PROTOCOL FOR ADMINISTRATION OF VACCINES BY PHARMACISTS

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PROTOCOL FOR ADMINISTRATION OF VACCINES BY PHARMACISTS

I. Introduction

To help increase the vaccination rates in Kansas, a licensed pharmacist may administer vaccines according to K.S.A. 65-1635a. Unless a licensed pharmacist is prohibited from administering a vaccine by the U.S. Centers for Disease Control (CDC), the Kansas Department of Health and Environment (KDHE), or the Kansas State Board of Pharmacy (Board), there shall be written protocol for the administration of vaccines by a pharmacist.

II. Authorization

Subject to the requirements of this Protocol, pharmacists that meet the qualifications specified in Section III below and all applicable law and regulations may:

(a) Determine vaccination needs in accordance with the current schedule recommended by the CDC's Advisory Committee on Immunization Practices (ACIP);
(b) Screen all patients for contraindications and precautions for vaccines needed using screening questions for all vaccines (Appendix E), live vaccines (Appendix D), and vaccine-specific screening as set forth in other Appendices as indicated in this Protocol;
(c) Administer vaccines according to directions provided in section XII of this Protocol; and
(d) Administer epinephrine and diphenhydramine in response to acute allergic reactions precipitated by vaccination as delineated in this Protocol.

This Protocol shall be effective on the date signed by the pharmacist and shall expire two years from the date signed by the authorizing physician.

III. Qualifications

A pharmacist or pharmacy intern supervised by a pharmacist seeking authorization to administer vaccines pursuant to this Protocol shall meet the following qualifications:

(a) Licensure—The pharmacist must be actively licensed and in good standing with the Board. The pharmacy intern must have a valid permit from and be in good standing with the Board.
(b) Cardiopulmonary Resuscitation (CPR) Certification—The pharmacist and pharmacy intern must at a minimum obtain and maintain certification in CPR. A pharmacist may substitute one of the following courses, which are required to be renewed every two years from a national accredited program:
    (1) Basic Life Support (BLS) for healthcare provider course
    (2) Advance Life Support (ACLS) for healthcare provider course
(c) Training—The pharmacist and pharmacy intern must complete an approved pharmacy-based Immunization training program that is accredited by the Accreditation Council for Pharmacy Education (ACPE) or the Board. Training must comply with current CDC guidelines and should include study materials, hands-on training, techniques for administering vaccines, vaccination storage, protocols, injection technique, emergency procedures, and recordkeeping. At the conclusion of any training course, the pharmacist or pharmacy intern should have knowledge in the following content areas:
    (1) Mechanisms of action for vaccines, contraindications, drug interactions, and monitoring. After vaccine administration, in the event of a conflict between information provided in package inserts and ACIP recommended guidelines, pharmacists administering vaccines pursuant to this Protocol should adhere to ACIP guidelines;
    (2) Standards for vaccination practices;
    (3) Basic immunology and vaccine protection;
    (4) Vaccine-preventable diseases;
    (5) Recommended immunization schedules;

(6) Vaccine storage management;
(7) Biohazard waste disposal and sterile technique;
(8) Physiology and techniques for vaccine administration;
(9) Pre-vaccine and post-vaccine assessment and counseling;
(10) Vaccine record management;
(11) Management of adverse events, including identification, appropriate response, emergency procedures, documentation, and reporting; and
(12) Needle-stick management.

(d) Continuing Education—The pharmacist and pharmacy interns are encouraged to annually complete at least one hour of Board-approved or ACPE-approved continuing education related to the administration of vaccines.
(e) Liability Insurance—The pharmacist must maintain liability insurance that covers the administration of vaccines.

IV. Limitations on Pharmacy-based Vaccination

(a) Age—The administration of non-influenza vaccines pursuant to this Protocol must not be to any persons under the age of twelve (12) years. The administration of influenza vaccines pursuant to this protocol may not be to any persons under the age of six (6) years.
(b) Delegation—A pharmacist may not delegate the administration of vaccines to any other person.
(c) Patient Specific Factors—Potential vaccinees with any contraindications and/or complex medical issues including immunosuppression or history of Guillain-Barré syndrome should be referred to the person's primary care practitioner.

V. Protocol, Facility and Equipment

Any immunization protocol, pharmacist immunization training certificate, and CPR certification shall be maintained for at least five years and shall be made available to the Board upon request at each location at which a pharmacist administers a vaccine. Pharmacists administering vaccines under this Protocol shall maintain an appropriate area for administering vaccines with the supplies and equipment listed in Appendix B.

VI. Informed Consent

Before receiving the vaccine, the vaccinee (or his or her legal representative) must be given information about the risks and benefits associated with vaccination.

(a) Consent Form—Any pharmacist administering vaccines pursuant to this Protocol must document the vaccinee or the legal representative's informed consent in writing prior to administration of a vaccine. Either the pharmacist or the pharmacy intern and supervising pharmacist must be identified on the consent form. A sample consent form can be found in Appendix E.
(b) Vaccine Information Statements —Each vaccinee or legal representative must be provided with a copy of the most current Vaccine Information Statement (VIS) for the vaccine provided. The vaccinee or legal representative must be given the opportunity to read the VIS prior to administration of the vaccine, and the pharmacist must provide answers to any questions raised. Non-English-speaking persons must receive a copy of the VIS in their native language, if available. The publication date of the VIS and the date it was provided to the vaccinee must be included in the vaccination documentation. https://vaers.hhs.gov/reportevent.html

VII. Pharmacy-based Vaccination Record

A pharmacist or pharmacy intern supervised by a pharmacist administering a vaccine pursuant to this Protocol must create a vaccination record for each vaccinee and must maintain this record for a period of at least ten (10) years for patients at least 18 years of age and at least thirteen (13) years for patients under 18 years of age. This vaccination record must be securely stored and readily retrievable during the facility's normal operating hours, and shall include the CDC documentation requirements (https://www.cdc.gov/vaccines/hcp/admin/document-vaccines.html) including the following:

(a) The name, address, date of birth, gender, and telephone number of the vaccinee;

(b) A copy of the vaccinee's responses to eligibility questionnaires;
(c) The name, dose, manufacturer, and lot number of the vaccine administered;
(d) The date of the administration of the vaccine and the injection site;
(e) A signed and dated consent form by which the vaccinee acknowledges receipt of the VIS, the publication date of the VIS, and the date the VIS was provided to the vaccinee, as well as the consent to administration of the vaccine;
(f) A record of any adverse events or complications that arose following vaccination;
(g) The name and license number of the administering pharmacist or the administering pharmacy intern and supervising pharmacist;
(h) The name, address, and telephone number of the pharmacy or facility in custody of the vaccination records;
(i) The name of the authorizing prescriber under this Protocol; and
(j) If the vaccinee designates a primary care provider, a copy of the notification letter sent to the designated primary care provider of any vaccine administered.

