KERN HEALTH SYSTEMS

| KERN HEALTH SYSTEMS<br><br>POLICY AND PROCEDURES | | | | | |
|---|---|---|---|---|---|
| SUBJECT: Administration of Vaccines by Pharmacist | | | | POLICY #: 13.07-P | |
| DEPARTMENT: Pharmacy | | | | | |
| Effective Date:<br>08/30/2016 | Review/Revised Date: | DMHC | | PAC | |
| | | DHCS | | QI/UM COMMITTEE | |
| | | BOD | | FINANCE COMMITTEE | |

Douglas A. Hayward
Chief Executive Officer — Date 8/30/16

Chief Medical Officer — Date 8/30/16

Chief Financial Officer — Date 8/25/16

Chief Operating Officer — Date 8/24/16

Director of Claims — Date 8/24/16

Administrative Director of Health Services — Date 8/22/16

Director of Pharmacy — Date August 22, 2016

**POLICY:**
Kern Health Systems (KHS) will allow network pharmacies to administer and to bill vaccinations for members age 19 or older by pharmacists. Pharmacists must comply and meet the criteria established by the State. Authority to do so is granted by California Business and Professions Code[i].

**PROCEDURES:**
Perform procedures or functions as part of the care provided by a provider who contracts with a licensed health care service plan with regard to the care or services provided to the enrollees of the health care service plan.

## 1.0 TRAINING REQUIREMENTS:

**Pharmacist Requirements:**

A. CPR Certified by American Red Cross or American Health Association or equivalent.
B. Certificate of completion of an appropriate immunization-training program that includes the current guidelines and recommendations of the Advisory Committee on Immunization Practices.
C. Current professional liability insurance that covers immunization services.
D. National Provider Identifier (NPI) Number

An appropriate training program shall include, at a minimum, instruction on how to:

a. Identify persons eligible for vaccination based on current ACIP guidelines. Factors taken into consideration will include age, vaccination status e.g. persons previously or due or vaccination according to the recommended schedule, or the presence of a medical condition that put them at high risk.
b. Screen patients for contraindications and precautions to vaccination such as severe illness, previous allergic reaction, egg allergy.
c. Provide adequate information to patients or their guardians regarding the risks for and benefits of a vaccine and documenting the delivery of that information. (i.e. Distribution/discussion of Vaccination Information
Statements as required by law).
d. Administer vaccines.
e. Monitor patients for adverse events.
f. Manage anaphylactic according to protocol. (*See Attachment A* Sample Protocol for Allergic and Anaphylactic Reactions.)
g. Report adverse outcomes to the Vaccine Adverse Events Reporting System (VAERS).
h. Record administration of a vaccine.
i. Provide documentation of vaccine administration to patients, their primary-care providers. (*See Attachment B* Sample Physician Notification form.)
j. Follow Universal Precautions and Infection Control and pertinent OSHA regulations for Blood Bourne Pathogens.
k. Report administration to the California Immunization Registry (CAIR).

## 2.0 CREDENTIALING:

Certificates, protocols and the other above mentioned documents shall be maintained by the pharmacy of record. The documents shall available for audit. It is the pharmacist, not the pharmacy that is credentialed. As the collaborative agreement is between the physician and pharmacist, the renewal will be done yearly.

## 3.0 PRIOR AUTHORIZATION:

KHS will reimburse only for those services covered by the Medicaid systems, abiding by their protocols. Prior authorization is not required for the vaccines listed on *Attachment C* following the CDC guidelines and DHCS criteria. All other vaccines require prior authorization; except for travel vaccines which are not a covered benefit.

## 4.0 MEMBER ACKNOWLEDGMENT:

Written informed consent will be obtained for each member prior to receiving a vaccination. Pharmacists provide each adult member with a Vaccine Administration Record and Patient Consent (*See Sample Attachment D*). If the member has difficulty understanding the form the pharmacists shall explain the information provided about the vaccine and answer any questions the member may have.

## 5.0 BILLING GUIDELINES AND CLAIMS SUBMISSION:

Pharmacies will submit the claim electronically through KHS' Pharmacy Benefit Manager (PBM). Note that claims eligible for the Vaccines for Children Program, those for members up to 19 years of age, are carved out of the plan and not payable through the PBM. Pharmacies will submit claims for these ingredient costs to the Vaccines for Children Program, and separate claims for the administration through KHS Claims Department by billing the vaccine code. Vaccines needed for travel are excluded from coverage.

