How to Establish a Pharmacy-Based Immunization Program

MODULE #6

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Disclosures

- Chasity Mease reported the following financial relationships or relationships to products or devices she or her spouse/life partner have with commercial interests related to the content of this CE activity:
  - Dr. Mease reports no conflict of interest for this presentation
Learning Objectives

- List legal requirements in your state for immunization delivery by a pharmacist.
- Develop a plan for implementing immunization services to adults in a pharmacy.
- Describe methods for reimbursement for immunization services.
- Identify required forms and supplies for a pharmacist-led vaccine administration program.
- Discuss site-specific challenges such as scheduling and workflow that may impact the pharmacist’s ability to administer vaccinations.

Quality Standards

- Quality standards in this presentation follow those of the Advisory Committee on Immunization Practices and the National Vaccine Advisory Committee outlined in:

  Adult Immunization Programs in Nontraditional Settings: Quality Standards and Guidance for Program Evaluation - A Report of the National Vaccine Advisory Committee and Use of Standing Orders Programs to Increase Adult Vaccination Rates - Recommendations of the ACIP; CDC MMWR; 3-2000
State-Specific Legal Requirements

- Which vaccines are you authorized to administer in your state?

State-Specific Legal Requirements

- How are you authorized to administer immunizations?
  - Individual prescriptions
  - Standing order
    - What are the reporting requirements?
  - Protocol with physician
    - What are the reporting requirements?
  - Collaborative practice agreement
    - What are the reporting requirements?
  - Prescriptive Authority
- Different authorization required for different vaccines? If so, how?
## State-Specific Legal Requirements

- How are you authorized to administer immunizations (check all that apply)?
  - Individual prescriptions
  - Standing order
  - Protocol with physician
  - Collaborative practice agreement
  - Prescriptive Authority
  - Other (write in)

## State-Specific Legal Requirements

- Patient age limitations?
- Specialized training required?
  - Immunization training program
  - CPR
  - OSHA/blood-borne pathogen
  - Annual CE regarding vaccine administration
State-Specific Legal Requirements

- True or False
  - Your state board of pharmacy requires annual CE regarding vaccine administration

State-Specific Legal Requirements

- Registration with your state required?
- Are you required to report immunizations administered to a state vaccine registry?
- Can student pharmacist interns administer immunizations? Any related requirements?
Liability

- Professional liability insurance coverage
  - Usually covers all activities in pharmacist’s scope of practice
  - Check with insurance carrier

- Screening and documentation important (review in Module 2)

Education for Immunizers

- Immunization training
- Ongoing updates
  - http://www.cdc.gov/mmwr/
  - www.TheCEInstitute.org
  - www.cedrugstorenews.com
  - www.pharmacist.com
  - www.immunize.org
Education for Immunizers

- Go to the following website and find the new releases link for one idea on keeping up to date
  - www.immunize.org
- How do you plan to keep up to date on immunizations? (write in)

Education for Immunizers

- Cardiopulmonary resuscitation (CPR)
  - Requirement in some states
- Fraud, waste and abuse training
  - Annual training if billing Medicare
- Occupational Safety and Health Administration (OSHA)
  - 1 hour annual training
  - www.osha.gov
Education for Immunizers

- OSHA
  - 1 hour annual training
    - Online, in-pharmacy, etc.
    - Required by Federal regulations
    - For all individuals with potential occupational exposure to blood-borne pathogens
  - Exposure control plan (www.osha.gov)
  - Sharps injury log
  - Annual OSHA training plan/documentation

Requirements for Immunizers

- Hepatitis B Immunization
  - OSHA requirement for those with potential blood-borne pathogen exposure
  - Employee must receive the series or sign a waiver
  - Employee must receive at least 1st dose in 3-dose series before administering immunizations
  - Employer must offer hepatitis series free of charge for employee
Guidance for Nontraditional Settings

- National Vaccine Advisory Committee, 2000
- [http://www.cdc.gov/mmwr/PDF/rr/rr4901.pdf](http://www.cdc.gov/mmwr/PDF/rr/rr4901.pdf)
- Seven quality standards

