
Georgia Department of Human Resources

Division of Public Health

Standards for Nurse Agent Agreements to Administer Selected Vaccines under Nurse Protocol

<http://health.state.ga.us/programs/immunization/index.asp>

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**GEORGIA DEPARTMENT OF HUMAN RESOURCES
DIVISION OF PUBLIC HEALTH
STANDARDS FOR NURSE AGENT AGREEMENTS
TO ADMINISTER VACCINES UNDER NURSE PROTOCOL**

A. PURPOSE

The purpose of these standards is to specify the conditions, terms and expectations, that nurses serving as Agents of the Georgia Department of Human Resources, Division of Public Health (hereinafter referred to as the Department), pursuant to O.C.G.A. § 43-34-26.1, must comply with in order to administer selected vaccines under nurse protocol and to assure that practice under nurse protocol is in compliance with all applicable statutes, rules and regulations and requirements of the Department.

B. DEFINITIONS

1. Agent

An agent is defined as an individual Registered Professional Nurse (RN) currently licensed by the Georgia Board of Nursing or an Advanced Practice Registered Nurse (APRN) currently licensed by the Georgia Board of Nursing. It does **not** include companies, businesses, business trusts, trusts, estates, corporations, governmental subdivisions or agencies, partnerships, associations, groups or entities that employ RNs and/or APRNs. The Department's Agent referred to hereinafter is the aforementioned individual RN or APRN.

2. Nurse Protocol

Nurse Protocol means a written document mutually agreed upon and signed by a nurse and a licensed physician, by which the physician delegates to that nurse the authority to perform certain medical acts pursuant to subsection (b) of this Code Section, and which acts shall include, without being limited to, the administering and ordering of any drug.¹

Each registered professional nurse (RN) must have access to the current nurse protocol(s), under which the RN is practicing at the practice site. Each RN must have his/her individual set of nurse protocols which are signed by the nurse and the delegating physician(s).

3. Order

Order means to select a drug, medical treatment or diagnostic study through physician delegation in accordance with a nurse protocol or a physician assistant's job description. Ordering under such delegation shall not be construed to be prescribing, which act can only be performed by the physician, nor shall ordering of a drug be construed to authorize the issuance of a written

¹ O.C.G.A. § 43-34-26.1

prescription.²

The RN shall write the drug order in accordance with the nurse protocol and based on a client assessment each time the drug is ordered. If the client continues the drug on subsequent visits, the nurse must reorder the drug based on the nurse protocol. Documentation of the written drug order by the RN shall include the following components:

- Date ordered
- National Drug Code (NDC) number
- Generic name or actual brand name of drug
- Strength of drug
- Dose
- Dosage form
- Route of administration
- Frequency
- Duration of therapy
- Quantity dispensed/provided
- Signature of RN or APRN who ordered the drug

Example: Influenza vaccine 0.5 ml IM x 1 dose.

4. Nurse
Nurse means Registered Professional Nurse (RN) or Advanced Practice Registered Nurse (APRN) currently licensed by the Georgia Board of Nursing.
5. Delegating Physician
The delegating physician must hold a current license by the Georgia Composite State Board of Medical Examiners and are encouraged to be engaged in current clinical practice on a full-time or part-time basis. Delegating physician means the physician(s) who has/have mutually agreed to and signed the nurse protocol.
6. Legal Signature
Entries into the client's medical record must be dated and signed by the person who makes the entry, using full name and letters that denote professional title (e.g., Suzie A. Jones, R.N. or Suzie A. Jones, R.N., A.P.R.N.) and be in compliance with the Department policy, *Documentation of Nursing License and Certification*, Division of Public Health, July 1, 2008 (<http://health.state.ga.us/programs/nursing/index.asp>).
7. Dispense
Dispense means to issue one or more doses of any drug in a suitable container with appropriate labeling for subsequent administration to, or use by, a patient.

