration, contraindication, or refusal; and any follow-up activities.

## ILLINOIS REGISTER

---

### DEPARTMENT OF PUBLIC HEALTH

#### NOTICE OF PROPOSED AMENDMENTS

B) Standardized check-off form recording client/patient specific information, including the assessment for the need of vaccination; date of offer or referral; client/patient response; administration, contraindication, or refusal; and any follow-up activities.

b) Pneumococcal pneumonia

1) A home health agency shall administer or arrange for administration of a pneumococcal vaccination, in accordance with the recommendations of the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention titled Morbidity and Mortality Weekly Report, General Recommendations on Immunization (see Section 245.25), to each client/patient who is age 65 or over and who has not received this immunization prior to or upon service initiation, unless the client/patient refuses the offer for vaccination or the vaccination is medically contraindicated. (Section 6.5(b) of the Act)

2) The following activities by home health agencies shall be considered to be “arranging for” a home health client/patient to receive a pneumonia vaccination:

A) Referring a client/patient to the physician who is supervising his/her home care, or to his/her primary care physician; or

B) Referring a client/patient to the hospital affiliated with the home health agency; or

C) Referring a client/patient to the local health department or other community location (e.g., local pharmacy, clinic, hospital) where pneumonia vaccinations are available; or

D) Arranging for the local health department or other private or community health organization to provide the vaccination in the client/patient’s home.

3) When a referral or arrangement is made, home health agency staff shall assist the client/patient in developing a plan for implementing the referral or arrangement and shall assess implementation of the plan and document the outcome.

4) A home health agency shall document in each client/patient’s medical

## ILLINOIS REGISTER

---

### DEPARTMENT OF PUBLIC HEALTH

#### NOTICE OF PROPOSED AMENDMENTS

*record that a vaccination against pneumococcal pneumonia was offered and was administered, arranged, refused, or medically contraindicated or that the client/patient is not a member of a vaccination priority population. (Section 6.5(b) of the Act)*

- 5) The following shall be considered to be documentation approaches that meet the requirements of Section 6.5 of the Act:
  - A) Individual client/patient record entries identifying the assessment for the need of vaccination; date of offer or referral; client/patient response; administration, contraindication, or refusal; and any follow-up activities.
  - B) Standardized check-off form recording client/patient specific information, including the assessment for the need of vaccination; date of offer or referral; client/patient response; administration, contraindication, or refusal; and any follow-up activities.

(Source: Added at 31 Ill. Reg. \_\_\_\_\_, effective \_\_\_\_\_)