

GETTING INVOLVED: A Look at Pharmacist Administered Immunizations



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Goals and Objectives:

- Describe the importance of pharmacist involvement in immunization outcomes.
- Discuss the reasons why pharmacies are an ideal setting to provide vaccines to the community.
- Explain key components related to obtaining reimbursement for the Michigan-based pharmacist.
- List the various channels for vaccine service compensation.
- Identify immunization-related resources for implementation and maintenance of a pharmacy-based immunization service.

Background of Pharmacy Immunization Services

Most healthcare professionals agree that the development of vaccines has been one of the greatest medical achievements of the 20th century. The first vaccine dates back to 1796, involving the English doctor Edward Jenner and the smallpox vaccination. Dr. Jenner observed a decreased incidence of smallpox infection among milkmaids who

were infected with cowpox. Following through with this observation, Dr. Jenner inoculated a quantity of the cowpox blister into a young village boy. The boy later showed immunity to smallpox. The term vaccination was then derived from the Latin word cow, “vacca.” It was Jenner’s observation that led to the prevention of disease through vaccinations.

Ever since Edward Jenner, vaccines have

prevented disability and death from various infectious diseases. Vaccines also control the spread of infections within communities throughout the world. However, prevention and education is still needed within the United States. Even with the necessary supply of vaccinations, many of America’s most frequent pharmacy visitors fail to get immunized. Listed below are several facts highlighting the importance of improved vaccination rates throughout the community setting.

- It is estimated that half of seniors living until the age of 85 years will have developed shingles.
- According to the Centers for Disease Control and Prevention (CDC), influenza is the leading cause of a vaccine preventable death in the U.S.
- More than 50,000 people die due to pneumococcal disease and influenza each year. This number is equivalent to 100 jumbo jet crashes annually.

How a Pharmacist Can Get Involved

Vaccination services can be incorporated by pharmacies in three ways: Pharmacists as Advocates, Pharmacists as Facilitators and Pharmacists as Immunizers.

Advocates

Pharmacists are widely known as the most readily accessible healthcare professionals and can play a key role in assessing a patient’s immunization status, identifying patients who at risk for vaccine preventable illness and providing necessary education.

Facilitators

Pharmacists can function as “facilitators” by partnering with vaccine providers, such as hosting visiting nurses to provide vaccination-related services. Referral to other healthcare providers can also be done to establish relationships.

Immunizers

Lastly, by completing a certification course, licensed pharmacists in Michigan can become immunizers. Legal authority granting pharmacists the permission to vaccinate has been approved in 49 states. Again and again, pharmacists have been noted as one of the most accessible healthcare providers in the industry. At risk patients can be easily identified by their prescription drug history. Immunizing pharmacists are appealing to patients due to the trust they have in the profession, the convenience and the personalized service. Allowing pharmacists to immunize is just one more step to removing

as many barriers as possible for patients in need of vaccines. In Michigan, with the addition of physician-based standing orders, pharmacists are capable of immunizing patients without the need of a physician-generated prescription. For an example of a commonly used "Standing Order for Influenza," refer to Appendix D.

Influenza, Pneumonia and Shingles Zoster Basic Information

Influenza

Influenza-related illnesses cause more than 36,000 deaths each year. The pathogenesis of the disease is through the respiratory track. Viral shedding in the respiratory secretions occurs for five to 10 days following initial infection, with estimated incubation ranging from one to four days. Typical symptoms of influenza include: quick onset of fever, sore throat, myalgia, headache and nonproductive cough. The most prevalent complications associated with influenza infection include: pneumonia, Reyes Syndrome, myocarditis and death. With yearly variations in the influenza strain, the Advisory Committee on Immunization Practices (ACIP) recommends yearly vaccinations for the following individuals:

- Children six months to 18 years old
- All persons 50 years of age and older
- Women pregnant or expecting to be pregnant during the flu season
- People of any age with certain chronic medical conditions
- People who live in long-term care facilities or nursing homes
- Those who live with, or take care of, individuals at high risk for complications of influenza infection

The influenza vaccination is available in two forms: Inactivated for intramuscularly (IM) injection or live attenuated influenza vaccine (LAIV) for intranasal administration. The inactivated injection is available for all the above ACIP-recommended individuals, while the LAIV is approved for only nonpregnant, healthy individuals ages two to 49.

Pneumonia

The major clinical syndromes of pneumococcal disease are pneumonia, bacteremia and meningitis. Due to increased bacterial resistance, treatment of pneumococcal related syndromes is becoming increasingly difficult. Interestingly, Michigan is among the bottom 25 percent for state ratings regarding statewide pneumococcal vaccination rates. The map here illustrates the significance that a pharmacy based immunization service could provide.

