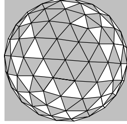

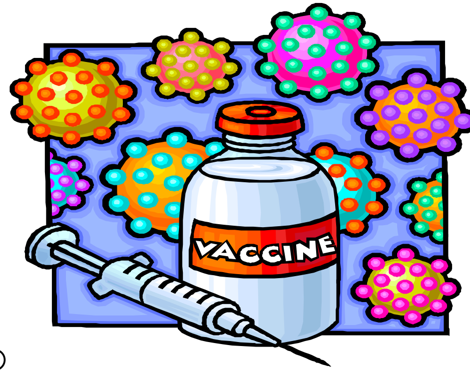

Adherence, Inc. ®

Pharmacist provided immunization & Ohio law.

Jack Justice, MBA, PharmD, MA (Theol)

Ohio: 036-309-09-003-H03 Expires: 2/2/12

Goals and objectives:

The objective of this program is that the participant, upon completion, will be thoroughly familiar with the laws of Ohio in respect to pharmacist provision of immunization services.

The goals will be:

- To provide a brief history of pharmacist involvement in providing immunization services.
- To introduce the Ohio law that authorizes pharmacists to administer immunization.
- To introduce and discuss Ohio state board of pharmacy rules that enable pharmacists to comply with the law authorizing them to administer vaccines.

The Ohio State Board of Pharmacy has approved Adherence, Inc. as a provider of continuing education. This program is approved by the board and provides 0.1 CEUs of jurisprudence continuing education.

PO Box 42407, Cincinnati, OH 45242-0407 Phone: (513) 794-1642 Fax: (513) 794-1669

From advocacy to provider

One of the first published report of pharmacist involvement in immunization services appeared in 1982. Spruii and Cooper [1] described how pharmacists coordinated a program in an ambulatory center to identify high-risk candidates to be immunized against pneumococcal pneumonia. This program was a success and showed that pharmacists can increase vaccine utilization and decrease morbidity for those diseases preventable by immunization.

In June of 2009, Maine became the last of 50 states to approve immunization by pharmacists. The bill allows pharmacists to administer certain drugs and immunizations, including the influenza, intranasal influenza, pneumococcal, herpes zoster (shingles), tetanus–diphtheria–pertussis, and tetanus–diphtheria vaccines with certain restrictions.

Historically, Health and Human Services Secretary in 1993 asked the APhA to help determine how pharmacist could assist in a national vaccine program for children. In 1994 fifty Washington State pharmacists attended the first organized immunization training program in Seattle [US Pharm 2009;34(8):39-45]. The following year, under collaborative practice agreements with physicians, two of the Washington State pharmacists began administering influenza vaccine, and for the first time took an active role in preventing vaccine-preventable diseases. That same year the Heath Care Finance Administration officially recognized pharmacists as providers, thus allowing the administration of vaccines to be a pharmacy-billable service.

This made sense since previously Grabenstein [2] (1992) had developed a model to assess the cost-effectiveness of a cue to influenza vaccination provided by community pharmacists, and found such services cost-effective. A decision tree was constructed of the consequences of implementing a pharmacy-based vaccine-advocacy program, based on experience gained in an experiment

involving three community pharmacies in Durham County, North Carolina. The model used morbidity and mortality assumptions derived from the infectious-disease literature and cost assumptions based on 1990-91 Medicare Part A and Part B reimbursement costs. This analysis suggests that if Medicare reimbursed pharmacists for advising 100,000 patients at risk to accept influenza vaccine through vaccine-advocacy messages, for an apparent expenditure of $110,000, the increased rate of influenza vaccinations would avert 139 hospitalizations and 63 deaths, and actually yield Medicare a net savings of $280,588. Because only direct costs to the single government agency were computed and no cost was attributed to death or lost earnings, these calculations probably underestimated the benefit to society of a pharmacy-based vaccine-advocacy program