2 Ibid.

8. Dispensing Procedure
Dispensing procedure means a written document signed by a licensed pharmacist and a licensed physician, which establishes the appropriate manner under which drugs may be dispensed pursuant to this Code Section.³ The dispensing procedure must be signed by a pharmacist licensed by the Georgia Board of Pharmacy and by a physician who is licensed by the Georgia Composite State Board of Medical Examiners.

9. Dangerous Drugs
Dangerous Drug means any dangerous drug as defined in O.C.G.A. §16-13-71, but does not include any controlled substance or Schedule I controlled substance.⁴

Dangerous drugs are required to bear upon the package the words "Caution Federal Law Prohibits Dispensing Without Prescription," "Rx Only" or words of like import. These drugs may also be referred to as "Legend" drugs.

10. Standard Abbreviations
Standard Abbreviations refer to those found in the Department policy, *Statewide Standard List, Abbreviations, Acronyms and Symbols*, Division of Public Health, May 21, 2008 (<http://health.state.ga.us/programs/nursing/index.asp>).

C. HIPAA REQUIREMENTS

1. Agents shall maintain documentation evidencing that they have received adequate training by a competent professional on the HIPAA statutes and requirements. Documentation shall include, but not limited to, the date of training and course title.
2. Agents shall comply with all Federal and State laws, rules and regulations governing HIPAA, the Privacy & Security Act and confidentiality of client information.
3. Agents shall inform all clients of their rights under HIPAA, which shall also include the right to forward Complaints to the Department and The Office of Civil Rights.
4. Agents must document all HIPAA violations, HIPAA related inquiries and complaints concerning the confidentiality of client information. All violations and complaints shall be forwarded to the Department within 24 hours following receipt. The Department will forward the complaint to the Office of Civil Rights, where appropriate.

3 O.C.G.A. § 43-34-26.1.

4 Ibid.

D. SELECTED VACCINES TO BE ADMINISTERED UNDER NURSE PROTOCOL

1. The RN or APRN is limited to administering the following vaccines under nurse protocol:
 - a. Influenza Vaccine
 - b. Meningococcal Vaccine
 - c. Pneumococcal Vaccine
 - d. Tetanus-containing VaccineNote: See section P, Emergency Protocols, Procedures, Equipment and Supplies, regarding administration of emergency drugs.
2. The nurse protocols for the above listed vaccines shall be in compliance with the Advisory Committee of Immunization Practices (ACIP).
3. The RN or APRN shall provide the current Vaccine Information Statements (VIS) in accordance with the National Childhood Vaccine Injury Act (42 U.S.C. § 300aa-26) and according to the following standards:
 - a. Each VIS shall be the approved statement by the Centers for Disease Control and Prevention.
 - b. Each VIS shall be provided to the client at the time that the vaccination is given.
 - c. The following VISs shall be used unless a more current version is published:
 - 1) Inactivated Influenza: 7/24/08
 - 2) Live, Intranasal Influenza: 7/24/08
 - 3) Meningococcal Vaccine: 1/28/08
 - 4) Pneumococcal Polysaccharide: 7/29/97
 - 5) Tetanus Diphtheria (Td): 6/10/94
 - 6) Tetanus, Diphtheria, Pertussis (Tdap): 7/12/06
 - d. The Agent administering the above selected vaccines shall document in the client's medical record the following (42 U.S.C. § 300aa-25):
 - 1) The name and title of the individual who administers the vaccine
 - 2) The name of the vaccine
 - 3) The date of administration
 - 4) The vaccine manufacturer and lot number of the vaccine used
 - 5) The publication date of the VISs and the date they were provided to the client
 - 6) The address of the location where the vaccine was given

E. PROPER STORAGE AND HANDLING OF VACCINE

1. Equipment Requirements for Vaccine Storage
 - a. The refrigerator and freezer must have **externally separate, sealed doors.**
 - b. The refrigerator compartment must maintain temperatures between **35 degrees and 46 degrees Fahrenheit (2 degrees and 8 degree**

Centigrade).