Guidance for Nontraditional Settings

- **Standard 1**: Information and Education for Vaccines
- **Standard 2**: Vaccine Storage and Handling
- **Standard 3**: Immunization History
- **Standard 4**: Contraindications
- **Standard 5**: Recordkeeping
- **Standard 6**: Vaccine Administration
- **Standard 7**: Adverse Events
Standard 1: Information and Education for Vaccinees

- Vaccine Information Statements (VIS)
  - Information about the risks and benefits of vaccination
  - Available at www.cdc.gov
  - Requirement of the National Childhood Vaccine Injury Act of 1986
  - Translated into 30 languages

Standard 1: Information and Education for Vaccinees

- VIS required
  - For any vaccine covered by the Vaccine Injury Compensation Program
  - As of June 2009, DTaP, Td, MMR, Polio, Hepatitis A, Hepatitis B, Hib, Varicella, Influenza, Pneumococcal Conjugate

- VIS strongly recommended
  - Pneumococcal Polysaccharide, Meningococcal, Tdap, Rabies, Rotavirus, HPV, Shingles, Yellow Fever, Typhoid, Japanese Encephalitis, Anthrax, Smallpox
VIS Sample

- Update picture to 10-11 VIS


VIS Active Learning

- Go to www.cdc.gov using another browser window and find the link to the Shingles VIS and answer the following question.
- What is the date that the Shingles VIS was last updated?
Standard 2: Vaccine Storage and Handling

- Protect Your Vaccine Supply
- Protect Your Patients
- Protect your Inventory

- Maintain the cold chain
- Proper refrigerator and/or freezer
- Proper thermometer
- Temperature logs
- Trouble shooting logs
Standard 2: Vaccine Storage and Handling

- Have an emergency plan in place
- Avoid common vaccine storage mistakes
  - Avoid pre-filling syringes
  - Avoid using expired vaccines
  - Protect vaccines from light
  - Do not transport frozen vaccines

Refrigerated Vaccines
- TIV, LAIV
- HPV
- MCV, MPSV
- PPSV, PCV
- Td, Tdap, DTaP, DT, Hib, IPV
- Rotavirus
- HepA, HepB
Standard 2: Vaccine Storage and Handling

- Frozen Vaccines
  - Herpes Zoster
  - Varicella
  - MMRV
  - Note: MMR may be stored in the freezer or refrigerator

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Standard 2: Vaccine Storage and Handling

- Which vaccines must be kept in the refrigerator?
Standard 2: Vaccine Storage and Handling

- Case:
  - You come in to your pharmacy in the morning and your technician reports to you that the temperature on the refrigerator was 50 degrees F. It appeared the door was left slightly ajar overnight. What is the proper course of action?
Standard 3: Immunization History

- Does your state require the use of an immunization registry?

Standard 4: Contraindications

True Contraindications (do NOT administer vaccine):
- Anaphylactic reaction to a vaccine
- Anaphylactic reaction to a vaccine component
- Moderate or severe illness with or without fever
- Pregnancy
- Compromised immune system

National Vaccine Advisory Committee’s Standards for recommendations of the National Vaccine Advisory Committee. MMWR 1993;42[No. RR-51].
### Standard 4: Contraindications

**False Contraindications (vaccine may be administered):**
- Mild to moderate local reaction following injectable antigen
- Low-grade or moderate fever following a previous vaccine dosage
- Mild acute illness with or without fever
- Current antimicrobial therapy
- Convalescent phase of illness
- Prematurity
- Recent exposure to an infectious disease
- History of penicillin or other nonspecific allergies (or history among family members)
- Pregnancy or mother or household contact
- Unvaccinated household contact
- Breast-feeding

### Standard 5: Record Keeping

- Vaccinee’s name
- Age
- Preexisting health conditions
- Type of vaccine
- Dose
- Site and route of administration
- Name of the vaccine provider
- Date vaccine was administered
- Manufacturer and lot number
- Date that the next dose is due
Standard 6: Vaccine Administration