Weitzel [3] (2000) described procedures for implementing a pharmacy-based immunization program in a supermarket chain. The supermarket chain with 27 stores was located in the greater area of Richmond, Fredericksburg, and Williamsburg, Virginia. Nineteen of the stores had pharmacies. The chain offered enhanced patient care services including immunizations, diabetes, asthma, hypertension, hyperlipidemia monitoring, and smoking cessation. All pharmacies also offered adult immunizations and hosted periodic diabetes, hypertension, and hyperlipidemia screening events. Each pharmacy offered influenza and pneumococcal vaccinations on a walk-up basis during pharmacy hours and during clinics held at least 3 days per week. Immunizations were also offered periodically at off-site locations. Distribution of letters and chart stickers to patients' physicians, and even partnership with a physician to establish the immunization protocol, helped increase awareness of the pharmacy immunization services. This service involved a core group of immunizing pharmacists who developed a policies and procedures manual, distributed the vaccine, and handled additional staffing requirements. Between September and December 1998, the pharmacists administered 5,137 influenza vaccinations and 613 pneumococcal vaccinations. Between September 1999 and January 2000,

the pharmacists administered 18,000 influenza vaccinations and 1,200 pneumococcal vaccinations. In addition to immunizing thousands of people in its first year, the program served as a successful marketing tool to increase awareness of enhanced pharmacy services in the community and among local physicians.

Currently, it is estimated that almost 80,000 pharmacists have been trained to administer immunizations and have the authority to administer vaccines in all 50 states, excluding the District of Columbia.

People vaccinated by pharmacists

Annually 5 to 20 percent of the US population is infected by influenza, resulting in nearly 36,000 deaths and over 200,000 hospitalizations, according to the Centers for Disease Control (CDC). Any advocacy role that pharmacy can provide in improving these numbers provides an much needed service to the community at large.

A study in Oregon illustrates the impact that pharmacists can have in reducing the incidence of vaccine-preventable diseases. Oregon law afforded pharmacists the right to provide adult immunizations in 2000. **By law, every vaccine delivered by a pharmacist had to be documented and reported to the state health department.** The researchers collected mandated administration reports and they were analyzed for the 2000-2001 and 2001-2002 influenza seasons. **Previous reports had indicated that pharmacists capture individuals unlikely to receive vaccinations elsewhere and increase total vaccination rates.**

The number of pharmacies participating, the type and quantity of vaccinations, and the county where provided were analyzed. To verify reporting, electronic records from participating pharmacies were obtained and compared to health

department records. Differences in data between the first and second years of pharmacist provided immunizations were also compared.

During the 2000-2001 influenza season (the first with Oregon pharmacist provided immunizations), 13,116 adult patients received influenza vaccines at 56 pharmacies. The mean number of influenza vaccinations per pharmacy was 234 +/- 236, with a range of 3-1525 per site. During the 2001-2002 influenza season, 88 pharmacies provided 25,785 influenza vaccinations. Influenza vaccinations were underreported by 14%. The median number of vaccinations increased 150% at sites participating during both years. 48% and 46% of influenza vaccinations were provided in rural counties during the two seasons. Pneumococcal immunizations were provided to 307 adults in 2000-2001 and 487 in 2001-2002.

The researchers concluded that pharmacists provided a substantial number of influenza vaccinations in the two influenza seasons since they were allowed to do so by the state legislature. 2. Nearly half of the vaccinations were provided in rural counties. 3. This report provides further evidence that non-traditional providers can have a wide-reaching impact on immunizations.

(BEARDEN DT, HOLT T. Presented at the Interscience Conference on Antimicrobial Agents and Chemotherapy (43rd: 2003: Chicago, Ill.).

Ohio law

Ohio Revised Code (ORC) 4729.41 allows for immunization services to be provided by pharmacists. **The ORC represent statutes written into law by the legislative bodies and approved by the governor of the state**. The law will typically be written in such a manner to authorize a regulatory office, such as the board of pharmacy, to develop a process to enact and enforce the law. The process is usually made explicit (though it may allow significant latitude to the professional to act in good faith) by a set of rules developed by the regulatory

office. Such rules are written into the **Ohio Administrative Code (OAC)** and provide compliance guidance to those affected by the law.

Text of Statute of ORC 4729.41

(A) (1) A pharmacist licensed under this chapter who meets the requirements of division (B) mat do any of the following:

(a) Administer immunizations for influenza to individuals fourteen years of age or older.