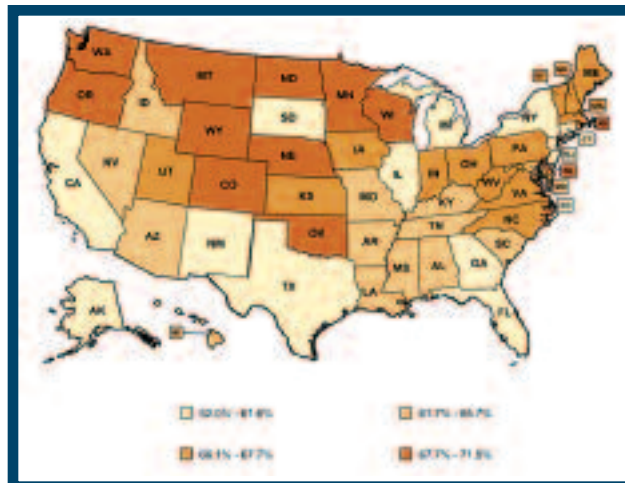


Image obtained from the Henry J Kaiser Foundation.

Vaccination with the Pneumococcal Polysaccharide Vaccination (PPSV) can prevent development of related illnesses year long. Vaccination is recommended for the following individuals:

- All persons 65 years or older (only one dose needed), unless a dose was given before 65 years of age, of which a second dosage is required five years after the first dose.
- Individuals with chronic illness who are two years or older. This includes: those with chronic lung disease (including asthma), cardiovascular or liver disease; diabetes; chronic alcoholism; chronic renal failure or nephritic syndrome; functional or anatomic asplenia; those who are immunocompromised; cochlear implants; cerebrospinal fluid leaks; and residents of nursing homes or long-term care facilities.
- Those, greater than 19 years of age, who smoke cigarettes are also included in the recommendation. Commercially-available PPSV can be given via the intramuscular or subcutaneous route.

Shingles Zoster

Herpes Zoster, or more commonly referred to as shingles, is a reactivation of the varicella zoster virus (VZV). The disease typically occurs with the vesicular eruption of zoster virus in patients with previous infection (childhood chicken pox). The reactivation occurs unilaterally in the distribution of a sensory nerve. Patients may complain of pain and paresthesia in the affected area two to four days prior to initial rash. Reactivation is closely linked with advancing age and immunosuppression. Complications of VZV include: postherpetic neuralgia (PHN), scarring, bacterial infections or ocular abnormalities. More than 40 percent of patients that develop VZV will also develop PHN,

which may last months to years. An estimated one million episodes of VZV occur every year in the U.S. Vaccination is recommended for all individuals 60 years of age and older with present contraindications (please refer to prescribing information). Commercially available varicella zoster virus vaccinations are given via the subcutaneous route.

Other Immunizing Opportunities

Several opportunities exist for the pharmacist to be involved in other unique immunization-related services

outside of the scope of this article. Possible services include child and teen vaccinations, international travel counseling and vaccinations and routine vaccinations including Hepatitis B, Human Papillomavirus (HPV) and many more.

For several years, pharmacy practitioners have been poised to capitalize on reimbursement-related cognitive services within the community and hospital setting. Despite readiness by many pharmacies, barriers proved to be present. These barriers have included pharmacy appropriate billing codes for services, along with lack of knowledge and understanding by pharmacists regarding reimbursement mechanisms.

The rest of this article will help to explain key information, including obtaining reimbursement for the three most "in demand" vaccinations at a retail pharmacy setting: influenza, pneumonia and herpes zoster. It is the writers' objective to convey the basics of vaccination services that can easily translate to any vaccination in demand within the outpatient setting.

Vaccine Reimbursement Options

As a pharmacy, billing a third party for immunization services can vary greatly from billing the average prescription drug. With immunizations, reimbursement for vaccine and administration must be considered. Vaccine administration is one component of pharmacy where pharmacists can receive compensation for the cognitive services provided.

Depending on the type of vaccine, there are two divisions of Medicare which may provide payment. The Medicare Part B program covers the majority of vaccines indicated for Medicare recipients. This includes Pneumococcal Pneumonia, Influenza Virus, Hepatitis B for people at high or intermediate risk, and

Vaccine	Reimbursement	Administration
Influenza	\$13.21	Locality 01 (Detroit) \$20.93
Pneumococcal	\$29.73	Locality 02 (rest of MI) \$18.48

other vaccines, such as Tetanus, when directly related to treatment of an injury or direct exposure. Part B will pay 100 percent of the approved amount for vaccine and administration. Copayment and deductibles do not apply. The following lists the reimbursement rate in Michigan for 2008-2009. Please note that the reimbursement for administration is the same for both vaccines, but the amount varies depending on the locality.