- c. The freezer compartment must maintain temperature of **5 degrees Fahrenheit (-15 degrees Centigrade)** or colder.
- d. Household-style refrigerator units must have **separate thermostat/temperature controls** for the refrigerator and freezer.
- e. Both the refrigerator and freezer compartments must contain an **NIST- or ASTM-certified thermometer**.
- f. Dormitory-type refrigerators may be used only for temporary (< 8 hours) storage of vaccine and are not acceptable for long-term vaccine storage. The temperature of any dormitory-type refrigerator used temporarily should be monitored throughout the day.
- g. Routinely placing vaccine in portable coolers during the clinic day is not acceptable.
- h. Refrigerator and freezer temperatures shall be documented twice daily using an approved temperature log. Sample log may be found at <http://www.health.state.ga.us/pdfs/prevention/immunization/vfc.templog.05.pdf>
- i. All standards outlined on The *Checklist for Safe Vaccine Handling and Storage* (www.immunize.org) shall be met prior to the Georgia Immunization Program Consultant's inspection visit. The DHR-DPH Agent shall be suspended from practicing under nurse protocol and/or the agency agreement will be terminated if any deficiencies are identified during the site visit or at any time.
- j. The Agent may only possess and transport the quantity of vaccine that would be used for one day. The Agent shall not store any vaccines in their homes, automobiles, business offices or other unauthorized locations.

F. VACCINE ADVERSE EVENT REPORTING SYSTEM

1. The Agent is required by law (42 USC 300aa-25) to report reactions to vaccines listed in the Table of Reportable Events Following Immunization. The table may be found at <http://www.vaers.hhs.gov/pdf/ReportableEventsTable.pdf>.
2. The Vaccine Adverse Event Reporting System form shall be used and is available online at www.vaers.hhs.gov or 1-800-822-7967.

G. GEORGIA REGISTRY OF IMMUNIZATION TRANSACTIONS AND SERVICES (GRITS)

1. The Agent shall complete training on GRITS and obtain an Organizational ID number prior to administering vaccines.
2. The Georgia Immunization Program will provide dates and times available for the GRITS training.
3. The Agent shall submit all data regarding vaccines administered to GRITS within two business days of vaccine administration (O.C.G.A. § 31-12-3.1).

H. REQUIREMENTS FOR A REGISTERED PROFESSIONAL NURSE OR ADVANCED PRACTICE REGISTERED NURSE WHO USES A NURSE PROTOCOL

A Registered Professional Nurse (or APRN) who uses a nurse protocol must:⁵

1. Hold a current license to practice as a registered professional nurse (RN) in Georgia.
2. Document preparation and performance specific to each medical act authorized by a nurse protocol, including ordering dangerous drugs, medical treatments or diagnostic studies. Prior to the RN functioning under a nurse protocol, there shall be written documentation that the RN has training, preparation and/or orientation relative to each medical act authorized by the specific nurse protocol and can perform such acts. Documentation may include supervisory notes, orientation plans, direct observation of clinical performance, skills checklist(s) and/or performance appraisal(s).
3. Adhere to the written nurse protocol.

I. CREDENTIALING OF NURSES AUTHORIZED TO PRACTICE UNDER NURSE PROTOCOL

1. The Agent shall provide verification that the Registered Professional Nurse (RN) or Advanced Practice Nurse (APRN) is currently licensed by the Georgia Board of Nursing.
2. Verification of the RN and APRN license shall be confirmed through the Internet at www.sos.state.ga.us.
3. There is no statutory authority for Licensed Practical Nurses (LPNs) to practice under nurse protocol. Therefore, an LPN may not serve as an agent. However, since the RN may supervise the provision of care provided by an LPN, the RN may delegate to the LPN the administration of drugs (e.g., vaccines). Since the LPN is not authorized to order dangerous drugs or dispense dangerous drugs, the decision to order such drugs is the responsibility of the RN working under the nurse protocol, who has responsibility for possession of dangerous drugs [O.C.G.A. § 16-13-72 (4.1)].