(b) Administer immunizations to individuals eighteen years of age or older for any of the following:

(I) Pneumonia;
(ii) Tetanus;
(iii) Hepatitis A;
(iv) Hepatitis B
(v) Meningitis
(vi) Diphtheria
(vii) Pertussis
.

Prior to this update in 4729.41 any individual receiving immunization had to be eighteen years or older. Now the age for those immunized for influenza has been lowered to age fourteen and older. It is important to note that a parent or guardian of those under eighteen years of age must grant permission for influenza immunization Lastly, Meningitis, Diphtheria and Pertussis have been added to the immunizations the pharmacist can

(c) Administer to individuals eighteen years of age or older any other immunization listed in the rule adopted under division (E)(1) of this section.

Basically, the section above permits the state board of pharmacy to amend the list under (A)(b) above in consultation with the state medical and nursing boards. One can see that this is an important rule in the event that a public emergency involving an unlisted pathogen arises in the future.

(2) A pharmacy intern licensed under this chapter who meets the requirements of division (B) of this section and is working under the direct supervision of a pharmacist who meets the requirements of this division may administer immunizations for influenza to individuals eighteen years of age or older.

The above must be read carefully. The requirements of division (B) are listed below. However, notice that the only immunization the pharmacy intern may administer is for influenza – and for those eighteen years of age or older. The intern must be under the direct supervision of a pharmacist while administering the influenza immunization and the pharmacist must also have met the requirements of Division (B). Even with this limited authorization the intern receives excellent training for he or she is a pharmacist and can assume all the authority allowed under this code.

(3) As part of engaging in the administration of immunizations or supervising a pharmacy intern's administration of immunizations, a pharmacist may administer epinephrine or diphenhydramine, or both, to individuals in emergency situations resulting from adverse reactions to the immunizations administered by the pharmacist or pharmacy intern.

For the protection and safety of the patient this is a very important improvement over the original code.

(B) For a pharmacist or pharmacy intern to be authorized to engage in the administration of immunizations as specified in division (A) of this section -*above*- the pharmacist or pharmacy intern shall do all of the following:

(1) Successfully complete a course in the administration of immunizations that has been approved by the state board of pharmacy as meeting the standards established for such courses by the centers for disease control and prevention in the public health service of the United States department of Health and Human Services;
(2) Receive and maintain certification to perform basic life-support procedures by successfully completing a basic life-support training course certified by the American Red Cross or American Heart Association;
(3) Practice in accordance with a definitive set of treatment guidelines specified in a protocol established by a physician and approved by the state board of pharmacy.

It is the protocol guidelines that are defined and approved by the state board of pharmacy. As long as the guidelines are written in accordance with the protocol (See 4729-5-37) prior approval of individual protocols by the board is not required. However, upon the request of the state board of pharmacy the protocols must be made available to the board. This is dicussed later under 4729-5-37.

(C) The protocol required by division (B)(3) –*above*- of this section shall include provisions for implementation of the following requirements:
(1) The pharmacist or pharmacy intern who administers an immunization shall observe the individual who receives the immunization to determine whether the individual has an adverse reaction to the immunization. The length of time and location of the observation shall comply with the standards specified in rules adopted by the state board of pharmacy under division (E) of this section for the approval of protocols. The protocol shall specify procedures to be followed by a pharmacist when administering epinephrine, diphenhydramine, or both, to an individual who has an adverse reaction to an immunization administered by the pharmacist or a pharmacy intern.

A couple of notes: only the pharmacist is permitted to give epinephrine, diphenhydramine, or both, to a patient experiencing an adverse reaction to immunization. A pharmacy intern is not granted this authority. In addition, the protocol must specify the time a patient is to be observed after immunization. Prior to immunization the patient should be told that he or she will have to remain for observation for a set time after immunization.

(2) For each immunization administered to an individual by a pharmacist, other than an immunization for influenza administered to an individual eighteen years of age or older, the pharmacist shall notify the individual's family physician or, if the individual has no family physician, the board of health of the health district in which the individual resides or the authority having duties of the board of health for that district under section 3709.05 of the revised code. The notice shall be given not later than thirty days after the immunization is administered.