There are two steps required to become a Part B provider. First, it is necessary for the pharmacy or pharmacist to have a National Provider Identification (NPI) number. For many pharmacies, this step is already completed. If not, applications for NPI can be found at www.nppes.cms.hhs.gov/NPPES.

Secondly, enrollment as a Medicare Part B mass immunizer is necessary. There are two forms to choose from, depending on registration as an individual pharmacist or a pharmacy practice. The CMS 8551 form is required for individuals and the CMS 855B is required for group practices/clinics, including pharmacies. These forms may be found at www.cms.hhs.gov/cmsforms/downloads.cms855b.pdf. The approval process may take six to eight weeks. Once approved, vaccine claims can be billed by filling out a HCFA 1500 form, although electronic billing is encouraged. Only one claim submission is necessary for both vaccine and administration. Instructions for the HCFA 1500 form can be found at the CMS website.

If a patient has opted out of Medicare Part B and has enrolled in a Medicare Advantage plan, online billing is not currently available. To obtain reimbursement, a paper claim or a roster billing paper claim must be completed. There forms may be found on each individual Medicare Advantage plan website.

Roster billing is available for pneumococcal (PPV) and influenza virus vaccination programs. Properly licensed individuals and entities conducting mass immunization programs may submit multiple claims using a simplified claim filing procedure known as roster billing. The provider must accept assignment and cannot collect payment from the Medicare beneficiaries for these claims. There is no minimum beneficiary requirement, although the roster should not be used for single patients.

Centralized billing is also available to providers who enroll as a mass immunizer.

To qualify for centralized billing, a mass immunizer must be operating in at least three payment localities for which there are three different carriers processing claims. Centralized billers must roster bill, accept assignment and bill electronically. Providers interested in centralized billing must contact the CMS central office in writing by June 1 of the year they wish to begin billing. Requests should be mailed to:

**Centers for Medicare and Medicaid Services
Division of Practitioner Claims
and Processing
Provider Billing and Education Group
7500 Security Boulevard
Mail Stop C4-10-07
Baltimore, Maryland 21244**

As of January 2008, Medicare Part D covers all new vaccines, along with administration fees under its contracted prescription drug plan. Zostavax[®] for Herpes Zoster is the first example of this. Since physicians are no longer able to bill Part B for Part D covered vaccines, this is a great opportunity for pharmacists to provide their immunizing services. Currently for a Part D recipient, a nonpharmacy provider would need to bill the patient for vaccine and administration, and the patient would then be responsible for submitting the claim to Part D. As with Part B, only one claim is required for both vaccine and administration reimbursement. Deductibles and doughnut holes do apply to Part D covered vaccines. Since this program is fairly new, provisions and changes with billing are to be expected.

Another opportunity to expand immunization services is through private employers. A great example of this is an employer-sponsored flu clinic. The influenza virus thrives in the typical workplace and will infect one in four workers this season. An employee absent from work due to influenza is out approximately three to five days. It is estimated that \$9.4 billion is paid in sick leave due to the flu every year in the United States. This service is very appealing to employers, since it could potentially decrease absenteeism and increase productivity.

There are some cases where traditional prescription drug plans will cover the vaccine but not the administration fee at a pharmacy setting. This would allow the

pharmacist to administer the vaccine and electronically submit the claim. The insurance company would then reimburse the pharmacy directly for the vaccine only. Thus, it is up to the pharmacy to decide if an administration fee will be charged directly to the patient. Since most vaccines are quite costly, it is recommended that insurance benefits are verified before administration.

Many patients are willing to pay out-of-pocket for immunizations. This may be due to several circumstances: lack of insurance, high deductibles, health saving accounts or a claim not covered by insurance. Whatever the case may be, always discuss the cost and collect payment before administration. Afterward, provide the patient with an itemized receipt for the service. Depending on the individual's circumstance, this may be used for a health savings account or flexible spending account, may be applied towards a deductible or the patient may seek reimbursement from the insurance company independently.

Conclusion

Pharmacists are the most accessible healthcare providers in the United States and have the potential to increase immunization rates by acting as advocates, facilitators and immunizers. Through the outlined reimbursement channels described above, vaccinating existing patients can provide both a clinical service and financial revenue to any community or hospital pharmacy. Throughout Michigan, pharmacists in any clinical setting are in a key position to prevent and eliminate infectious disease without drastically increasing overall healthcare costs.

