



### **Protocol for Pharmacist-Administered Vaccines**

This Protocol (**Agreement**) is made effective as January 5, 2022 ("Effective Date"), by and between zaheer shah (**Authorizing Physician**), a physician licensed in and actively practicing in the State of Rhode Island who is authorized to prescribe drugs, and **Genoa Healthcare, LLC** (**Pharmacy**), a Rhode Island licensed pharmacy, for the purpose of setting forth the terms under which a pharmacist (**Pharmacist**), who is employed by Pharmacy, may administer vaccines without a prescription.

1. **Pharmacist Qualifications.** Pharmacy must ensure that Pharmacist meets the following requirements prior to administering a vaccine to an individual under this Agreement.
  - a. **Relationship with Pharmacy.** Pharmacist must be an employee of Pharmacy. If Pharmacist's employment with Pharmacy ends, Pharmacist's authorization to administer vaccines under this Agreement is immediately terminated.
  - b. **Training.** Pharmacist must have successfully completed the following training and certification:
    - i. Immunization training within an accredited college of pharmacy program or twenty (20) hour course recognized by the Rhode Island Board of Pharmacy including: mechanisms of action of immunizations, contraindications, drug interactions, and monitoring after immunization administration; immunization schedules; immunization screening questions, informed consent, recordkeeping, registries and state/federal reporting mechanisms; vaccine storage and handling; biohazard waste disposal; sterile techniques; establishing protocols and standing orders; immunization coalitions and other community resources available; identifying, managing, and responding to adverse events associated with immunization administration; reporting adverse events to the Vaccine Adverse Event Reporting System (VAERS); reimbursement procedures and immunization coverage by federal, state, and local entities; and administration techniques;<sup>1</sup> and
    - ii. Basic Cardiopulmonary Resuscitation (CPR) training issued by the American Heart Association, the American Red Cross, or other such training organization.<sup>2</sup>
  - c. **Continuing Competency.** Pharmacist must complete at least one (1) hour of continuing pharmacy education related to vaccines each year.<sup>3</sup> In addition, Pharmacist must maintain current CPR certification.<sup>4</sup>
  - d. **License in Good Standing.** Pharmacist must be licensed and in good standing with the Rhode Island Board of Pharmacy.
2. **Pharmacy Duties.**
  - a. **Evaluation.** Pharmacy must ensure that professional judgment is exercised in determining whether a vaccine is appropriate for an individual. Decisions concerning the administration of a vaccine must be made in compliance with the current recommendations of the Advisory Committee on Immunization Practices (ACIP) published by the Centers for Disease Control and Prevention (CDC) and the protocol for the vaccine (available in Exhibit A).
  - b. **Policies and Procedures.** Pharmacy must maintain policies and procedures, decision criteria, or plan for Pharmacist to follow when exercising administration authority, including when to refer individual to Authorizing Physician or other physician.<sup>5</sup>
  - c. **Contraindications and Precautions.** Each individual must be screened for contraindications and precautions. If an individual has one or more of the contraindications or precautions present, the individual's primary care provider or Authorizing Physician must give approval before the vaccine is administered. The individual record must include:

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<sup>1</sup> 216-RICR-40-15-1.11.1.

<sup>2</sup> *Id.*

<sup>3</sup> 216-RICR-40-15-1.4.19.

<sup>4</sup> 216-RICR-40-15-1.4.17.