3709.05 establishes how a population area is to establish a board of health or it equivalent. A couple of points here: (1) Notifying the physician for influenza immunization would require an unreasonable amount of time on the part of the pharmacist and is probably unnecessary, as recognized here. However, note that influenza immunization for those under eighteen years of age must be reported.

(D)(1) No pharmacist shall do either of the following:

This section lists a number of admonitions. Pay close attention to any part of t he revised code or administrative code that states or implies "shall not" as part of the heading

(a) Engage in the administration of immunizations unless the requirements of division (B) of this section have been met;
(b) Delegate to any person the pharmacist's authority to engage in or supervise the administration of immunizations;
(2) No pharmacy intern shall engage in the administration of immunizations for influenza unless the requirements of division (B) of this section have been met

(E)(1) The state board of pharmacy shall adopt rules to implement this section. The rules shall be adopted in accordance with Chapter 119 of the Revised Code and shall include the following:

What follows is a list of the authority and responsibilities of the board in fulfilling the requirements of Chapter 4729 off the ORC, or Ohio Revised Code. The **Ohio Revised Code** contains all acts passed by the Ohio General Assembly and signed by the governor. The board uses the authority granted by 4729 to establish rules found the OAC, or Ohio Administrative Code. Chapter 119 is found under Title 1 of the Revised Code, State Government, and provides the administrative procedure for rule making and approval.

(a) Provisions for approval of courses in administration of immunizations;
(b) Provisions for approval of protocols to be followed by pharmacists and pharmacy interns in engaging in the administration of immunizations, including protocols that contain provisions specifying the locations at which a pharmacist or pharmacy intern may engage in the administration of immunizations;
(c) Procedures to be followed by pharmacists and pharmacy interns in obtaining from the individual's parent or guardian permission to administer influenza immunizations to an individual younger than eighteen years of age pursuant to division (A)(1)(a) of this section;

(d) A list of immunizations that may be administered under division (A)(1)(c) of this section.

(d) above is in reference to those "other" immunizations that might be approved in consultation with the state medical and nursing boards not listed in (A)(1)(b)

(2) Prior to adopting rules regarding approval of protocols to be followed by pharmacists and pharmacy interns in engaging in the administration of immunizations, the state board of pharmacy shall consult with the state medical board and the board of nursing.

In essence this means that any protocol developed based on the rules adopted by the board of pharmacy should have few if any problems if reviewed by the board. In addition, it maintain that spirit of cooperation that ought to exist between the various agencies responsible for the health of Ohio's citizens.

(3) Prior to adopting a rule listing immunizations that may be administered under division (A)(1)(c) of this section, the state board of pharmacy shall consult with the state medical board.

It was such consultation that led to amending the initial rule to expand the list to include Meningitis, Diphtheria and Pertussis.

Ohio Administrative Rules Adopted by the Board

4729-5-08

The first rule of interest is that giving interns the privilege of administering immunization. It simply state that one of the professional functions of pharmacy interns is (F) the administration of influenza immunizations to individuals eighteen years of age or older pursuant to section 4729041 of the Revised Code. This is an important function in respect to training, but limited in comparison to that afforded to a licensed pharmacist.

4729-5-38

This is a rule that became effective in June, 2009 that allows, under certain restrictions, that the pharmacist may administer zoster vaccine. The requirements are that:

(A) The pharmacist must receive a patient specific prescription prior to administration of the drug;

(B) The vaccine must be administered within thirty days of the issuance of the prescription;

(C) The patient must meet the age criteria specified in the F.D.A. approved labeling; and

(D) The pharmacist must be able to document meeting the training criteria required by rule 4729-5-36.

The approved labeling for Zostavax ® (Merck) indicates that Zostavax is a live attenuated virus vaccine indicated for prevention of herpes zoster (shingles) in individuals 60 years of age and older.

4729-5-36 Course requirements in the administration of adult immunizations. [Rule effective 6/21/2009]

(A) A course in the administration of adult immunizations developed pursuant to division (B)(1) of section 4729.41 of the Revised Code shall meet at least the following requirements:

(1) The instructor shall be a licensed health care professional and have the appropriate education and experience to teach a course in the administration of adult immunizations.

(2) The content must meet the standards established for such courses by the centers for disease control and prevention in the public health service of the United States department of Health and Human Services.