Affiliation and Financial Disclosures

Shannon Ferguson is an immunizing pharmacist and the community outreach advocate for Diplomat Specialty Pharmacy. No financial disclosures. H. Brent Hubble is an immunizing pharmacist and the manager of clinical programs and development for Diplomat Specialty Pharmacy. No financial disclosures. References available upon request to the MPA office.

APPENDICES

APPENDIX A: Immunization Capable Pharmacy Software Vendors

- Emdeon Business Services
www.emdeon.com
- eRx Network, L.L.C./Allwin Data
www.erxnetwork.com
- Freedom Data Services
www.freedomdataservices.com/products/dme_cl
- HCC
www.hcccare.com/products/dme_ezdme.htm
- OmniSYS, LLC
www.omnisis-inc.com
- QS/1
www.qs1.com/systemone_claims_clearing_house
- Speed Script
www.speedscript.com
- Health Business Systems, Inc.
www.sxc.com/provider.asp

APPENDIX D: Influenza Standing Orders obtained from www.immunize.org

APPENDIX B: Immunization Websites and Tools

Vaccine Information Statements (VIS)	www.immunize.org/vis/ www.cdc.gov/vaccines/pubs/vis/default.htm
Current Adult Immunization Schedule	www.cdc.gov/vaccines/recs/schedules/adult-schedule.htm
Immunization Schedule Summary	www.immunize.org/catg.d/p2011.pdf
Influenza Q&A	www.immunize.org/catg.d/p4208.pdf www.immunize.org/catg.d/p2013.pdf www.flumist.com/pdf/FluMist-prescribing-information.pdf
Administration Information	www.immunize.org/catg.d/p2020.pdf www.immunize.org/catg.d/p2020a.pdf www.immunize.org/catg.d/p3085.pdf www.immunize.org/catg.d/p3084.pdf
Vaccination Storage	www.cdc.gov/vaccines/pubs/vac-mgt-book.htm www.immunize.org/catg.d/p3036.pdf www.immunize.org/catg.d/p3048.pdf www.immunize.org/catg.d/p3049.pdf
ADE and Emergency Information	www.immunize.org/catg.d/p3082.pdf
Vaccine Forms, Logs and Checklists	www.immunize.org
Medicare Form 855b Application	www.cms.hhs.gov/cmsforms/downloads/cms855b.pdf
CMS Form 1500 Application	www.cms.hhs.gov/cmsforms/downloads/cms1500805.pdf

Standing Orders for Administering Influenza Vaccine to Adults

Purpose: To reduce morbidity and mortality from influenza by vaccinating all adults who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices.

Policy: Under these standing orders, eligible nurses and other healthcare professionals (e.g., pharmacists), where allowed by state law, may vaccinate patients who meet any of the criteria below.

Procedure:

1. Identify adults in need of influenza vaccination based on meeting any of the following criteria:
 - a. Want to reduce the likelihood of becoming ill with influenza or of transmitting it to others
 - b. Age 50 years or older
 - c. Having any of the following conditions:
 - Chronic disorder of the pulmonary or cardiovascular system, including asthma
 - Chronic metabolic disease (e.g., diabetes), renal dysfunction, hemoglobinopathy, or immunosuppression (e.g., caused by medications, HIV)
 - Any condition that compromises respiratory function or the handling of respiratory secretions or that can increase the risk of aspiration (e.g., cognitive dysfunction, spinal cord injury, seizure disorder or other neuromuscular disorder)
 - d. Being pregnant during the influenza season
 - e. Residence in a nursing home or other chronic-care facility that houses persons of any age who have chronic medical conditions
 - f. In an occupation or living situation that puts one in proximity to persons at high risk, including:
 - A healthcare worker, caregiver, or household member in contact with person(s) at high risk of developing complications from influenza
 - A household contact or out-of-home caretaker of a child age 0-59 months or of an adult age 50 years or older
2. Screen all patients for contraindications and precautions to influenza vaccine:
 - a. Contraindications: serious reaction (e.g., anaphylaxis) after ingesting eggs or after receiving a previous dose of influenza vaccine or an influenza vaccine component. For a list of vaccine components, go to www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/B/excipient-table-2.pdf. Do not give live attenuated influenza vaccine (LAIV) to an adult who is pregnant or who has any of the conditions described in 1.b. or 1.c.

above. Use of inactivated influenza vaccine is preferred over LAIV for close contacts of severely immunosuppressed persons during periods when the immunocompromised person requires a protective environment.