<sup>5</sup> *Id.*



- i. Any contraindications or precautions identified;
    - ii. A summary of the discussion with the individual;
    - iii. If the individual still wants to receive the vaccine, a summary of the discussion with the physician; and
    - iv. If the individual receives the vaccine, the authorization from the physician.
  - d. **Informed Consent.** Pharmacy must obtain parental consent for all immunizations administered to individuals under the age of eighteen (18) years.<sup>6</sup>
  - e. **Vaccines and Emergency Medications that may be Administered.** The following vaccines and immunizations may be administered in compliance with applicable regulations, the recommendations of the ACIP, and the attached protocol for the vaccine available in Exhibit A.
    - i. **Children between nine (9) and eighteen (18) years of age with parental consent.**<sup>7</sup>
      - 1. Influenza.....(Exhibit A-2)
    - ii. **Adults who are eighteen (18) years of age and older.**<sup>8</sup>
      - 1. HepA.....(Exhibit A-6)
      - 2. HepB.....(Exhibit A-8)
      - 3. Hib.....(Exhibit A-3)
      - 4. HPV.....(Exhibit A-10)
      - 5. Influenza.....(Exhibit A-4)
      - 6. MenACWY or MPSV4, MenB.....(Exhibits A-14, A-15)
      - 7. MMR.....(Exhibit A-12)
      - 8. PCV13, PPSV23.....(Exhibit A-18)
      - 9. Tdap/Td.....(Exhibit A-23a, A-23b)
      - 10. Varicella.....(Exhibit A-25)
      - 11. Zoster (>50 years old) .....(Exhibit A-27)
      - 12. COVID-19 ..... (Exhibit A-34)
    - iii. **Emergencies or Disasters.** In the event that a governmental agency declares a disaster or emergency and grants pharmacists expanded scope of practice to administer vaccines in addition to those set forth in this Agreement, Pharmacy may authorize Pharmacist to administer those vaccines in accordance with the governmental guidelines.
  - f. **Documentation.** All vaccines administered must be properly documented.
    - i. **Individual Records.** Pharmacy must maintain an individual record of administration including: individual name, address, date of birth; date of administration and site of injection; name, dose, manufacturer, lot number, and expiration date of vaccine; name and address of individual's primary care provider, as identified by individual; and name or identifiable initials of Pharmacist or intern, if applicable.<sup>9</sup>
    - ii. **Vaccine Information Statement.** The current Vaccine Information Statement (VIS) for each vaccine to be administered must be discussed and provided to each individual (or if the individual is a minor, the individual's parent or guardian).<sup>10</sup> The VIS is available at <http://www.cdc.gov/vaccines/hcp/vis/>. The publication date of the VIS and the date the VIS was provided to the patient must be included in the individual record maintained pursuant to Section 2.e.i., supra.<sup>11</sup>

<sup>6</sup> R.I. Gen. Laws 5-19.1-31(a).

<sup>7</sup> R.I. Gen. Laws 5-19.1-31(a); 216-RICR-40-15-1.11.1.

<sup>8</sup> 216-RICR-40-15-1.11.1

<sup>9</sup> *Id.*

<sup>10</sup> *Id.*

<sup>11</sup> *Id.*



- iii. **Record Retention.** Pharmacy must maintain records for at least five (5) years after the date of administration.<sup>12</sup>
- g. **Emergency Procedures for Adverse Reactions.** Allergic, anaphylactic, or other emergency conditions must be managed according to the emergency protocol (Exhibits A-32, A-33).<sup>13</sup>
- h. **Reporting.**
  - i. **Primary Care Provider.** Pharmacy must make a good faith effort to provide notification of an individual's vaccination to the individual's primary care provider within fourteen (14) days of administration.<sup>14</sup>
  - ii. **State.** Pharmacy must report the administration of vaccines for children between the ages of nine (9) and eighteen (18) years of age for influenza vaccines to the state registry, KIDSNET, within seven (7) days of administration.<sup>15</sup>
  - iii. **Adverse Events.** Pharmacy must report adverse events to the Vaccine Adverse Events Reporting System (VAERS) and to the individual's primary care provider within ten (10) days of the adverse event.<sup>16</sup>
- i. **Delegation.**<sup>17</sup> Pharmacy may delegate administration of a vaccine to a licensed intern or a licensed Pharmacy Technician II provided that:
  - i. The intern or pharmacy technician is directly supervised by Pharmacist and the Pharmacist is on the premises for post-immunization monitoring of the patient;
  - ii. The intern or pharmacy technician has completed a recognized vaccine certificate training program; and
  - iii. The intern or pharmacy technician holds a current basic cardiopulmonary resuscitation (CPR) training certificate.
- j. **Disposal.** Pharmacy must ensure appropriate handling and disposal of used or contaminated equipment and supplies.<sup>18</sup>
- k. **References.** Pharmacy must maintain a copy of this Agreement, including all Exhibits, at all places where Pharmacist administers vaccines.