(3) The course must be a minimum of five hours in length and include at least the following:

(a) A review of immunology that includes a discussion of the body's immune system reaction to the immunizations.

(b) A review of each immunization listed in division (A) of section 4729.41 of the Revised Code that includes the following:

(i) Disease states associated with the immunization;
(ii) Type or nature of activity of the immunization;
(iii) Appropriate administration schedules;
(iv) Appropriate routes of administration;
(v) Appropriate injection sites;

(vi) Appropriate dosages;
(vii)Appropriate monitoring of the patient for adverse reactions;
(viii) Appropriate patient populations;
(ix) Precautions and contraindications;
(x) Proper storage requirements for the immunization.

(c) A review of sterile technique in injectable dosage preparation and administration.

(d) A minimum of one hour of instruction and physical participation in administration techniques.

(e) A review of the proper disposal procedures for contaminated needles and immunizations.

(f) A review of the proper procedures for accidental needle sticks.

(4) The course must provide a method to evaluate the successful mastery of the content.

(B) All courses in adult immunizations must be submitted to the state board of pharmacy for approval. The courses may be reviewed with the state medical board and the board of nursing, as appropriate. Any subsequent revisions to the course, after the initial approval, must be submitted to the state board of pharmacy for approval.

The required course content must meet the standards established for such courses by the Center for Disease Control (CDC) for administration of adult immunization [(A)(2) above and 4729.41 (B)(1)]. One must realize, however, that such information is frequently updated. The pharmacist should make sure that he/she knows current CDC recommendations for the vaccines administered in his or her practice. The guidelines are readily available on the CDC web site.

http://www.cdc.gov/vaccines/pubs/ACIP-list.htm

4729-5-37 Protocols for the administration of adult immunizations. [Rule effective 6/21/2009]

(A) To be considered an approved protocol pursuant to division (B)(3) of section 4729.41 of the Revised Code, the physician-established protocol for the administration of adult immunizations must include at least the following:

(1) For each immunization listed in division (a) of section 4729.41 of the Revised Code and in rule 4729-5-38of the Administrative Code:

(a) Name and strength;
(b) Precautions and contraindications;
(c) Intended audience or patient population;
(d) Appropriate dosage;
(e) Appropriate administration schedules;
(f) Appropriate routes of administration;
(g) Appropriate injection sites.

(2) The length of time the pharmacist or pharmacy intern under the direct supervision of a pharmacist must observe an individual for adverse effects, which shall be based on appropriate standards of care established by the physician. The location of the observation shall be in the general vicinity of the administering pharmacist to allow for on-going evaluation.

(3) A method to address emergency situations including, but not limited to, adverse reactions, anaphylactic reactions, and accidental needle sticks.

(4) A method to notify an individual's physician or the applicable board of health within thirty days after administering medication, except for influenza immunizations administered to individuals eighteen years of age or older. .

The pharmacist or pharmacy intern must perform these tasks. 4 is an issue that should be covered in the consent form. The patient, for some reason, may not want the physician notified. He or she can certainly make this choice. If so, however, the pharmacist can provide immunization provided the patient approves notification of the applicable board of health. Actual notification of the physician or applicable board of health is a task that probably can be delegated. This issue can be covered in the protocol for board approval.

(B) All physician-established protocols must be signed and dated by the physician prior to implementation and maintained by the administering pharmacist. The pharmacist must renew the protocol annually with the physician.

A protocol does not need prior approval by the board of pharmacy. It must, however, conform to the requirements of 4729-5-37. The protocol is signed and dated by the physician and the administering pharmacist(s) prior to implementation. The protocol is maintained by the pharmacist and is valid for for one year, after which it must be renewed. The protocol is subject to inspection at any time by the state board of pharmacy.

Prior to renewal the pharmacist should consider the scope of the protocol, any problems that occurred during the year, and any deficiencies in the protocol. The protocol can be revised prior to one year but any revised protocol must, as before, meet the requirements of 4729-5-37. For instance, the initial protocol may not have included administration of hepatitis A or B vaccines, but within a short time hepatitis emerged as a serious concern within the community. After consultation, the pharmacist and physician decide to amend the protocol to allow immunization for hepatitis A and B. The date of renewal of the amended protocol would remain one year from the date of approval of the initial protocol.