VIII. Reporting Requirements

(a) Personal Immunization Record—The pharmacist or pharmacy intern should encourage all vaccinees to carry a personal immunization record card in their wallet. All vaccinees will be given a written immunization record for their personal files in compliance with K.S.A. 65-1635a.
(b) Medical Home Notification—When a vaccinee receives a vaccine, the pharmacist or pharmacy intern shall report such vaccine to the designated primary care provider. If the vaccinee does not designate a primary care provider, notification to the physician authorizing this Protocol shall be satisfied by reporting to KsWebIZ pursuant to paragraph (c) below.
(c) Immunization Registry (KsWebIZ)—The pharmacist or pharmacy intern shall report administration of all vaccinations to the Kansas Immunization Registry in compliance with K.S.A. 65-1635a for reporting vaccinations.
(d) Adverse Event Reporting—The pharmacist or pharmacy intern shall report any clinically significant event that occurs following vaccine administration to the Vaccine Adverse Event Reporting System (VAERS), even if it is unclear whether the event was caused by the vaccine. Clinically significant events include but are not limited to death, hypersensitivity reactions, and those events described in the manufacturer's package insert as contraindications to additional doses of vaccine. https://vaers.hhs.gov/reportevent.html

IX. Vaccination Safety

(a) Infection Control and Sterile Technique—Pharmacists and pharmacy interns administering vaccines must follow appropriate precautions to minimize risk for spread of disease. Hands must be cleansed with an alcohol-based waterless antiseptic hand rub or washed with soap and water between each contact. Gloves must be worn if the pharmacist or pharmacy intern administering the vaccine is likely to come into contact with potentially infectious bodily fluids or has open lesions on his/her hands. Needles used for injections must be sterile and disposable to minimize the risk for contamination.
(b) Prevention of Needle-stick Injuries—To prevent inadvertent needle-stick injury or reuse, needles and syringes must be discarded immediately after use in labeled, puncture-proof containers located in the same room where the vaccine is administered. Needles must not be recapped before being placed in the container. Safety needles or needle-free injection devices should be used to reduce the risk for injury.
(c) Hepatitis B Vaccine—The cost of the vaccine is usually covered by the employer. Pharmacists and pharmacy interns who administer vaccines shall receive the Hepatitis B vaccine series unless:
    (1) the pharmacist or pharmacy intern has previously received the complete Hepatitis B vaccination series;
    (2) antibody testing has revealed that the pharmacist or pharmacy intern is immune;
    (3) the vaccine is contraindicated for medical reasons; or
    (4) the pharmacist or pharmacy intern signs a Hepatitis B Vaccine Declination Statement.

(d) Occupational Safety and Health Administration (OSHA) Compliance—Pharmacists must comply with OSHA regulations and applicable state law and regulations regarding the storage and disposal of injection supplies and the disposal of, and prevention of exposure to, biological hazards. A table of VAERS reportable events can be found at https://vaers.hhs.gov/docs/vaers_table_of_reportable_events_following_vaccination.pdf.

X. Management of Adverse Events

All vaccines have the potential to cause an adverse reaction. In order to minimize adverse reactions, vaccinees must be carefully screened for precautions and contraindications before the vaccine is administered. Even with careful screening, reactions may occur. These reactions can vary from trivial and inconvenient (e.g. soreness, itching) to severe and life threatening (e.g. anaphylaxis). If reactions occur, the pharmacist or pharmacy intern must be prepared with procedures for reaction management. The procedures for managing adverse reactions are set forth in Appendix F.

XI. Supply Considerations

The supply of vaccines and the timing of distribution is based on CDC guidance and is not guaranteed. If supplies of vaccines are delayed or limited, the pharmacist or pharmacy intern must comply with state and national guidance and directives for the tiered use of vaccines and must cooperate with health officials and local practitioners to ensure that limited supplies of vaccines are targeted to and reserved for those persons at higher risk for disease and disease-related complications.

XII. Vaccines

Pharmacists or pharmacy interns supervised by a pharmacist may administer U.S. Food and Drug Administration (FDA) authorized or approved formulations of the vaccines listed below, alone or in combination, provided they follow all requirements set forth in this Protocol, assess patient eligibility according to indications, precautions, and contraindications recommended in current guidelines from the ACIP, and adhere to dosing and administration information provided by the package inserts and ACIP recommended guidelines. Pharmacists or pharmacy interns should encourage the patient to complete the vaccination series.

(a) COVID-19
(b) Haemophilus Influenzae
(c) Hepatitis A
(d) Hepatitis B
(e) Human Papillomavirus
(f) Influenza
(g) Measles, Mumps, Rubella
(h) Meningococcal (MCV4 and MenB)
(i) Pneumococcal (PPSV23 and PCV13)
(j) Tetanus and diphtheria/Tetanus, diphtheria, and pertussis (Td/Tdap)
(k) Varicella
(l) Typhoid
(m) Zoster

CERTIFICATION

PHYSICIAN AUTHORIZATION

Name LEE A. NORMAN, M.D.	Kansas License Number 04-32391

I hereby authorize the pharmacist below to administer vaccinations in accordance with this protocol.

Lee A. Norman MD — 10-1-2021

SIGNATURE — DATE SIGNED

PHARMACIST AUTHORIZATION*

Name	Kansas License Number

I hereby accept responsibility under the authority of the above-named physician for administration of vaccines under this protocol.

SIGNATURE — DATE SIGNED

APPENDIX A—KANSAS VACCINATION LAWS

https://pharmacy.ks.gov/statutes-regs/statutes-regs

65-1626. Definitions.
For purposes of this act:
(www) "Vaccination protocol" means a written protocol, agreed to and signed by a pharmacist and a person licensed to practice medicine and surgery by the state board of healing arts, that establishes procedures and recordkeeping and reporting requirements for administering a vaccine by the pharmacist for a period of time specified therein, not to exceed two years.