**3. Authorizing Physician Duties.**

- a. **Availability.** Authorizing Physician must be available for consultation, questions about contraindications or precautions, and advice in the event of an adverse reaction.
- b. **Protocol Review.** Authorizing Physician must review the services provided under the Agreement on a biennial basis.<sup>19</sup>

**4. Term and Termination.** Unless rescinded earlier in writing by either party for any reason, the term of this Agreement shall commence on the Effective Date and shall continue in effect for one (1) year (the "Term") for activities performed by Pharmacist in Pharmacy. If Pharmacist's employment with Pharmacy ends, Pharmacist's authorization under this Agreement is automatically terminated.

**5. Miscellaneous.**

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<sup>12</sup> *Id.*  
<sup>13</sup> *Id.*  
<sup>14</sup> *Id.*  
<sup>15</sup> *Id.*  
<sup>16</sup> *Id.*  
<sup>17</sup> *Id.*  
<sup>18</sup> *Id.*  
<sup>19</sup> *Id.*



- a. **Changes to Agreement.** This Agreement may be modified only by a written instrument signed by both Parties.
- b. **Entire Agreement.** This Agreement, the Protocols and any Exhibits constitute the entire understanding of the Parties regarding the subject matter hereof, and supersede any prior agreements, writings or understandings, whether oral or written. This Agreement may be executed in multiple counterparts, all of which will constitute one and the same agreement. Each Party intends the facsimile of its signature printed by a receiving fax machine to be an original signature.
- c. **Jurisdiction.** This Agreement will be governed by and construed in accordance with the laws of the State of Rhode Island, without reference to its conflict of law provisions.
- d. **Headings.** The headings to the sections and subsections of this Agreement must be disregarded in its interpretation.
- e. **Assignment.** This Agreement is binding upon the Parties and their successors and permitted assigns. Neither Party must assign its rights or delegate or subcontract its duties under this Agreement without prior written consent of the other Party.
- f. **Notice.** All notices required or permitted hereunder will be deemed sufficiently given if hand-delivered or sent by certified mail or by facsimile, with confirmation receipt, addressed as follows:

If to Pharmacy: **Name:** Genoa Healthcare, LLC.  
**Address:** 707 S. Grady Way, Suite 700  
Renton, WA 98057  
**Facsimile:** (253) 218-0336

If to Authorizing Physician: **Name:** zaheer shah  
**Facsimile:** 678-222-7107


- g. **Privacy of Medical Records.** The Parties will treat all medical records or other health and enrollment information as confidential and protected against unauthorized disclosure so as to comply with all state and federal laws regarding the privacy, security, confidentiality and disclosure of individuals' health information. The Parties must allow each other to use medical records as necessary to provide appropriate individual care.
- h. **Exclusion from Federal Health Care Programs.**
  - i. **Pharmacy.** Pharmacy hereby represents that neither Pharmacy, nor, to the best of Pharmacy's knowledge, Pharmacist, Pharmacy's employees, agents or independent contractors involved in the provision of services have been excluded from participation in any Federally-funded health care programs, including, but not limited to, Medicare and Medicaid.
  - ii. **Physician.** Authorizing Physician hereby represents that neither Authorizing Physician, the company under which Authorizing Physician submits claims to Medicare (Group Practice) nor, to the best of Authorizing Physician's knowledge, Group Practice's employees, agents or independent contractors involved in the provision of services have been excluded from participation in any Federally-funded health care programs, including, but not limited to, Medicare and Medicaid.
- i. **Independent Contractors.** Each Party is an independent entity and nothing in this Agreement must be construed to establish an employer/employee or principal/agent relationship or any fiduciary or other relationship other than independent parties contracting with each other for the purpose of carrying out the duties and obligations of this Agreement.
- j. **Severability and Waiver.** The invalidity or unenforceability of any term or provision of this Agreement must in no way affect the validity or enforceability of any other term or provision. The waiver by either Party of a breach of any provision of this Agreement must not operate as or be construed as a waiver of any subsequent breach thereof.

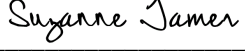


The undersigned represent that they are duly authorized to execute this Agreement on behalf of the party for whom they sign; and such party shall be bound by the terms of this Agreement.