(C) Upon the request of the state board of pharmacy, a pharmacist shall immediately provide the protocols for adult immunizations pursuant to division (B)(3) of section 4729.41 of the Revised Code. The state board of pharmacy, after review, may approve the protocol or return it to the pharmacist for revision without approval. If a protocol has been returned for revision without approval, it may not be implemented until the board has approved it. The state board of pharmacy may review the protocols with the state medical board and the board of nursing, as appropriate.

4729-5-27

This rule is simply title “Record Keeping” that is visited and amended rather frequently since the scope of the rule covers all pharmacy activities where records must be maintained in a prescribed format and on a consistent basis, such as those required for immunization services. The following is a synopsis of the rule as it relates to immunization.

1. Records concerning immunizations must show positive identification of the pharmacist or pharmacists responsible for performing this function.

For hard copy a full signature is generally considered positive identification. For electronic a unique sign-on and password are generally considered positive identification. Other methods offering surety may also be acceptable, .

2. Immunization records are a part of pharmacy practice and must be maintained for three years. They must be made readily available for inspection by representatives of the state board.

3. The records may be microfilmed or placed on electronic, magnetic media. These, too, must be readily available for inspection by the state board

4. The board must be informed if the records are kept in a location other than the place licensed by the state board of pharmacy, and prior approval must be granted.

5. For immunization records in particular, each individual record must include the following information:

a. Full name and address of the patient;

b, Patient's date of birth or age;

c. Patient's gender;

d. Patient's applicable allergy information;

e. Date of administration;

f. Name, strength, and dose of the immunization administered;

g. Lot number and expiration date of the immunization;

h. Route of administration;

i. Location of the injection site;

j Positive identification of the administering pharmacist or the administering pharmacy intern and supervising pharmacist;

k. Positive identification of the patient, parent, or legal guardian of the patient who gives informed consent to administer an immunization

6. A pharmacist or pharmacy intern under the direct supervision of a pharmacist who administers immunization shall maintain and immediately make available, upon request of the state board of pharmacy, the following records

a. Documentation of the successful completion of a board approved course in the administration of immunizations.
b. Documentation of current certification to perform basic life support procedures.

Remember in respect to b above that only the pharmacist is authorized to perform basic life support procedures. It is reasonable, on the other hand, that the pharmacy intern might assist the pharmacist, especially if cardiopulmonary resuscitation is required.

By law administering adult immunization now becomes a recognized professional activity of pharmacists who comply with the board rules. Administering adult immunization is included in the practice of pharmacy. This has important implications for the "responsible pharmacist" in a practice environment. Whether the responsible pharmacist chooses to participate in providing immunization or not, he or she is responsible for seeing that the process is handled in compliance with 4729.41 and the board rules that implement this law.

The requirements above seem straightforward but notice that informed consent is obviously required. There is no requirement that the training courses (4729-5-36) cover this important requirement. Informed consent is also not required in the protocol (4729-5-37). There are two samples of consent forms attached to this program as examples. An important aspect to consent is that the individual granting consent must understand what he/she is consenting to. You will notice, for instance, that the consent form covers issues important to avoid allergic reactions. Having the individual simply sign the form does not indicate that he or she understands what is being signed. A standard policy should be that the pharmacist verbally covers the contents of the consent form with the patient.

Sample Forms

THIS PROTOCOL IS FOR ILLUSTRATION PURPOSES ONLY. IT IS FOR THE STATE OF UTAH AND DOES NOT CONFORM TO OHIO 4729-5-37, WHICH REQUIRES CONSIDERABLE MORE DETAIL.

The following pharmacist(s), according to and in compliance with Article 58-17a-102 (43)(b) and Article 58-17a-502 (9) of the Utah State Pharmacy Practice Act, may administer the medications listed below and for a fee.

Each below-mentioned pharmacist has completed training as prescribed in article R156-17a-620 of the Pharmacy Practice Act Rules.

To protect people from preventable infectious diseases, each pharmacist may administer the following immunizations to eligible adolescents (13-17) and adult patients, according to indications and contraindications recommended in current guidelines from the Advisory Committee on Immunization Practices (ACIP) of the U.S. Centers for Disease Control and Prevention (CDC) and other competent authorities.