- Supplies needed
  - Vaccine
  - Syringes/needles with safety device
  - Sharps disposal containers
  - Latex-free disposable gloves (verify state requirements)
  - Hand sanitizer or soap & water
  - Alcohol swabs
  - Latex-free bandages
  - Cotton balls or gauze squares
  - Trash can
  - Sterile pads or clean work station
  - Emergency kit

- Semi-private area

- Prepare for emergencies
  - Patient seated properly in a chair
  - Immunizer positioned to physically support vaccinee
  - Emergency kit at hand

- Patient observation area
Standard 6: Vaccine Administration

- **Workflow considerations**
  - Patient appointments
  - Immunization clinic events
  - Dedicated immunizing pharmacist
  - Technician utilization, depending on state law
  - Student pharmacist intern utilization, depending on state law

Standard 7: Adverse Events

- **How will emergencies be handled?**
- **Documentation**
  - ADRs requiring documentation
  - When to document? Designated time-frame?
  - Reporting to whom?
    - Vaccine Adverse Event Reporting System (VAERS)
      - Submit at vaers.hhs.gov or call 1-800-822-7967
  - Follow-up required?
Marketing

- Increase awareness of immunizations
- Develop a public health message

Marketing

- Communicate with current patients
  - Ask about immunizations at each patient encounter, including MTM
- Reach out to all potential patients, especially those in high-risk populations
- Advertising – signage and information in pharmacy
- Community resources
  - Contact local employers
  - Local immunization coalitions
Reimbursement

- Cash
- Medicare Part B
- Medicare Part D
- Medicare Advantage
- Other third party payors

Reimbursement

- Medicare
  - Reimbursement for Vaccines and Vaccine Administration Under Medicare Part D
  - Adult Immunization Provider Resources
    - [www.cms.hhs.gov/AdultImmunizations/02_Providerresources.asp](http://www.cms.hhs.gov/AdultImmunizations/02_Providerresources.asp)
Reimbursement

- Medicare Part B
  - Most vaccines indicated for Medicare population

- Medicare Part D
  - Vaccines not available under Part B when administration is reasonable and necessary for the prevention of illness

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Reimbursement

- Medicare Part B coverage
  - Pneumococcal pneumonia vaccine
    - One for all beneficiaries
    - Booster for high-risk if 5 years have passed since their last vaccination
    - Separate rates for cost of the vaccine and administration
Reimbursement

- Medicare Part B coverage
  - Influenza virus vaccine
    - One each season for all beneficiaries
    - Separate rates for cost of the vaccine and administration

- Medicare Part B coverage
  - Hepatitis B vaccine
    - For individuals at high or immediate risk
    - Medicare Part B deductible and coinsurance or co-payment applies
    - Separate rates for cost of the vaccine and administration
Reimbursement

- Medicare Part B coverage
  - Other vaccines
    - (e.g. tetanus toxoid) when directly related to the treatment of an injury or direct exposure to a disease or condition

Reimbursement

- Medicare Part B billing
  - 2 procedure codes (vaccine and administration)
  - Same billing as other services using 1500 paper claim forms or electronically
  - Mass immunizer or “community vaccinator”
    - Enroll and follow special instructions
    - Provider specialty number
  - 2 options to bill
    - Roster billing
    - Centralized billing
### Medicare Part B billing

- **Roster billing**
  - Complete one 1500 or 1450 paper form
  - Attach a roster listing the beneficiaries who received the vaccine

- **Electronic Billing**
  - [www.cms.hhs.gov/electronicbillingeditrans/08_healthcareclaims.asp](http://www.cms.hhs.gov/electronicbillingeditrans/08_healthcareclaims.asp)

### Medicare Part D coverage

- As of 2008, all Part D plans’ formularies must contain all commercially available vaccines (unless available under Part B)
Reimbursement

- Medicare Part D billing
  - Negotiated price comprised of:
    - Vaccine ingredient cost
    - Dispensing fee (if applicable)
    - Sales tax (if applicable)
    - Vaccine administration fee

- Billed electronically

Reimbursement

- Medicare Advantage Plans
  - Contact number on beneficiary’s card
Reimbursement

- Other Third Party Payors

Reimbursement

Which of the following is the copay amount paid by Medicare Part D beneficiaries for herpes zoster immunization?