65-1635a. Administration of vaccine; education and reporting requirements; delegation of authority prohibited; "pharmacist" defined.
(a) A pharmacist or a pharmacy student or intern who is working under the direct supervision and control of a pharmacist may administer influenza vaccine to a person six years of age or older and may administer vaccine, other than influenza vaccine, to a person 12 years of age or older pursuant to a vaccination protocol if the pharmacist, pharmacy student or intern has successfully completed a course of study and training, approved by the accreditation council for pharmacy or the board, in vaccination storage, protocols, injection technique, emergency procedures and recordkeeping and has taken a course in cardiopulmonary resuscitation (CPR) and has a current CPR certificate when administering vaccine. A pharmacist or pharmacy student or intern who successfully completes such a course of study and training shall maintain proof of completion and, upon request, provide a copy of such proof to the board.
(b) All vaccinees will be given a written immunization record for their personal files. The administering pharmacist or pharmacist supervising an administering pharmacy student or intern shall promptly report a record of the immunization to the vaccinee's primary care provider by mail, electronic facsimile, e-mail or other electronic means. If the vaccinee does not have a primary care provider, then the administering pharmacist or pharmacist supervising an administering pharmacy student or intern shall promptly report a record of the immunization to the person licensed to practice medicine and surgery by the state board of healing arts who has entered into the vaccination protocol with the pharmacist. The immunization will also be reported to appropriate county or state immunization registries, except that if the person vaccinated or, if the person is a minor, the parent or guardian of the minor, objects to the report, the report shall not be made.
(c) A pharmacist, pharmacy student or intern may not delegate to any person the authority granted under this act to administer a vaccine.
(d) As used in this section, "pharmacist" means a pharmacist as defined in K.S.A. 65-1626, and amendments thereto, who has successfully completed a course of study and training, approved by the accreditation council for pharmacy or the board, in vaccination storage, protocols, injection technique, emergency procedures and recordkeeping and has taken a course in cardiopulmonary resuscitation (CPR) and has a current CPR certificate.

65-2886a. Reporting of administration of vaccines by physicians and other authorized individuals.
(a) On and after July 1, 2020, physicians and other persons authorized by law in this state to administer vaccines shall report the administration of a vaccine to a person in this state to the state registry maintained for such purpose by the secretary of health and environment in a manner and form as may be required by the secretary, except that if the person vaccinated or, if the person is a minor, the parent or guardian of the minor, objects to the report, the report shall not be made.
(b) As used in this section, "physician" means a person licensed to practice medicine and surgery.

APPENDIX B—REQUIRED SUPPLIES AND EQUIPMENT

The following items should be available in the area where vaccines are administered:

(a) A copy of any vaccination protocol, immunization certificates, and CPR certificates, which shall be retained for five years.
(b) A supply of the most current federal VIS for vaccines being administered, or electronic access to these statements.
(c) Aqueous epinephrine USP (1:1000), in ampules, vials of solution, or prefilled devices (example EpiPen). The pharmacy should determine how many adult and pediatric prefilled EpiPens need to be stocked depending on the estimated emergency medicine services (EMS) time of arrival at their pharmacy location.
(d) Diphenhydramine (Benadryl) injectable solution (50 mg per mL) and oral 25 mg dosage form, to include tablets, capsules or liquid.
(e) Syringes: 1-mL and 3-mL, 22g and 25g, 1-inch, and 1 ½-inch needles for epinephrine and diphenhydramine.
(f) Alcohol swabs and bandages.
(g) Blood pressure monitoring device or stethoscope and sphygmomanometer (with pediatric, adult, and extra-large cuffs).
(h) Adult and pediatric size pocket masks with one-way valve.
(i) Flashlight with extra batteries (for examination of mouth and throat).
(j) Timekeeping device with ability to count seconds.
(k) Telephone access.
(l) Equipment to enable the vaccinee to sit or lie down if he/she experiences an adverse reaction to the vaccine, such as a mat or a reclining chair.

APPENDIX C—CDC & KDHE VACCINE INFORMATION

CDC Immunization Schedules: https://www.cdc.gov/vaccines/schedules/index.html

Vaccine Information Statements (VIS): https://www.cdc.gov/vaccines/hcp/vis/index.html

CDC Requirements and Laws: https://www.cdc.gov/vaccines/imz-managers/laws/index.html

CDC Common Vaccine Safety Concerns: https://www.cdc.gov/vaccinesafety/concerns/index.html

Multiple Vaccines and the Immune System: https://www.cdc.gov/vaccinesafety/concerns/multiple-vaccines-immunity.html

KDHE Kansas Immunization Information System (KSWebIZ): https://webiz.kdhe.ks.gov/webiznet_ks/login.aspx

APPENDIX D—GENERAL SCREENING QUESTIONNAIRE TO DETERMINE SAFETY OF LIVE VACCINES

Below is a list of screening questions the pharmacist or pharmacy intern must ask a patient prior to administration of a live vaccine (in addition to the standard questionnaire). This is a list of general questions. Vaccine-specific screening questions must also be asked based on the vaccine's contraindications and precautions according to ACIP guidelines.

(a) Are you currently on home infusions or weekly injections (such as Remicade, Humira, Enbrel, Cimzia, Simponi, Simponi Aria, Xeljanz, Orencia, Arava, Actermra, Cytoxan, Rituxan, adalimumab, infliximab or etanercept), high-dose methotrexate, azathioprine or 6-mercaptopurine, antivirals, anticancer drugs or radiation treatments?
(b) Have you received any vaccinations or skin tests in the past four weeks?
(c) Have you received a transfusion of blood, blood products, or been given a medication called immune (gamma) globulin in the past year?
(d) Are you currently taking high-dose steroid therapy (prednisone >20mg/day or equivalent) for longer than two weeks?

APPENDIX E—KDHE VACCINE DOCUMENTATION/CONSENT FORM

VACCINE DOCUMENTATION/CONSENT FORM

I have been offered a copy of the Vaccine Information Statement(s) (VIS) checked below. I have read, had explained to me, and understand the information in the VIS(s). I ask that the vaccine(s) checked below be given to me or to the person named below for whom I am authorized to make this request. I consent to inclusion of this immunization data in the Kansas Immunization Registry for myself or on behalf of the person named below.