Influenza Vaccine
Pneumococcal Vaccine
Hepatitis B Vaccine
Hepatitis A Vaccine
Varicella Vaccine
Measles-Mumps-Rubella
Tetanus-Diphtheria Toxoids (Adult, Td)

Striking through the name of any of the above Vaccines will indicate deletion from this protocol. Additions must be submitted in writing to the Utah Division of Occupational and Professional Licensing (DOPL) for their approval.

The pharmacy shall post in a prominent place an emergency plan to be implemented in case of an adverse event. Such plan shall include the phone number of the local EMS, phone number of the undersigned licensed practitioner, and the role of the pharmacist and other participants. In the course of treating adverse events following immunization, the pharmacist is authorized to administer epinephrine (at a dose of approximately 0.01mg/kg body weight; maximum of 0.5mg per dose) and diphenhydramine (at a dose of approximately 1mg/kg; maximum dose of 50-100mg per dose) by appropriate routes pending availability of emergency medical services. The pharmacist may provide cardiopulmonary resuscitation as needed. For adverse events the pharmacist shall complete and submit the Vaccine Adverse Event Reporting System (VAERS) form to the CDC, the undersigned licensed practitioner, and the patient's primary care practitioner, if known.

In the course of immunizing, the pharmacist must maintain perpetual-records of all immunizations administered including patient name; primary care practitioner (if known); vaccination date; name, address, title of pharmacist administering; name of vaccine; manufacturer; lot number. Before immunization, all vaccine candidates will be questioned regarding previous adverse events after immunization, food or drug allergies, current health conditions, immunosuppression, recent receipt of blood or antibody products, pregnancy, and underlying diseases. All vaccine candidates will be informed of the specific benefits and risks of the vaccine(s) offered.

As the authorizing licensed practitioner, I will periodically review (not less than annually) the activities of the pharmacist(s) administering vaccines under this protocol and deem authorization valid one year from the date indicated below, unless otherwise revoked or extended in writing

Pharmacist: ___________________________**License Number**_________________________

Pharmacist: ___________________________**License Number** _____________________

Pharmacist: ___________________________**License Number** _____________________

Licensed Practitioner Name: ______________________________________

Licensed Practitioner Signature: ______________________________________ **Date**: ________________

Address:

City: ________________________________ **State:** _____________________________ **Zip:** _________________

Practitioner License # _____________________________**State:** ____

Consent forms may be for individual vaccines or one listing multiple vaccines. A sample consent form from the Internet is shown below. There is certainly good argument that consent forms should be for individual vaccines.

COMMUNITY HEALTH SERVICES DEPARTMENT
Environmental Health & Prevention Services
160 Exmouth Street
Point Edward, ON N7T 7Z6
Telephone: 519 383-8331
Toll Free: 1-800-667-1839
Fax: 519 383-7092
www.lambtonhealth.on.ca

HEPATITIS B VACCINE CONSENT FORM

Student's Name (last): First name:
Date of Birth: Year Month ______ Day ____ Gender M _ F _ School: ____________
____
Parent/Guardian's home number: ______________________ Parent/Guardian's business number: _______________
Street Address: ________________ _____________________________________
City: ___________________ Postal Code: ___________________ Health Card Number______________________
Is the student feeling ill today? (Asked by nurse on clinic day) No _ Yes _ If yes, please explain below
Has the student ever had an allergic reaction to a vaccine? No _ Yes _ If yes, please explain below
Is the student known to be allergic to any of the following components of the vaccine?
Thimerosal (mercury) No _ Yes _ If yes, please explain below
Aluminum No _ Yes _ If yes, please explain below
Formaldehyde No _ Yes _ If yes, please explain below
Yeast No _ Yes _ If yes, please explain below
Latex No _ Yes _ If yes, please explain below
Does the student have a serious problem with their immune system? No _ Yes _ If yes, please explain below
Does the student have a bleeding disorder? No _ Yes _ If yes, please explain below
Is the student pregnant? No _ Yes _ If yes, please explain below
To your knowledge, has the student ever had a hepatitis B infection? No _ Yes _ If yes, please explain below
Has the student ever had the hepatitis B vaccine? No _ Yes _ If yes, please provide dates below
Please explain any "Yes" answers provided above:
____
____
____
_______ ___________

I have read and understand the "Hepatitis B Vaccine Fact Sheet". I have had the chance to ask questions, and understand the answers provided to me. I am aware that personal health information collected on this form may be released, when requested, to my physician, other health units, a hospital, youth center and/or the Children's Aid Society. This is done to ensure that vaccines are administered at the right time and are not given more often than needed. This consent is valid until series is complete.