J. REQUIREMENTS FOR NURSE PROTOCOLS

A nurse protocol must:

1. Be reviewed, revised or updated annually. The nurse protocol must bear the current review date and signatures of the delegating physician(s) and RN(s) or APRN(s).

⁵ Georgia Board of Nursing: Regulation of Protocol Use by Registered Nurses, Chapters 410-13.

2. Specify that record reviews of nursing practice under nurse protocol (of RNs and APRNs) by the delegating physician will be completed at least monthly.
3. Be available or accessible in each of the specific settings where RN(s) and APRN(s) practice under nurse protocols, and be available upon request.
4. Include the specific terms/conditions under which delegated medical acts may be performed.
5. Include the condition(s) for immediate consultation with a delegating physician or a physician designated in his or her absence.
6. Include a statement that the RN or APRN has read and understands all statutes, rules and regulations pertaining to nursing practice under nurse protocol and has read and understands the drug dispensing procedure.

K. DELEGATED AUTHORITY FOR ORDERING DANGEROUS DRUGS

1. RNs and APRNs who are delegated the authority to order dangerous drugs must do so in accordance with written nurse protocols. The nurse protocol must outline the parameters that must be followed pursuant to ordering the drug and must also specify the drug and the specific conditions under which it may be ordered.

L. CONSULTATION AND REFERRAL

1. If the Agent seeks medical consultation, the results of the consultation must be documented in the client's chart. Based on the medical consultation and clinical assessment of the client, the RN or APRN decides whether to order any of the drugs in the nurse protocol, to seek further medical consultation, or to refer the client. This includes when the medical consultation results in a dosage, drug, or any medical act which is not covered by the current nurse protocol.
2. If the Agent decides to refer the client, the referral must be documented in the client's chart. The documentation should include where/to whom the client was referred, what medical information was sent with the client or authorized to be released, and any assistance and/or instructions provided to the client. Results of the referral and any changes in the client's plan of care shall be documented, if/when such information is known.

M. DISPENSING DANGEROUS DRUGS

If the nurse protocol does not include any dispensing of drugs, a dispensing procedure is not required. If the nurse protocol does include any dispensing of drugs, the Agent

must use a current dispensing procedure approved by the Georgia State Board of Pharmacy, signed by a current Georgia licensed pharmacist and signed by the delegating physician. RNs and APRNs are authorized to dispense dangerous drugs only under the following conditions:

1. The dispensing is in accordance with a written drug dispensing procedure⁶ and under the authority of an order issued in conformity with a nurse protocol.
2. All licensed pharmacists who sign a dispensing procedure must submit such document to the Georgia State Board of Pharmacy for review. Any such dispensing procedure must be in conformity with this Chapter and O.C.G.A. § 43-34.26.1, and shall include the names of all persons dispensing drugs pursuant to such dispensing procedure (Georgia State Board of Pharmacy Rules 480-30-.07).
3. There must be documented preparation and performance (i.e. ability to perform) specific to dispensing dangerous drugs based on a written dispensing procedure.⁷ Documentation shall include that each RN or APRN has read and understands the drug dispensing procedure.
4. A copy of the drug dispensing procedure must be accessible in each of the specific settings where RNs and APRNs dispense under nurse protocols, and be available upon request. The procedure must be signed by the pharmacist and physician who have established it.
5. A current drug reference book shall be available in all sites where vaccines are administered under nurse protocol. At least one of the following references must be available in all sites: Drug Facts and Comparisons [eFacts and Comparisons], American Hospital Formulary Service or Lexi-Comp Drug Information Handbook.
6. The RN and APRN shall exercise diligence in protecting drugs and records from loss or theft, in accordance with the rules of the Georgia Board of Pharmacy.
7. The RN or APRN is not authorized to dispense a drug:
 - a. Based on a prescription written by either a public health or private physician.
 - b. Pursuant to an order written on a client's chart by a physician, physician's assistant or another RN or APRN.
 - c. Based on a written or verbal recommendation from a co-worker.