DT DTaP Tdap Td HepA HepB Hib HPV Influenza MCV4/MenB

MMR PCV13 PPV23 Polio/IPV Rotavirus Varicella Other_____

_____ Signature of Patient or Parent/Guardian

_____ Date

PATIENT INFORMATION				
Patient's Last Name:	**Patient's First Name:**	**Phone Number:**	**Age:**	**Birth date:**
Street Address:	**City:**	**County:**	**State:**	**Zip Code:**

Ethnicity: Hispanic or Latino ___ Yes ___ No **Gender** ___ Male ___ Female	**Race:** (Select one or more.) ___ AS-Asian/Pacific Islander/Other ___ BL-Black or African American ___ CA-Caucasian/Mexican/Puerto Rican ___ CH-Chinese ___ FI-Filipino	___ HA-Hawaiian ___ IN-Native American/Alaska Native ___ JA-Japanese ___ NW-Other Non-White ___ UN-Unknown	
Primary Care Physician:	**Street Address:** **City:**	**State:** **Zip:**	**Phone:** **Fax:**

PATIENT ELIGIBILITY						
__T19-MED	__No health insurance	__Native Am/Alaska Native	__Underinsured*	__Underserved**	__ T21-SCHIP	__Fully Insured

*Underinsured children: insurance does not cover immunizations. Eligible through VFC program if vaccinated at a FQHC, RHC or delegated county health department.
**Underserved (State) children: Are not VFC eligible. May only be vaccinated with KIP vaccines needed at school (K-12) entry at a county health department if enrolled in free or reduced-price school lunch program.

IMMUNIZATION SCREENING QUESTIONNAIRE	
1. Is the patient to be vaccinated currently sick or experiencing a high fever?	__yes __no
2. Does the patient have allergies to medications, food, a vaccine component, or latex?	__yes __no
3. Has the patient had a serious reaction to a vaccine in the past?	__yes __no
4. Has the patient had a health problem with lung, heart, kidney or metabolic disease (e.g., diabetes), asthma, or a blood disorder? Is he/she on long-term aspirin therapy?	__yes __no
5. If the patient to be vaccinated is between the ages of 2 and 4 years, has a healthcare provider told you that the child had wheezing or asthma in the past 12 months?	__yes __no
6. If the patient is a baby, have you ever been told he or she has had intussusceptions?	__yes __no
7. Has the patient, a sibling, or a parent had a seizure; has the child had brain or other nervous system problems?	__yes __no
8. Does the patient have cancer, leukemia, HIV/AIDS, or any other immune system problem	__yes __no
9. In the past 3 months, has the patient taken medications that weaken their immune system such as cortisone, prednisone, other steroids, or anticancer drugs, or had radiation treatments?	__yes __no
10. In the past year, has the patient received a transfusion of blood or blood products, or been given immune (gamma) globulin or an antiviral drug?	__yes __no
11. Is the patient pregnant or is there a chance she could become pregnant during the next month?	__yes __no
12. Has the patient received vaccinations in the past 4 weeks?	__yes __no

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NAME_____ AGE_____ DOB_____

PROVIDER INFORMATION					
Vaccine Provider:			Clinic Site:		
Street Address:	State:	Zip Code:	Street Address:	State:	Zip Code:

(Circle the appropriate vaccine, dose, extremity, site, route, and enter the manufacturer, lot #, and expiration date.)

FOR CLINICAL USE ONLY

VACCINE	DOSE	EXT	SITE	ROUTE	VIS DATE	MANUFACTURER LOT #	EXP DATE
DTaP DT Td Tdap	0.5 mL 1 2 3 4 5 6	RT LT	Deltoid Vastus Lat	IM			
DTaP/IPV	0.5 mL 5th DTaP--4th IPV	RT LT	Deltoid Vastus Lat	IM			
DTaP/HepB/IPV	0.5 mL 1 2 3	RT LT	Deltoid Vastus Lat	IM			
DTaP/Hib/IPV	0.5 mL 1 2 3 4	RT LT	Deltoid Vastus Lat	IM			
Hep A	0.5 mL 1.0 mL 1 2	RT LT	Deltoid Vastus Lat	IM			
Hep B	0.5 mL 1.0 mL 1 2 3	RT LT	Deltoid Vastus Lat	IM			
Hep B/Hib	0.5 mL 1 2 3	RT LT	Deltoid Vastus Lat	IM			
Hib	0.5 mL 1 2 3 4	RT LT	Deltoid Vastus Lat	IM			
HPV	0.5 mL 1 2 3	RT LT	Deltoid	IM			
Influenza LAIV4 IIV3 IIV4	0.1mL 0.2mL 0.25mL 0.50mL 1 2	RT LT	Upper Arm Deltoid Vastus Lat	Intradermal Intranasal IM			
MCV4	0.5 mL 1 2	RT LT	Deltoid	IM			
MENB	0.5 mL 1 2 3	RT LT	Deltoid	IM			
MMR	0.5 mL 1 2	RT LT	Upper Arm Thigh	SC			
MMR-V	0.5 mL 1 2	RT LT	Upper Arm Thigh	SC			
PCV13	0.5 mL 1 2 3 4	RT LT	Deltoid Vastus Lat	IM			
Polio/IPV	0.5 mL 1 2 3 4 5	RT LT	Upper Arm Thigh	IM SC			
PPV23	0.5 mL 1 2	RT LT	Upper Arm Deltoid Vastus Lat	SC IM			
Rotavirus	2.0 mL 1 2 3		By Mouth	Oral			
Varicella	0.5 mL 1 2	RT LT	Upper Arm Thigh	SC			
Other							

_____ _____
Signature and Title of Vaccine Administrator Date

DOCUMENTACION DE LAS VACUNAS/FORMULARIO PARA EL CONSENTIMIENTO

Se me ha ofrecido una copia de la "Declaración sobre la información de las vacuna(s)" marcadas abajo. He leído o se me ha explicado la información en la "Declaración sobre la información de las vacuna(s)". Mis preguntas fueron contestadas a satisfacción y yo pido que las vacuna(s) marcadas abajo sean aplicadas a mi, o a la persona nombrada abajo por quien yo doy autorización. Doy mi consentimiento para incluir la información de mis vacunas y la de las personas nombradas abajo en el Registro de Vacunas de Kansas.