## 6.0 REIMBURSEMENT:

Reimbursement for the pharmacist will include inpatient cost; dispense fee, and administration fee.

## ATTACHMENTS:

- Attachment A – *Sample Protocol for Allergic and Anaphylactic Reactions*
- Attachment B – *Sample Physician Notification Form*
- Attachment C – *Vaccine Listing and Billing Criteria*
- Attachment D – *Vaccine Administration Record and Patient Consent*

## REFERENCE:

**Revision 2016-08:** New policy. Created to allow pharmacist to administer vaccines. Section 3.0 Site Review delete as requested by Administrative Director of Health Services.

[1] California Business and Professions Code §4052.

# Sample Protocol for ALLERGIC and ANAPHYLACTIC REACTIONS to Vaccines

If an allergic reaction occurs, the following protocol will be followed:

## Standing orders for management of ALLERGIC REACTION and ANAPHYLAXIS:

**I. Supplies to stock**

A. Epinephrine Injection, USP, 1:1000. Preferably, this will be in pre-drawn syringes with 0.1mL gradations on the barrel (EpiPen or equivalent). If pre-drawn syringes are not used, 1cc tuberculin syringes with 1/2-inch or 5/8-inch 26 ga. needle will be used.

B. Diphenhydramine hydrochloride injection.

C. Blood pressure cuffs, pedi-size and adult regular, with stethoscope.

**II. Recognition of anaphylactic reaction**

A. Sudden onset of itching, redness, with or without hives, within several minutes after injecting a vaccine. The symptoms may be localized or generalized.

B. Angioedema (swelling of the lips, face, throat), anxiety, difficulty swallowing, syncope, fall in blood pressure, lightheadedness, paresthesias, flushing, sweating, palpitations.

C. Bronchospasm, wheezing, tightness in chest, shock.

**III. Emergency treatment**

A. If itching and swelling are confined to the extremity where the immunization was given, observe patient closely for 30 minutes, watching for generalized symptoms. If none occur, go to III. (G).

B. If symptoms are generalized, activate the emergency response system (911) and notify the ordering physician. This should be done by another person, while the agent treats and observes the patient.

C. Administer epinephrine according to dose in the table below, subcutaneously or intramuscular. Site of administration can be the anterior thigh or deltoid muscle.

D. Administer diphenhydramine by IM injection according to the dose in the table below. DO NOT administer diphenhydramine or anything else by mouth if the patient is not fully alert or if patient has respiratory distress.

E. Monitor the patient until EMS arrives; perform CPR and maintain airway if necessary.

1. Keep patient in supine position unless there are breathing difficulties. If breathing is difficult, patients head may be elevated, provided blood pressure is adequate to prevent loss of consciousness.

2. Monitor vital signs frequently.

F. If EMS has not arrived and symptoms are still present, repeat the dose of epinephrine every 15 minutes.

G. Patient must be referred for medical evaluation, even if symptoms resolve completely. Symptoms may recur after epinephrine and diphenhydramine wear off, as much as 24 hours later.

**Dosage of Epinephrine**

| Weight (kg) | Weight (lb) | Dose (cc) | Age | Dose (cc) |
|---|---|---|---|---|
| 3-16 | 6-35 | 0.1 | 0-24 mo | 0.1 |
| 17-25 | 36-55 | 0.2 | 2-8 yrs | 0.2 |
| 26-34 | 55-75 | 0.3 | 9+ yrs | 0.3 |
| 35-45 | 76-99 | 0.4 | | |
| 46+ | 100+ | 0.5 | | |

If using commercially available pre-drawn epinephrine injections, use the adult formulation containing 0.3mg/ 0.3 cc per injection for adults and adolescents.

**Note:** Most accurate dosage is based on weight, at 0.01 cc/kg body weight, with a maximum dose of 0.5 cc. Injections should be SC or IM. Doses over 0.3 cc should be based on weight NOT age.