6 Georgia Board of Pharmacy Rules 480-30-.02- General Requirements, "Any person who dispenses drugs in accordance with a dispensing procedure and under the authority of a job description or nurse protocol shall comply with all record keeping, labeling, packaging and storage requirements imposed upon pharmacists and pharmacies with regard to such drugs pursuant to O.C.C.A. 26-4 and 16-13, and those regulations contained in this chapter."

7 Georgia Board of Nursing: Regulation of Protocol Use by Registered Nurses, Chapters 410-13.

- d. Based on a drug order received over the phone.
- e. When any of the above situations occur, the RN or APRN practicing under nurse protocol:
 - 1) Adds the written information or documents the oral information received (e.g., medical diagnosis, physician's prescription) to the client's chart,
 - 2) Reviews any written information in the chart, and
 - 3) Based on his/her review of the information and clinical assessment of the client, decides whether to order any of the drugs listed in the appropriate nurse protocol, to seek medical consultation, or to refer the client.
- f. If the RN or APRN decides to order a drug listed in the nurse protocol, he/she assumes responsibility for ordering the drug in accordance with the nurse protocol and dispensing the drug according to a written drug dispensing procedure.
NOTE: The RN or APRN can dispense drugs only on his/her own order, and in accordance with a nurse protocol agreement and a drug dispensing procedure.

N. ACCOUNTABILITY AND QUALITY ASSURANCE PLAN

- 1. The Agent and the Delegating Physician are accountable for the quality of care provided under a nurse protocol.
- 2. The Agent shall develop a written Quality Assurance Plan that outlines the specific Quality Assurance activities that will be used to provide the necessary monitoring, supervision and management necessary to assure that the nurse practicing under nurse protocol complies with all applicable statutes, rules and regulations pertaining to practice under nurse protocol and all DHR requirements and as specified in these standards.
- 3. The Quality Assurance Plan shall include plans for the delegating physician to review at least 10% of the medical records of clients served each month.
- 4. The Division of Public Health Immunization Program Consultant shall conduct a site visit audit of the Agent to assure compliance with all vaccine storage and handling requirements. A summary of this site visit audit shall be submitted to the Agent within 30 days of when the site visit audit occurred. Original site visit documentation will remain on file at the Immunization Program state office for a period of three years.
- 5. The Department shall have access to the Agent's records with or without prior notice.

O. SIGNING NURSE PROTOCOL AGREEMENTS

1. Signature Requirements

- a. Items to include on the signature page to document compliance with specific rules and regulations of the Georgia Board of Nursing (GBON) and the Georgia State Board of Pharmacy:
 - 1) That the RN or APRN is adequately trained and prepared to perform the delegated medical acts (document the specific training in the nurse's personnel or supervisory file).
 - 2) That the RN or APRN has read and understands all statutes, rules, and regulations pertaining to nursing and nursing practice under nurse protocol and has read and understands the drug dispensing procedure.
 - 3) That 10% of the records will be reviewed by the delegating physician at least monthly.
- b. The signature page shall represent a mutual agreement between the delegating physician(s) and the RN(s) or APRN(s).
- c. Each person shall use his/her legal signature as it appears in client records (i.e., full name/letters denoting the professional title - MD, APRN, RN). Each RN or APRN shall document their signature on each client medical record in accordance with the DHR policy, *Documentation of Nursing License and Certification Credentials*, Division of Public Health, July 1, 2008 (<http://health.state.ga.us/programs/nursing/index.asp>).
- d. A single signature page shall be signed by each individual RN and APRN and each respective delegating physician. Each signature page shall include the printed name of each RN or APRN and each respective delegating physician and the current Georgia license number of each RN or APRN and the delegating physician.