DT DTaP Tdap Td HepA HepB Hib HPV Influenza MCV4/MenB

MMR PCV13 PPV23 Polio/IPV Rotavirus Varicella Other _____

_____ Firma de Paciente o de Padre/Guardian

_____ Fecha

Información Del Paciente				
Apellido del paciente:	**Nombre del paciente:**	**Número de teléfono:**	**Edad:**	**Fecha de nacimeinto:**
Dirección:	**Ciudad:**	**Condado:**	**Estado:**	**Código postal:**

Etnicidad: Hispano o Latino ___ Si ___ No ___ Masculino ___ Femenino	___ Asiático/Isleño del pacífico ___ Negro o Africano Americano ___ Caucásico/Mejicano/Puertorriqueño ___ Chino ___ Filipino	___ Hawaiian ___ Indio Americano/Nativo ___ Japonés ___ Otro/Non-Blanco ___ Desconocido

Médico Primario:	**Dirección:** **Ciudad:**	**Estado:**	**Teléfono:** **Fax:**

Elegibilidad del paciente: __ T19-MED __No Tiene Seguro __Indio Americano __Insuficientemente Asegurados* __Insuficientemente Servidos** __ T21-SCHIP __Enteramente Asegurados

*Niños con seguro insuficiente: El seguro no cubre las vacunas. Elegibles a través del programa VFC si son vacunados en un FQHC, RHC o departamento de salud del condado.

**Niños sin seguro o sin cobertura médica: No son elegibles para VFC. Sólo pueden ser vacunados con vacunas de KIP (State) necesarias para ingresar a la escuela (K-12) en un departamento de salud del condado si están inscritos en el programa federal escolare gratuito o en el program de almuerzo a precio reducido.

CUESTIONARIO DE ANÁLISIS PARA VACUNACIÓN	
1. ¿Está enferma en este momento o tiene fiebre alta la paciente que va a ser vacunada?	____sí ____no
2. ¿Tiene el paciente(a) alergias a medicamentos, comida, componentes de vacunas, o al látex?	____sí ____no
3. ¿Ha tenido el paciente(a) algún tipo de reacción seria a las vacunas en el pasado?	____sí ____no
4. ¿Ha tenido el paciente(a) problemas de salud de los pulmones, corazón, riñones o enfermedades metabólicas (como diabetes), asma, o enfermedades sanguíneas? ¿Está el paciente(a) en terapias de aspirina a largo plazo?	____sí ____no
5. Si el paciente(a) que va a ser vacunado tiene entre 2 a 4 años, ¿el doctor le ha dicho en los últimos 12 meses que el paciente tiene resollados o asma?	____sí ____no
6. Si su paciente(a) es un bebé, le han dicho en algún momento que su niño tiene intususcepción (es el deslizamiento de una parte del intestino dentro de otra)	____sí ____no
7. ¿Han tenido ataques epilépticos ya sea el paciente(a), un hermano(a), o los padres? ¿Ha tenido el niño(a) problemas en el cerebro o en el sistema nervioso?	____sí ____no
8. ¿Tiene el paciente(a) cáncer, leucemia, VHI/SIDA o algún otro problema en el sistema inmunológico?	____sí ____no
9. En los últimos 3 meses, ¿ha tomado el paciente(a) medicamentos que debiliten su sistema inmunológico tales como cortisona (cortisone), prednisona (prednison), otro tipo de esteroides, medicamentos contra el cáncer, o ha tenido tratamientos de radiación?	____sí ____no
10. En el último año, ¿ha recibido el paciente(a) transfusiones de sangre o productos de sangre, o ha recibido gama globulina (trata el sistema inmunológico) o medicina antiviral (para combatir infecciones de virus)?	____sí ____no
11. ¿Está el paciente o muchacha embarazada o habría alguna probabilidad que se embarazará en el próximo mes?	____sí ____no
12. ¿Ha recibido el paciente(a) alguna vacuna en las últimas cuatro semanas?	____sí ____no

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NAME_____ AGE_____ DOB_____

PROVIDER INFORMATION					
			Clinic Site:		
Street Address:	State:	Zip Code:	Street Address:	State:	Zip Code:

(Circle the appropriate vaccine, dose, extremity, site, route, and enter the manufacturer, lot #, and expiration date.)

FOR CLINICAL USE ONLY							
VACCINE	DOSE	EXT	SITE	ROUTE	VIS DATE	MANUFACTURER LOT #	EXP DATE
DTaP DT Td Tdap	0.5 mL 1 2 3 4 5 6	RT LT	Deltoid Vastus Lat	IM			
DTaP/IPV	0.5 mL 5th DTaP--4th IPV	RT LT	Deltoid Vastus Lat	IM			
DTaP/HepB/IPV	0.5 mL 1 2 3	RT LT	Deltoid Vastus Lat	IM			
DTaP/Hib/IPV	0.5 mL 1 2 3 4	RT LT	Deltoid Vastus Lat	IM			
Hep A	0.5 mL 1.0 mL 1 2	RT LT	Deltoid Vastus Lat	IM			
Hep B	0.5 mL 1.0 mL 1 2 3	RT LT	Deltoid Vastus Lat	IM			
Hep B/Hib	0.5 mL 1 2 3	RT LT	Deltoid Vastus Lat	IM			
Hib	0.5 mL 1 2 3 4	RT LT	Deltoid Vastus Lat	IM			
HPV	0.5 mL 1 2 3	RT LT	Deltoid	IM			
Influenza LAIV4 IIV3 IIV4	0.1mL 0.2mL 0.25mL 0.50mL 1 2	RT LT	Upper Arm Deltoid Vastus Lat	Intradermal Intranasal IM			
MCV4	0.5 mL 1 2	RT LT	Deltoid	IM			
MenB	0.5 mL 1 2 3	RT LT	Deltoid	IM			
MMR	0.5 mL 1 2	RT LT	Upper Arm Thigh	SC			
MMR-V	0.5 mL 1 2	RT LT	Upper Arm Thigh	SC			
PCV13	0.5 mL 1 2 3 4	RT LT	Deltoid Vastus Lat	IM			
Polio/IPV	0.5 mL 1 2 3 4 5	RT LT	Upper Arm Thigh	IM SC			
PPV23	0.5 mL 1 2	RT LT	Upper Arm Deltoid Vastus Lat	SC IM			
Rotavirus	2.0 mL 1 2 3		By Mouth	Oral			
Varicella	0.5 mL 1 2	RT LT	Upper Arm Thigh	SC			
Other							

_____ Signature and Title of Vaccine Administrator

_____ Date

APPENDIX F—PROCEDURES FOR MANAGEMENT OF ADVERSE REACTIONS TO VACCINES

Anaphylactic Reactions

Signs and symptoms of anaphylactic reaction include:

- the sudden or gradual onset of generalized itching, erythema (redness), or urticaria (hives);
- angioedema (swelling of the lips, face, or throat);
- bronchospasm (wheezing);
- shortness of breath;
- shock;
- abdominal cramping; or
- cardiovascular collapse

The following procedures should be used to manage anaphylactic reactions following vaccination:

(a) If itching and swelling are confined to the injection site where the vaccination was given, observe the vaccinee closely for at least 30 minutes, watching for the development of generalized symptoms.