**Dosage of Diphenydramine**

| Weight (kg) | Weight (lb) | Dose (mg) | Age | Dose (mg) |
|---|---|---|---|---|
| 3-16 | 6-35 | 10 | 0-24 mo | 10 |
| 17-25 | 35-55 | 20 | 2-8 yrs | 20 |
| 26-34 | 56-75 | 30 | 9+ yrs | 30 |
| 35-45 | 76-99 | 40 | | |
| 46+ | 100+ | 50 | | |

**Note:** Dose is to be administered IM. Doses over 30 mg should be based on weight, NOT age.

## Immunization Standing Orders
## Policy, Procedures and Protocol

# Physician Notification Form

**Pharmacy Name:**_____

**Address:**_____

_____

**Phone:**_____

## Facsimile Transmittal

| | |
|---|---|
| To: | Fax: ( ) - |
| From: | Date: / / |
| Re: Patient Name | Pt. DOB: |
| CC: | Pages: |

This fax has been sent to you with the consent of your patient to notify you that the patient named above received the following vaccination(s) at our pharmacy on the date that is listed above. Please make a note of this in the patient's chart and feel free to call at the number above with any questions.

| Administration Date | Product | Dose | Comments |
|---|---|---|---|
| | | | |
| | | | |
| | | | |

# Vaccine Listing and Billing Criteria

| Generic Name | Age | Fill Limit | RX/Fill Limit |
|---|---|---|---|
| DIPH, PERTUSS(ACELL), TET VAC/PF | ≥ 19 | N/A | 1 |
| DIPHTH, PERTUSS(ACELL) TET VAC | ≥ 19 | N/A | 1 |
| FLU VACCINES | ≥ 19 | 1/270 days | 1 |
| HAEMOPH B POLY CONJ-TER TOX/PF | ≥ 19 | N/A | 1 |
| HEPATITIS A & B VACCINE/PF | ≥ 19 | 3/lifetime | 1 |
| HEPATITIS A VIRUS VACCINE/PF | ≥ 19 | 2/lifetime | 1 |
| HEPATITIS B VIRUS VACCINE/PF | ≥ 19 | 3/lifetime | 1 |
| HPV VACCINE 9-VALENT/PF | ≥ 19 – 26 | 3/lifetime | 1 |
| HUMAN PAPILLOMAV VACC BIVAL/PF | ≥ 19 – 26 | 3/lifetime | 1 |
| HUMAN PAPILOMVIRUS VAC, QVAL/PF | ≥ 19 – 26 | 3/lifetime | 1 |
| MEASLES, MUMPS&RUBELLA VACC/PF | ≥ 19 | 2/lifetime | 1 |
| MENING VAC A, C, Y, W-135 DIP/PF | ≥ 19 | 2/lifetime | 1 |
| MENINGOCOCCAL B VACC, 4-COMP/PF | ≥ 19 | 2/lifetime | 1 |
| MENINGOCOCCAL VAC A, C, Y, W-135 | ≥ 19 | 1/lifetime | 1 |
| N.MENINGITIDIS B, LIPID FHBP RC | ≥ 19 | 3/lifetime | 1 |
| PNEUMOC 23-VAL CONH-DIP CRM/PF | ≥ 50 | 2/lifetime | 1 |
| PENUMOC 23-VAL CONJ-P-SAC CRM/PF | ≥ 50 | 2/lifetime | 1 |
| TETANUS & DIPHTERIA TOX, ADULT | ≥ 19 | N/A | 1 |
| TETANUS AND DIPTHERIA TOX/PF | ≥ 19 | N/A | 1 |
| VARICELLA VACCINE LIVE/PF | ≥ 19 | 2/lifetime | 1 |
| ZOSTER VACCINE LIVE/PF | ≥ 60 | 1/lifetime | 1 |

Attachment D

# CONSENT AND RELEASE - INJECTABLE VACCINATIONS

Vaccine(s) Requested: Injection Site: LD RD LPLUA RPLUA

Last Name of Patient First Middle ___/___/___ (___) ☐ M ☐ F
Birth Date Age Gender

Permanent Address City State Zip (___)___-___
Home Phone

Primary Insurance Insurance ID # or Medicare B Number *(Include numbers and letters)* Primary Care Physician Phone #