**Authorizing Physician Signature:**

**Genoa Healthcare, LLC:**

Signature:   
Print Name: zaheer shah  
Address: 65 Eddie Dowling Highway  
City/State/Zip: N. Smithfield, RI 02896  
Medical License#: RI MD 9877  
Phone#: 401-769-2222  
Date: Dec 2, 2021

Signature:   
ED57D390BD834C0...  
Print Name: **Suzanne Tamer, RPh, MS**  
Title: Regional VP of Operations – East Division  
Address: 707 S. Grady Way, Suite 700  
City/State/Zip: Renton, WA 98057  
Phone#: (888) 436-6279  
Date: 12/13/2021 | 1:50 PM PST

**Exhibit A: Protocols**

Exhibit A-1	Haemophilus influenzae type b (Hib) — Children	<a href="#">Not permitted by protocol in Rhode Island</a>
Exhibit A-2	Influenza inactivated and live intranasal – Children	<a href="http://www.immunize.org/catg.d/p3074a.pdf">www.immunize.org/catg.d/p3074a.pdf</a>
Exhibit A-3	Haemophilus influenzae type b (Hib) – Adults	<a href="http://www.immunize.org/catg.d/p3083.pdf">www.immunize.org/catg.d/p3083.pdf</a>
Exhibit A-4	Influenza inactivated and live intranasal – Adults	<a href="http://www.immunize.org/catg.d/p3074.pdf">www.immunize.org/catg.d/p3074.pdf</a>
Exhibit A-5	Hepatitis A — Children	<a href="#">Not permitted by protocol in Rhode Island</a>
Exhibit A-6	Hepatitis A – Adults	<a href="http://www.immunize.org/catg.d/p3077.pdf">www.immunize.org/catg.d/p3077.pdf</a>
Exhibit A-7	Hepatitis B — Children	<a href="#">Not permitted by protocol in Rhode Island</a>
Exhibit A-8	Hepatitis B – Adults	<a href="http://www.immunize.org/catg.d/p3076.pdf">www.immunize.org/catg.d/p3076.pdf</a>
Exhibit A-9	HPV — Children	<a href="#">Not permitted by protocol in Rhode Island</a>
Exhibit A-10	HPV – Adults	<a href="http://www.immunize.org/catg.d/p3091.pdf">www.immunize.org/catg.d/p3091.pdf</a>
Exhibit A-11	MMR — Children	<a href="#">Not permitted by protocol in Rhode Island</a>
Exhibit A-12	MMR – Adults	<a href="http://www.immunize.org/catg.d/p3079.pdf">www.immunize.org/catg.d/p3079.pdf</a>
Exhibit A-13	Meningococcal (MenACWY) — Children	<a href="#">Not permitted by protocol in Rhode Island</a>
Exhibit A-14	Meningococcal (MenACWY) – Adults	<a href="http://www.immunize.org/catg.d/p3081.pdf">www.immunize.org/catg.d/p3081.pdf</a>
Exhibit A-15	Meningococcal B (MenB) – Children and Adults	<a href="http://www.immunize.org/catg.d/p3095.pdf">www.immunize.org/catg.d/p3095.pdf</a>
Exhibit A-16	Pneumococcal polysaccharide vaccine (PPSV) — Children	<a href="#">Not permitted by protocol in Rhode Island</a>
Exhibit A-17	Pneumococcal conjugate vaccine (PCV) — Children	<a href="#">Not permitted by protocol in Rhode Island</a>
Exhibit A-18	Pneumococcal (PPSV23 and PCV13) – Adults	<a href="http://www.immunize.org/catg.d/p3075.pdf">www.immunize.org/catg.d/p3075.pdf</a>
Exhibit A-19	Polio (IPV) — Children	<a href="#">Not permitted by protocol in Rhode Island</a>
Exhibit A-20	Rotavirus (RV) — Children	<a href="#">Not permitted by protocol in Rhode Island</a>
Exhibit A-21	Tetanus-diphtheria toxoids & pertussis (DTaP) — Children	<a href="#">Not permitted by protocol in Rhode Island</a>
Exhibit A-22	Tetanus-diphtheria toxoids & pertussis (Tdap/Td) — Children	<a href="#">Not permitted by protocol in Rhode Island</a>