(b) If symptoms are generalized, activate the emergency medical system (e.g., call 911) immediately. This should be done by a second person, while the pharmacist assesses the level of consciousness, circulation, airway and breathing of the vaccinee.

(c) Place vaccinee in a recumbent position and elevate legs.

(d) The first-line therapy in anaphylaxis is epinephrine. There are no contraindications to epinephrine in the setting of anaphylaxis.

(1) Administer aqueous epinephrine 1:1000 dilution intramuscularly, 0.01mL/kg/dose (adult dose ranges from 0.3mL to 0.5mL, with a maximum single dose of 0.5mL), as indicated:

Ampules or vials of solution:

Weight (lbs) Weight (kg) Epinephrine Dose

- 22-44 lbs (10-20 kg) = 0.15mg (or mL) IM X 1 dose
- 45-88 lbs (21-40 kg) = 0.30mg (or mL) IM X 1 dose
- 89-110 lbs (41-50 kg) = 0.45mg (or mL) IM X 1 dose
- 111 lbs+ (51 kg+) = 0.50mg (or mL) IM X 1 dose

Prefilled devices (i.e., EpiPen Jr. / EpiPen):

Weight (lbs) Weight (kg) Epinephrine Dose

- 33-66 lbs (15-30 kg) EpiPen®Jr - 0.15mg IM X 1 dose
- >66 lbs (>30 kg) EpiPen® - 0.30mg IM X 1 dose

The site of injection can be gently massaged to facilitate absorption.

(2) If EMS has not arrived and symptoms are still present, the dose of epinephrine may be repeated every 5 to 15 minutes for up to 3 doses, depending on the patient's response.

(e) Antihistamines may be given for hives or itching. Administer diphenhydramine either orally or by intramuscular injection. The standard dose is 1-2 mg/kg every 4-6 hours, up to 100 mg maximum single dose for adults, and 50 mg maximum single dose for children and adolescents. Do not attempt to give oral medications to a vaccinee who is not fully alert and able to swallow safely. Refer to the dosing chart below:

Age Group Weight (lbs) Weight (kg) Diphenhydramine Dose (Injectable dose based on 50 mg/ml solution)

- 1-6 months 9-15 lbs (4-7 kg) = 5 mg (0.1 mL) IM X 1 dose
- 7-36 months 16-31 lbs (8-14 kg) = 10-15 mg (0.2-0.3mL) IM X 1 dose
- 37-59 months 32-42 lbs (15-19 kg) = 20 mg (0.4mL) IM X 1 dose
- 5-12 yrs. 43-99 lbs (20-45 kg) = 30-40 mg (0.6- 0.8mL) IM X 1 dose
- 13 yrs. and older 100+ lbs (46+ kg) = 50-100 mg (1-2 mL) IM X 1 dose

(f) Monitor the vaccinee closely and check vital signs (blood pressure, pulse, and respirations) every 2 to 5 minutes.
(g) Stay with vaccinee until EMS arrives.
(h) If necessary, perform cardiopulmonary resuscitation (CPR) and maintain airway.
(i) Keep vaccinee in supine position unless he or she is having breathing difficulty. If breathing is difficult, vaccinee's head may be elevated, provided blood pressure is adequate to prevent loss of consciousness. If blood pressure is low, elevate legs.
(j) Record all vital signs, medications administered to the vaccinee (including the time, dosage, response, and the name of the person who administered the medication), and other relevant clinical information contemporaneously in an adverse reaction medication log to be maintained by the pharmacy, a copy of which may be provided to EMS and/or the vaccinee's primary care provider. A Vaccine Adverse Event Reporting System (VAERS) form is attached as Appendix G.
(k) Notify the vaccinee's primary care practitioner as soon as possible. All vaccinees experiencing anaphylactic reactions must be referred for evaluation, even if symptoms resolve completely.

References

Immunization Action Coalition. *Medical Management of Vaccine Reactions in Adult Patients.* Retrieved from http://www.immunize.org/catg.d/p3082.pdf. January 18, 2021.

Immunization Action Coalition. *Medical Management of Vaccine Reactions in Children and Teens.* Retrieved from http://www.immunize.org/catg.d/p3082a.pdf. January 18, 2021.

APPENDIX G—VACCINE ADVERSE EVENT REPORTING SYSTEM (VAERS)

https://vaers.hhs.gov/

VAERS Background

Online reporting is strongly encouraged. Please report clinically important adverse events that occur after vaccination of adults and children, even if you are not sure whether the vaccine caused the adverse event. The Vaccine Adverse Event Reporting System (VAERS) provides a table of reportable events following vaccination: https://vaers.hhs.gov/docs/vaers_table_of_reportable_events_following_vaccination.pdf.

The VAERS accepts all reports, including reports of vaccination errors. Guidance on reporting vaccination errors is available if you have additional questions. https://vaers.hhs.gov/reportevent.html

Information you will need to complete a VAERS.

(a) Patient information (age, date of birth, sex)
(b) Vaccine information (brand name, dosage)
(c) Date, time, and location administered
(d) Date and time when adverse event(s) started
(e) Symptoms and outcome of the adverse event(s)
(f) Medical tests and laboratory results (if applicable)
(g) Physician's contact information (if applicable)

Online VAERS Reporting: https://vaers.hhs.gov/esub/index.jsp
Download VAERS pdf form: https://vaers.hhs.gov/uploadFile/index.jsp

VAERS Vaccine Adverse Event Reporting System
www.vaers.hhs.gov

Adverse events are possible reactions or problems that occur during or after vaccination. Items **2, 3, 4, 5, 6, 17, 18** and **21** are **ESSENTIAL** and should be completed. Patient identity is kept confidential. Instructions are provided on the last two pages.