I acknowledge that I understand the benefits and risks of the requested vaccination as described in the Vaccine Information Sheet, a copy of which is provided with this Consent and Release. I confirm that on behalf of its pharmacy operations in all divisions, has answered to my satisfaction all of my questions about the vaccine and the vaccination procedure. I request and consent that the vaccination be given, as I direct either to me or to the person named above, a minor for whom I represent that I am authorized to sign this Consent and Release. I understand that I am giving permission to release any medical or other information necessary to my physician, Medicare, Medicare HMO, or insurance company or immunization registry, as applicable, to enable to process my insurance claims with respect to the vaccination. I, for myself (and for the recipient of the vaccination, if the recipient is a minor), my heirs, executors and assigns hereby release and its divisions and affiliates and their respective officers, directors, employees, agents and representatives from any and all claims arising out of or in connection with the quality of the above-described vaccine(s) as provided by the manufacturer and any negligence of in connection with the related injection of the vaccination. I understand that the laws of my state may affect my remedies in connection with this vaccination.

X ___ ___ ___
Signature of Person to Receive Vaccine(s)/Parent or Guardian of Minor Date Print Name of Parent or Guardian/ Phone #

**By checking this box ☐ I authorize the administration of vaccine(s) by an immunization trained student pharmacist**
**By checking this box ☐ I acknowledge that I have been advised that I should remain in the area for 15 minutes observation after vaccination, however I am declining to wait.**
**By checking this box ☐ I acknowledge that I have been counselled about potential side effects after vaccination, when they may occur, and when and where I should seek treatment.**

| | | Please answer these questions by checking the boxes. If the question is not clear, please ask your pharmacist. | Yes | No | Don't Know |
|---|---|---|---|---|---|
| Vaccine History | 1 | All Patients: How long has it been since your last TETANUS shot? | ___ yrs | | ☐ |
| | 2 | Please check all that apply to you:<br>☐ Asthma ☐ Diabetes ☐ Heart Disease ☐ Tobacco Smoker ☐ 65 years or older<br>If you checked any of the above, have you ever received the Pneumonia Vaccine? If yes, when? | ☐ | ☐ | ☐ |
| | 3 | Patients 60 years of age or older: Have you ever received the SHINGLES vaccine? | ☐ | ☐ | ☐ |
| All | 4 | Are you sick today? | ☐ | ☐ | ☐ |
| | 5 | Do you have a serious allergy to ANY medications or food? (Example: Eggs, Gelatin, Thimerosal, Neomycin, Gentamicin). If Yes, please list: | ☐ | ☐ | ☐ |
| | 6 | Have you ever had a serious reaction or fainted after receiving any vaccination? | ☐ | ☐ | ☐ |
| | 7 | Do you have sensitivity to latex? (Example: gloves or bandages) | ☐ | ☐ | ☐ |
| | 8 | For women: Are you pregnant or are you considering becoming pregnant? | ☐ | ☐ | ☐ |
| Tdap | 9 | Do you have a seizure disorder or a brain disorder? | ☐ | ☐ | ☐ |
| Live | 10 | Have you received any vaccination in the past 4 weeks? Which one(s)? | ☐ | ☐ | ☐ |
| | 11 | Do you have cancer, leukemia, HIV, active shingles or any other immune system problem? | ☐ | ☐ | ☐ |
| | 12 | Do you take prednisone, oral steroids, anticancer or antiviral drugs or medications that affect the immune system? | ☐ | ☐ | ☐ |
| | 13 | During the past year, have you received a transfusion of blood or blood products, been given a medicine called immune (gamma) globulin, or had radiation therapy? | ☐ | ☐ | ☐ |

----------**BELOW LINE FOR PHARMACY USE ONLY**----------

Check Box to Confirm Patient Identity Verified ☐ Check Box to Confirm Vaccine / Drug to be administered Verified ☐

| Vaccine | Lot# of Vaccine | Exp Date | Manufacturer | Dosage | Site of Injection | Time | VIS Date |
|---|---|---|---|---|---|---|---|
| Influenza (Seasonal) | | | | 0.5mL | IM L / R Deltoid | | July 2015 |
| Fluzone HD® (≥65 yrs) | | | Sanofi | 0.5mL | IM L / R Deltoid | | July 2015 |
| Zostavax® | | | Merck | 0.65mL | SC L / R PLUA | | Oct 6, 2009 |
| | | | | | | | |
| | | | | | | | |

Signature of Pharmacist: _____ RPh _____ Intern Initials Date VIS provided to patient: _____

Date / Time Faxed to MD _____ / _____ AM / PM Counseling: Accepted _____ Declined _____