- $0
- Herpes Zoster vaccination is not covered by Medicare Part D, therefore the patient would be charged the cash price
- The copay is dependent on the patient’s copay structure, whether they have met their deductible and if they are in their coverage gap.
Thank you for participating!

Thank you for your participation. This concludes Module 6. Please proceed to Module 7 – Case Discussion and Administration Technique.

This activity can be accessed by returning to “My Portfolio” within the CEI website and clicking on the activity name “Immunization Administration Training for Pharmacists.”
Module 6

CASE STUDIES

This case serves as a review of Module 6.

Aspects of the standards for immunization delivery in nontraditional settings put forward by the National Vaccine Advisory Committee have been addressed throughout this course. Because they are important they are reviewed in Module 6. For practical application of these standards through the review cases, the participant is referred to other modules.

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Case #1 (This review case is in follow up to the case presented in Module 2)

Andy is a newly licensed pharmacist who has been given the responsibility of setting up a pharmacy-based immunization service for Red Pharmacy with three other pharmacists. The pharmacy plans to offer influenza, pneumococcal polysaccharide, and zoster vaccines to adults and expand to all vaccines over the next two years. What steps should he take to prepare the pharmacy? Address legal requirements.

What considerations regarding workflow should be made as this new service is incorporated into the practice?

How should Andy address reimbursement issues for the Red Pharmacy?
Module 6  
CASE STUDIES ANSWERS

These case answers serve as a review of Module 6.

Case #1

Andy is a newly licensed pharmacist who has been given the responsibility of setting up a pharmacy-based immunization service for Red Pharmacy with three other pharmacists. The pharmacy plans to offer influenza, pneumococcal polysaccharide, and zoster vaccines to adults and expand to all vaccines over the next two years. What steps should he take to prepare the pharmacy? Address legal requirements.

Andy checked with the state board of pharmacy rules and the state’s laws to determine the scope of practice for the immunizing pharmacist in the state in which the pharmacy is located. He sought assistance from the state association and other immunizing pharmacists. The state required immunization training. Andy completed the training requirement as a pharmacy student, and the other three pharmacists have registered for a course to begin next month. He discovered that pharmacists must enter into a protocol or develop standing orders to administer vaccines to adults. Immunization of children requires an individual prescription. He adapted the standing order template from the Immunization Action Coalition (included in Module 6) to include all three vaccines that will be administered at Red Pharmacy. He also included epinephrine and diphendyramine administration in the event of an emergency in the protocol. He then approached a physician to sign the protocol as required by the state in which Red Pharmacy is located. The physician he chose to discuss this with first was the county medical director. Andy and Red Pharmacy have a good professional relationship with her and she is charged with promoting the health of the citizens of the county. She was eager to sign the protocol but asked that the pharmacy would enter all the immunization administered in the state immunization registry. Although this recordkeeping step is not required by state law, the pharmacists and the county medical director all believe the immunization registry is an important tool for clinical decision-making regarding immunization, so the protocol was amended and signed by the county medical director. Although not a legal requirement for immunizing pharmacists in this state, the pharmacists will all maintain certification in basic life support.

What considerations regarding workflow should be made as this new service is incorporated into the practice?

Since all the pharmacists who practice at Red Pharmacy will be immunizers, the group decided to offer immunizations during all hours of operation. They may increase staffing during times when high immunization demand is expected. For example, the pharmacists anticipate administering several hundred influenza vaccines as beginning as soon as their supply arrives in the pharmacy. Additional staff may be needed then.
How should Andy address reimbursement issues for the Red Pharmacy?

Influenza and pneumococcal polysaccharide vaccines are covered under Medicare Part B. Influenza vaccine is covered once a season for all beneficiaries. Pneumococcal polysaccharide vaccine is covered once for all beneficiaries. A second dose may be indicated for those at highest risk of disease (see Module 5). The pharmacy must obtain a Medicare Part B provider number. Andy should apply using the CMS 855. Claims are filed using the CMS 1500 form. For both influenza and pneumococcal vaccines, two procedure codes are needed and the provider should bill for both the vaccine and the vaccine administration. The reimbursement rates are set by region of the country and do not vary by provider type (i.e. physicians and pharmacists are offered the same reimbursement).