INFORMATION ABOUT THE PATIENT WHO RECEIVED THE VACCINE (Use **Continuation Page** if needed)

1. Patient name: (first) _____ (last) _____
Street address: _____
City: _____ State: _____ County: _____
ZIP code: _____ Phone: ( ) _____ Email: _____

2. Date of birth: (mm/dd/yyyy) _____ 3. Sex: ☐ Male ☐ Female ☐ Unknown

4. Date and time of vaccination: (mm/dd/yyyy) _____ Time: hh:mm ☐AM ☐PM

5. Date and time adverse event started: (mm/dd/yyyy) _____ Time: hh:mm ☐AM ☐PM

6. Age at vaccination: ___ Years ___ Months 7. Today's date: (mm/dd/yyyy) _____

8. Pregnant at time of vaccination?: ☐ Yes ☐ No ☐ Unknown
(If yes, describe the event, any pregnancy complications, and estimated due date if known in item 18)

9. Prescriptions, over-the-counter medications, dietary supplements, or herbal remedies being taken at the time of vaccination:

10. Allergies to medications, food, or other products:

11. Other illnesses at the time of vaccination and up to one month prior:

12. Chronic or long-standing health conditions:

INFORMATION ABOUT THE PERSON COMPLETING THIS FORM

13. Form completed by: (name) _____
Relation to patient: ☐ Healthcare professional/staff ☐ Patient (yourself) ☐ Parent/guardian/caregiver ☐ Other: _____
Street address: _____ ☐ Check if same as item 1
City: _____ State: _____ ZIP code: _____
Phone: ( ) _____ Email: _____

14. Best doctor/healthcare professional to contact about the adverse event: Name: _____ Phone: ( ) _____ Ext: _____

INFORMATION ABOUT THE FACILITY WHERE VACCINE WAS GIVEN

15. Facility/clinic name: _____
Fax: ( ) _____
Street address: ☐ Check if same as item 13
City: _____
State: _____ ZIP code: _____
Phone: ( ) _____

16. Type of facility: (Check one)
☐ Doctor's office, urgent care, or hospital
☐ Pharmacy or store
☐ Workplace clinic
☐ Public health clinic
☐ Nursing home or senior living facility
☐ School or student health clinic
☐ Other: _____
☐ Unknown

WHICH VACCINES WERE GIVEN? WHAT HAPPENED TO THE PATIENT?

17. Enter all vaccines given on the date listed in item 4: (Route is HOW vaccine was given, Body site is WHERE vaccine was given) Use **Continuation Page** if needed

Vaccine (type and brand name)	Manufacturer	Lot number	Route	Body site	Dose number in series
select			select	select	select
select			select	select	select
select			select	select	select
select			select	select	select

18. Describe the adverse event(s), treatment, and outcome(s), if any: (symptoms, signs, time course, etc.)
Use **Continuation Page** if needed

19. Medical tests and laboratory results related to the adverse event(s): (include dates)
Use **Continuation Page** if needed

20. Has the patient recovered from the adverse event(s)?: ☐ Yes ☐ No ☐ Unknown

21. Result or outcome of adverse event(s): (Check all that apply)
☐ Doctor or other healthcare professional office/clinic visit
☐ Emergency room/department or urgent care
☐ Hospitalization: Number of days (if known) _____
Hospital name: _____
City: _____ State: _____
☐ Prolongation of existing hospitalization (vaccine received during existing hospitalization)
☐ Life threatening illness (immediate risk of death from the event)
☐ Disability or permanent damage
☐ Patient died – Date of death: (mm/dd/yyyy) _____
☐ Congenital anomaly or birth defect
☐ None of the above

ADDITIONAL INFORMATION

22. Any other vaccines received within one month prior to the date listed in item 4: Use **Continuation Page** if needed

Vaccine (type and brand name)	Manufacturer	Lot number	Route	Body site	Dose number in series	Date Given
select			select	select	select	
select			select	select	select	

23. Has the patient ever had an adverse event following any previous vaccine?: (If yes, describe adverse event, patient age at vaccination, vaccination dates, vaccine type, and brand name)
☐ Yes _____ ☐ No ☐ Unknown

24. Patient's race: (Check all that apply) ☐ American Indian or Alaska Native ☐ Asian ☐ Black or African American ☐ Native Hawaiian or Other Pacific Islander ☐ White ☐ Unknown ☐ Other: _____

25. Patient's ethnicity: ☐ Hispanic or Latino ☐ Not Hispanic or Latino ☐ Unknown

26. Immuniz. proj. report number: (Health Dept use only) _____

COMPLETE ONLY FOR U.S. MILITARY/DEPARTMENT OF DEFENSE (DoD) RELATED REPORTS

27. Status at vaccination: ☐ Active duty ☐ Reserve ☐ National Guard ☐ Beneficiary ☐ Other: _____

28. Vaccinated at Military/DoD site: ☐ Yes ☐ No

FORM FDA VAERS 2.0 (03/21)

SAVE

VAERS

CONTINUATION PAGE (Use only if you need more space from the front page)

17. Enter all vaccines given on the date listed in item 4 (continued):					Dose number in series
Vaccine (type and brand name)	Manufacturer	Lot number	Route	Body site	
select			select	select	select
select			select	select	select
select			select	select	select
select			select	select	select

22. Any other vaccines received within one month prior to the date listed in item 4 (continued):					Dose number in series	Date Given
Vaccine (type and brand name)	Manufacturer	Lot number	Route	Body site		
select			select	select	select	
select			select	select	select	
select			select	select	select	
select			select	select	select	
select			select	select	select	
select			select	select	select	

Use the space below to provide any additional information (indicate item number):

FORM FDA VAERS 2.0 (03/21)

SAVE

RETURN TO PAGE 1

COMPLETING THE VACCINE ADVERSE EVENT REPORTING SYSTEM (VAERS) FORM

GENERAL INSTRUCTIONS

- Submit this form electronically using the Internet. For instructions, visit www.vaers.hhs.gov/uploadfile/.
- If you are unable to submit this form electronically, you may fax it to VAERS at 1-877-721-0366.
- If you need additional help submitting a report you may call the VAERS toll-free information line at 1-800-822-7967, or send an email to info@vaers.org.
- Fill out the VAERS form as completely as possible and use the **Continuation Page** if needed. Use a separate VAERS form for each individual patient.
- If you do not know exact numbers, dates, or times, please provide your best guess. You may leave these spaces blank if you are not comfortable guessing.
- You can get specific information on the vaccine and vaccine lot number by contacting the facility or clinic where the vaccine was administered.
- Please report all significant adverse events that occur after vaccination of adults and children, even if you are not sure whether the vaccine caused the adverse event.
- Healthcare professionals should refer to the VAERS Table of Reportable Events at www.vaers.hhs.gov/reportable.html for the list of adverse events that must be reported by law (42 USC 300aa-25).
- Healthcare professionals treating a patient for a suspected vaccine adverse event may need to contact the person who administered the vaccine in order to exchange information and decide how best to complete and submit the VAERS form.