- b. Precautions: moderate or severe acute illness with or without fever; history of Guillain Barré syndrome within 6 weeks of a previous influenza vaccination.
3. Provide all patients with a copy of the most current federal Vaccine Information Statement (VIS). You must document in the patient's medical record or office log, the publication date of the VIS and the date it was given to the patient. Provide non-English speaking patients with a copy of the BIS in their native language, if available; these can be found at www.immunize.org/vis.
4. Administer 0.5 mL of injectable trivalent inactivated influenza vaccine (TIV) IM (22-25g, 1-1½" needle) in the deltoid muscle. Alternatively, healthy adults younger than age 50 years without contraindications may be give 0.2 mL of intranasal LAIV; 0.1 mL is sprayed into each nostril while the patient is in an upright position.
5. Document each patient's vaccine administration information and follow up in the following places:
 - a. Medical chart: Record the date the vaccine was administered, the manufacturer and lot number, the vaccination site and route, and the name and title of the person administering the vaccine. If vaccine was not given, record the reason(s) for non-receipt of the vaccine (e.g., medical contraindication, patient refusal).
 - b. Personal Immunization record card: Record the date of vaccination and the name/location of the administering clinic.
6. Be prepared for management of a medical emergency related to the administration of vaccine by having a written emergency medical protocol available, as well as equipment and medications.
7. Report all adverse reactions to influenza vaccine to the federal Vaccine Adverse Event Reporting System (VAERS) at www.vaers.hhs.gov or (800) 882-7967. VAERS report forms are available at www.vaers.hhs.gov. This policy and procedure shall remain in effect for all patients of the _____ (name of practice or clinic) until rescinded or until _____ (date).

Medical Director's signature: _____ Effective date: _____
 Information from the Immunization Action Coalition, 1573 Selby Ave., St. Paul, MN 55104, (651) 647-9009, www.immunize.org, www.vaccineinformation.org

Continuing Education Self-Assessment Questions

- What was the first conceptualized and administered vaccination?
 - Herpes Zoster Vaccination
 - Influenza Vaccination
 - Smallpox Vaccination
 - Pneumonia Vaccination
- Pharmacists can become involved in vaccinations in what three ways?
 - Enforcers, Billers, Immunizers
 - Advocates, Assessors, Administrators
 - Advocates, Facilitators, Immunizers
 - None of the Above
- Pharmacists have legal authority to immunize in ___ out of 50 States in the U.S.?
 - 50
 - 49
 - 48
 - 47
- In order for a pharmacy practice to bill Medicare Part B, what form must be completed?
 - CMS 855B
 - OmniSYS provider agreement
 - DEA 106
 - CMS 8551
- Medicare Part B will pay which of the following fees to enrolled mass immunizers?
 - Influenza vaccine and administration
 - Pneumococcal vaccine
 - Pneumococcal administration
 - All of the above
- Which of the following is true regarding Zostavax®?
 - Physicians can bill Part D for the vaccine and administration, but choose not to stock due to storage limitations.
 - Deductibles and doughnut holes do apply under Part D.
 - Zostavax® is indicated for those 50 and older.
 - Pharmacies are only reimbursed for the vaccine under Part D.
- A pharmacy has the right to charge a Medicare patient out-of-pocket for the influenza vaccine.
 - True
 - False
- Which of the following is a great resource for virtually all immunization related forms, logs, checklists (based on Appendix B)?
 - www.quackwatch.com
 - www.immunize.org
 - www.turboimmunize.org
 - www.vaccinenow.com
- _____ is the leading cause of a vaccine preventable death in the United States
 - RSV
 - Shingles Zoster
 - Pneumonia
 - Influenza
- As of 2008, _____ covers all new vaccines along with administration fees under its contracted prescription drug plan.
 - Medicare Part A
 - Medicare Part B
 - Medicare Part C
 - Medicare Part D

Getting Involved: A Look at Pharmacist Administered Immunizations

March 2009 Enrollment Form
ACPE No. 112-000-09-001-L01-P
PTCE No. 112-000-09-975-L01-T

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Address _____ City _____ State _____ Zip _____

Signature _____

I enclose: Member Fee.....\$6 Nonmember Fee....\$12

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1. What is your evaluation of the article you read?
Poor 1 2 3 4 5 Excellent

2. The author's coverage of the subject material was:
Incomplete 1 2 3 4 5 Complete

3. How useful will the content of this article be in your practice?
Not at all 1 2 3 4 5 Very

4. To what degree did the article meet the stated objectives?
Not at all 1 2 3 4 5 Completely

It took me _____ hour(s) and _____ minute(s) to read this article and complete the questions.

What other topics would you like to see presented in MPA's home study articles? _____

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- _____
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