Exhibit A-23a	Tetanus-diphtheria toxoids & pertussis (Tdap/Td) – Adults	<a href="http://www.immunize.org/catg.d/p3078.pdf">www.immunize.org/catg.d/p3078.pdf</a>
Exhibit A-23b	Tetanus-diphtheria toxoids & pertussis (Tdap/Td) – Pregnant Women	<a href="http://www.immunize.org/catg.d/p3078b.pdf">www.immunize.org/catg.d/p3078b.pdf</a>
Exhibit A-24	Varicella (Chicken Pox) — Children	<a href="#">Not permitted by protocol in Rhode Island</a>
Exhibit A-25	Varicella (Chicken Pox) – Adults	<a href="http://www.immunize.org/catg.d/p3080.pdf">www.immunize.org/catg.d/p3080.pdf</a>
Exhibit A-26	Zoster — Adults CDC Guidance (>60 yr)	See Exhibit A-27
Exhibit A-27	Zoster – Adults FDA Labeling (>50 yr)	<a href="https://bula-docs.s3.amazonaws.com/immunization-cpas/zoster50.pdf">https://bula-docs.s3.amazonaws.com/immunization-cpas/zoster50.pdf</a>
Exhibit A-28	Japanese Encephalitis — Children and Adults	<a href="https://bula-docs.s3.amazonaws.com/immunization-cpas/vaccine-protocols/japanese-encephalitis-standing-order-9-2015.docx">https://bula-docs.s3.amazonaws.com/immunization-cpas/vaccine-protocols/japanese-encephalitis-standing-order-9-2015.docx</a>
Exhibit A-29	Rabies — Children and Adults	<a href="https://bula-docs.s3.amazonaws.com/immunization-cpas/vaccine-protocols/rabies-vaccine-standing-order-9-2015.docx">https://bula-docs.s3.amazonaws.com/immunization-cpas/vaccine-protocols/rabies-vaccine-standing-order-9-2015.docx</a>
Exhibit A-30	Typhoid — Children and Adults	<a href="https://bula-docs.s3.amazonaws.com/immunization-cpas/vaccine-protocols/typhoid-vaccine-standing-order-9-2015.docx">https://bula-docs.s3.amazonaws.com/immunization-cpas/vaccine-protocols/typhoid-vaccine-standing-order-9-2015.docx</a>
Exhibit A-31	Yellow Fever — Children and Adults	<a href="https://bula-docs.s3.amazonaws.com/immunization-cpas/vaccine-protocols/yellow-fever-standing-order-9-2015.docx">https://bula-docs.s3.amazonaws.com/immunization-cpas/vaccine-protocols/yellow-fever-standing-order-9-2015.docx</a>

**Exhibit A: Protocols**

Exhibit A-32	Medical Management of Vaccine Reactions in Adult Patients	<a href="http://www.immunize.org/catg.d/p3082.pdf">www.immunize.org/catg.d/p3082.pdf</a>
Exhibit A-33	Medical Management of Vaccine Reactions in Children and Teens	<a href="http://www.immunize.org/catg.d/p3082a.pdf">www.immunize.org/catg.d/p3082a.pdf</a>
Exhibit A-34	COVID-19 Vaccines	<b>Moderna:</b> <a href="https://www.cdc.gov/vaccines/covid-19/info-by-product/moderna/downloads/standing-orders.pdf">https://www.cdc.gov/vaccines/covid-19/info-by-product/moderna/downloads/standing-orders.pdf</a> <b>Pfizer-BioNTech:</b> <a href="https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/downloads/standing-orders.pdf">https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/downloads/standing-orders.pdf</a> <b>Janssen, Inc (Johnson &amp; Johnson):</b> <a href="https://www.cdc.gov/vaccines/covid-19/info-by-product/janssen/downloads/Janssen-Standing-Orders.pdf">https://www.cdc.gov/vaccines/covid-19/info-by-product/janssen/downloads/Janssen-Standing-Orders.pdf</a>