SPECIFIC INSTRUCTIONS

Items 2, 3, 4, 5, 6, 17, 18 and 21 are **ESSENTIAL** and should be completed.

- **Items 4 and 5**: Provide dates and times as specifically as you can and enter as much information as possible (e.g., enter the month and year even if you don't know the day). If you do not know the exact time, but know it was in the morning ("AM") or afternoon or evening ("PM"), please provide that information.
- **Item 6**: If you fill in the form by hand, provide age in years. If a child is less than 1 year old, provide months of age. If a child is more than 1 year old but less than 2 years old, provide year and months (e.g., 1 year and 6 months). If a child is less than 1 month of age when vaccinated (e.g., a birth dose of hepatitis B vaccine) then answer 0 years and 0 months, but be sure to include the patient's date of birth (item 2) and date and time of vaccination (item 4).
- **Item 8:** If the patient who received the vaccine was pregnant at time of vaccination, select "Yes" and describe the event, any pregnancy complications, and estimated due date if known in item 18. Otherwise, select "No" or "Unknown."
- **Item 9:** List any prescriptions, over-the-counter medications, dietary supplements, herbal remedies, or other non-traditional/ alternative medicines being taken by the patient when the vaccine(s) was given.
- **Item 10:** List any allergies the patient has to medications, foods, or other products.
- **Item 11:** List any short-term or acute illnesses the patient had on the date of vaccination AND up to one month prior to this date (e.g., cold, stomach flu, ear infection, etc.). This does **NOT** include the adverse event you are reporting.
- **Item 12:** List any chronic or long-standing health conditions the patient has (e.g., asthma, diabetes, heart disease).
- **Item 13:** List the name of the person who is completing the form. Select the "Check if same as item 1" box if you are the patient or if you live at the same address as the patient. The contact information you provided in item 1 will be automatically entered for you. Otherwise, please provide new contact information.
- **Item 14:** List the doctor or other healthcare professional who is the best person to contact to discuss the clinical details of the adverse event.
- **Item 15:** Select the "Check if same as item 13" box if the person completing the form works at the facility that administered the vaccine(s). The contact information provided in item 13 will be automatically entered for you. Otherwise, provide new contact information.
- **Item 16:** Select the option that best describes the type of facility where the vaccine(s) was given.

- **Item 17:** Include only vaccines given on the date provided in item 4. The vaccine route options include:
  - Injection/shot (intramuscular, subcutaneous, intradermal, jet injection, and unknown)
  - By mouth/oral
  - In nose/intranasal
  - Other (specify)
  - Unknown

  For body site, the options include:
  - Right arm
  - Left arm
  - Arm (side unknown)
  - Right thigh
  - Left thigh
  - Thigh (side unknown)
  - Nose
  - Mouth
  - Other (specify)
  - Unknown

  For vaccines given as a series (i.e., 2 or more doses of the same vaccine given to complete a series), list the dose number for the vaccine in the last column named "Dose number in series."
- **Item 18:** Describe the adverse event(s), treatment, and outcome(s). Include signs and symptoms, when the symptoms occurred, diagnosis, and treatment. Provide specific information if you can (e.g., if patient had a fever, provide the temperature).
- **Item 19:** List any medical tests and laboratory results related to the adverse event(s). Include abnormal findings as well as normal or negative findings.
- **Item 20:** Select "Yes" if the patient's health is the same as it was prior to the vaccination or "No" if the patient has not returned to the same state of health prior to the vaccination, and provide details in item 18. Select "Unknown" if the patient's present condition is not known.
- **Item 21:** Select the result(s) or outcome(s) for the patient. If the patient did not have any of the outcomes listed, select "None of the above." Prolongation of existing hospitalization means the patient received a vaccine during a hospital stay and an adverse event following vaccination occurred that resulted in the patient spending extra time in the hospital. Life threatening illness means you believe this adverse event could have resulted in the death of the patient.
- **Item 22:** List any other vaccines the patient received within one month prior to the vaccination date listed in item 4.
- **Item 23:** Describe the adverse event(s) following any previous vaccine(s). Include patient age at vaccination, dates of vaccination, vaccine type, and brand name.
- **Item 24:** Check all races that apply.
- **Item 25:** Check the single best answer for ethnicity.
- **Item 26:** For health department use only.
- **Items 27 and 28:** Complete only for U.S. Military or Department of Defense related reports. In addition to active duty service members, Reserve and National Guard members, beneficiaries include: retirees, their families, survivors, certain former spouses, and others who are registered in the Defense Enrollment Eligibility Reporting System (DEERS).

GENERAL INFORMATION

- VAERS (www.vaers.hhs.gov) is a national vaccine safety monitoring system that collects information about adverse events (possible reactions or problems) that occur during or after administration of vaccines licensed in the United States.
- VAERS protects patient identity and keeps patient identifying information confidential.
- The Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule permits reporting of protected health information to public health authorities including the Centers for Disease Control and Prevention (CDC) and U.S. Food and Drug Administration (FDA) (45 CFR § 164.512(b)).
- VAERS accepts all reports without judging the importance of the adverse event or whether a vaccine caused the adverse event.
- Acceptance of a VAERS report by CDC and FDA does not constitute admission that the vaccine or healthcare personnel caused or contributed to the reported event.
- The National Vaccine Injury Compensation Program (VICP) is administered by the Health Resources and Services Administration (HRSA). The VICP is separate from the VAERS program and reporting an event to VAERS does not constitute filing a claim for compensation to the VICP (see www.hrsa.gov/vaccinecompensation/index.html).
- Knowingly filing a false VAERS report with the intent to mislead the Department of Health and Human Services is a violation of Federal law (18 U.S. Code § 1001) punishable by fine and imprisonment.