I ask that the above named student be vaccinated against hepatitis B with two doses of Recombivax HB ®. I certify that I am the appropriate decision-maker / substitute decision-maker.

Signature of Parent/Guardian ____

Print name _____________________________

Date of signature: _______________________

Signature of student
receiving the vaccine: ____________________

Date of signature: ____________________

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4. Madhavan SS, Rosenbluth SA, Amonkar M, Borker RD, Richards R. Pharmacists and Immunizations: A National Survey J Am Pharm Assoc. 2001;41:46-52.

5. Ernst ME, Bergus R, Sorofman BA. Patients' Acceptance of Traditional and Nontraditional Immunization Providers. J Am Pharm Assoc. 2001;41:53-9.

There is one best answer to the questions below. Select the answer, which is most appropriate, and mark this on the attached answer sheet. Mail the answer sheet to Adherence, Inc. for continuing education credit.

1. It is estimated that 5 to 20% of the U.S. population is infected with influenza each year, resulting in _________ deaths.

a. 10,600
b. 25,200
c. 36,000
d. 48,000

2. A properly licensed pharmacy intern can administer influenza vaccines to persons 14 years of age or older.

a. True
b. False

3. In the event of an adverse reaction to immunization a properly licensed pharmacy intern can administer epinephrine and/or diphenhydramine to the patient affected.

a. True
b. False .

4. The pharmacist who provides immunization must utilize a physician-established immunization protocol.

a. True
b. False

5. The pharmacist must observe an individual receiving immunization for a minimum of __________.

a. 15 minutes
b. Time to be determined by the pharmacist
c. Time to be determined by the physician-established protocol
d. One hour.

6. The pharmacist is required to notify the patient's physician when he or she administers influenza vaccine to a patient under 18 years or age.

a. True
b. False

7. A prescription for zoster vaccine is valid for no more than _____ days.

a. 5
b. 10
c. 20
d. 30

8. Zoster immunization id limited to those individuals _______ years of age or older.

a. 50
b. 55
c. 60
d. 65

9. Course requirements in the administration of immunization must meet standards established by the ________________________.

a. CDC
b. Ohio State Medical Board
c. The Red Cross
d. The United State Department of Health and Human Services

10. Courses in immunization approved by the Ohio state board of pharmacy must be reviewed by the Ohio state medical board prior to approvals.

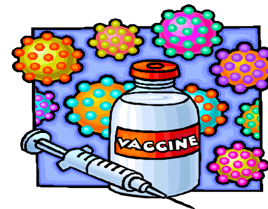
a. True
b. False

11. A physician-established protocol for immunization is valid for _______ before it must be reviewed by the physician and pharmacist.

a. one year
b. two years
c. six months
d. Nine months

12. Immunization records must retained by the pharmacist and made readily available to the state board of pharmacy for at least _________ years.

a. 1
b. 3
c. 5
d. 7



Adherence, Inc. educational program

Pharmacist provided immunization & Ohio law.

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Evaluation Question: Please help us evaluate this program by answering the following:

	POOR/	FAIR /	SATIS /	GOOD
1. QUALITY OF INFORMATION	1	2	3	4
2. USEFULNESS IN MY PRACTICE	1	2	3	4
3. READABILITY & PRESENTATION	1	2	3	4

4. How long did it take you to complete this program: ___________ hours

Continuing Education Answer Sheet: Please circle the appropriate answer for each question.

1. A B C D	5. A B C D	9. A B C D
2. A B C D	6. A B C D	10. A B C D
3. A B C D	7. A B C D	11. A B C D
4. A B C D	8. A B C D	12. A B C D

SIGNATURE: ________________________________

Please take the time for helpful comments. We are especially interested in knowing topics that would interest you for future modules.

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