2. Review/Revision Requirements

All nurse protocols must be reviewed, revised and updated at least annually. The responsibility for assuring that the nurse protocol is reviewed, revised and updated at least annually is shared among the delegating physician, the RN and the employer/organization for which the RN works. Changes in drug treatment and health care technology should be incorporated into revised nurse protocols in a timely manner. Each time the nurse protocol is reviewed, revised and updated, both the delegating physician and the individual RN or APRN shall sign and date the nurse protocol. The delegating physician shall assure that the RN or APRN is adequately prepared to practice the delegated medical acts, as outlined in the nurse protocol agreement.

EXAMPLE

NURSE PROTOCOL SIGNATURE PAGE

The signatures below indicate a mutual agreement between the delegating physician(s) and the registered professional nurse (RN) or the Advanced Practice Registered Nurse (APRN) that is authorized to perform the delegated medical acts contained in the nurse protocols for one year from the date that the nurse protocol is signed.

The RN or APRN whose signature appears on this page:

1. Has been adequately trained and is prepared to perform the delegated medical acts contained in the designated nurse protocols; such training is documented in the RN's or APRN's personnel/supervisory files.
2. Has read and understands all statutes, rules and regulations pertaining to nursing and practice under nurse protocol and has read and understands the drug dispensing procedure.

The delegating physician shall review 10% of the records monthly.

Signature of Delegating Physician

Date Signed by Delegating Physician

Print Name of Delegating Physician

Delegating Physician Georgia License #

Signature of RN or APRN

Date Signed by RN or APRN

Print Name of RN or APRN

RN or APRN Georgia License #

P. RETENTION OF NURSE PROTOCOLS

1. The Agent shall retain one copy of each nurse protocol for at least five years, so that it can be retrieved in case of an audit or legal issue.
2. The Agent shall retain copies of the medical record reviews completed by the delegating physician for at least five years.
3. The Department shall maintain copies of each Agent agreement for at least five years.

Q. EMERGENCY PROTOCOLS, PROCEDURES, EQUIPMENT AND SUPPLIES

1. The Agent shall provide emergency protocols to cover the following:
 - a. Allergic reactions, including acute anaphylaxis in adults, infants and children
 - b. Vasovagal Syncope (Fainting)
2. The Agent shall provide procedures to cover the following:
 - a. Provision of current and functioning medical emergency equipment and supplies
 - b. Security for all emergency drugs and equipment
 - c. Monthly inventory and documentation of all emergency drugs
 - d. Monthly inventory and working condition of all emergency equipment
 - e. Emergency phone numbers posted on each phone and in each site
 - f. A practice or mock emergency drill shall be conducted and documented prior to practicing under a nurse protocol
 - g. Documentation and reporting of allergic reaction/anaphylaxis
3. The Agent shall assure that all RNs and APRNs who practice under nurse protocol have current certification in CPR.
4. The Agent shall assure that all incidents involving allergic reaction/anaphylaxis are documented and reported to the Department within 24 hours of each occurrence.

R. FEES

1. The agent's fee shall not be less than that of the County Board of Health for the geographic area where vaccines are administered.
2. If the client is unable to pay for the vaccine(s) to be administered, the vaccine(s) shall be administered to the client at no charge to the client.

S. VACCINE AND SUPPLY PROCUREMENT

The procurement of vaccine or other drugs for adverse reactions to those vaccines must be in compliance with Georgia Code Title 16, Chapter 13, and Title 26, Chapter 4 and the Georgia State Board of Pharmacy Rules Chapter 480. The Agent must submit the legal printed name, signature and a copy of the Georgia license of the responsible party for purchasing, security, storage and distribution of dangerous drugs.