Zoster vaccine is covered by Medicare Part D. A copay is likely required of the beneficiary. The amount of that copay varies among the Medicare Part D plans. All future vaccines for this population will be covered by this medication benefit.

Some individuals presenting to the pharmacy for immunization will not be covered by Medicare. Most private health insurers consider immunization a medical benefit and will not routinely reimburse pharmacies for providing the service. Pharmacy-based immunization providers could try to negotiate such arrangements with insurers. Some patients will pay cash for immunization services. The pharmacy can set a price for this service. The cash price cannot be less than that is billed to Medicare Part B though. Pharmacists must charge cash paying customers the same amount as they bill to Medicare.
Module 6
SELF-ASSESSMENT QUESTIONS

The self-assessment questions below address the information contained in Module 6. The questions will be the same questions as what will appear in the final, self-assessment examination required to obtain your CE Statement of Credit upon completion of Modules 1-7. Because there are 100 questions and you have a time limit, it is suggested that you print these questions, answer them on your own, and save them to refer to when you are completing the final, self-assessment examination.

1. Which of the following vaccines is covered by Medicare Part D?
   a. Zoster vaccine
   b. Trivalent inactivated influenza vaccine
   c. Live attenuated influenza vaccine
   d. Hepatitis B vaccine

2. Which of the following methods describes how vaccines are covered under Medicare Part D?
   a. As a medical benefit
   b. With a universal copay of $10 for every patient enrolled
   c. Provider must submit a bill plus invoice documenting vaccine cost for reimbursement
   d. Reimbursement based on negotiated amount based on vaccine, dispensing fee, sales tax, and vaccine administration fee

3. Which of the following is the copay amount paid by Medicare Part B beneficiaries for influenza immunization when their provider accepts assignment?
   a. $0
   b. $5
   c. $10
   d. 50% of the pharmacy’s usual and customary charge

4. Which of the following skills is among the standards of practice among immunizing pharmacists?
   a. Basic life support (CPR)
   b. Advance cardiac life support
   c. Emergency medical technician
   d. First aid training

5. Which of the following may be a source for discovering legal requirements for vaccine administration by pharmacists?
   a. The American Medical Association
   b. The National Foundation for Infectious Diseases
   c. The state board of pharmacy
   d. The local health department
Module 6
SELF-ASSESSMENT QUESTIONS

6. Which of the following is recommended by the National Vaccine Advisory Committee as a critical component for their standard on information and education for vaccines?
   a. Refer all potential immunization candidates to the local health department for immunization
   b. Use Vaccine Information Statements (VIS) to assist with patient education
   c. Avoid discussing risks of vaccines because it may cause some patients to refuse immunization
   d. Only immunize going through the package insert with the patient to assure that she has received all the information regarding the benefits and risks of the vaccine

7. How should you proceed if vaccine arrives from the manufacturer under questionable conditions?
   a. Store the vaccine as recommended separately from other stock and call the manufacturer’s quality control office for advice
   b. Repack the vaccine and return it to the manufacturer
   c. Store the vaccine as recommended separately from other stock and call the Centers for Disease Control and Prevention for advice
   d. Place the vaccine in stock and use it first

8. Which of the following vaccines must be stored in the refrigerator?
   a. Varicella vaccine
   b. Zoster vaccine
   c. Live attenuated influenza vaccine
   d. Measles-mumps-rubella-varicella vaccine

9. Which of the following describes the space requirements for immunization?
   a. A separate room with a door that closes
   b. Large enough to house the refrigerator for vaccine storage immediately adjacent to the patient
   c. A semi private space with a chair for the patient
   d. A space with a bed or cot

10. Which of the following strategies could be useful for increasing the community’s immunization rates through the pharmacy-based immunization services?
    a. Limit immunization hours in the pharmacy
    b. Require a referral from another healthcare provider
    c. Offer immunizations during all hours of operation
    d. Order the vaccine when a patient with an indication for it is identified and then make an appointment with the patient to return when the vaccine arrives