Creating an Immunization Niche in the Community Pharmacy

Module 2: Reimbursement and Practice Tools

Jonathan G. Marquess, PharmD, CDE, CDM

Learning Objectives

• Identify and describe payers for vaccination services
• Complete Medicare Form 855B to bill Medicare
• Discuss forms, codes and documentation for billing Medicare and other payers
• Outline legal considerations and common causes of litigation
• Describe an example of in-store vaccine protocols
• Discuss storage requirements, storage monitoring, equipment and training needs for the immunization niche
Pre-Assessment Question #1

The pharmacy can charge less to cash paying customers than a Medicare recipient for getting their flu or pneumonia shot.

• A. True
• B. False
Correct Answer

The pharmacy can charge less to cash paying customers than a Medicare recipient for getting their flu or pneumonia shot.

• B. False

Pre-Assessment Question #2

Following routine vaccinations patients should be observed in the pharmacy for :

• A. Observation is not necessary on routine vaccinations
• B. 5 minutes
• C. 15-20 minutes
• D. 1 hour
Correct Answer

Following routine vaccinations patients should be observed in the pharmacy for:

• C. 15-20 minutes

Pre-Assessment Question #3

Most vaccines will store at room temperature for 12-18 months

• A. True
• B. False
Correct Answer

Most vaccines will store at room temperature for 12-18 months

• B. False

Introduction
Immunization Reimbursement

Who Do You Bill?
Identify Potential Payers
Billing Medicare

• Your most dependable source of reimbursement is **Medicare Part B**
• Pharmacists can receive compensation for immunizations according to state laws and regulations
Medicare Reimbursement

- Amount varies by state
- Must accept Medicare reimbursement in full
- Roster billing accepted (preferred) for more than 5 immunizations
- No deductible, no co-pay on flu and pneumonia

Steps to Bill Medicare

1. Apply to become a mass immunizer
2. After 6-8 weeks, you are able to bill Medicare
3. Use CMS 1500 Form or electronic billing company to submit claims for vaccine and administration
4. Send completed claim to the Medicare DMERC for reimbursement
Medicare Billing Forms

CMS 855B Form

Medicare Form 855b

WHO SHOULD SUBMIT THIS APPLICATION

The following suppliers must complete this application to initiate the enrollment process:

- Ambulance Service Supplier
- Ambulatory Surgical Center
- Clinic/Group Practice
- Competitive Acquisition Program (CAP)
- Part B Drug Vendor
- Independent Clinical Laboratory
- Independent Diagnostic Testing Facility (IDTF)

If your supplier type is not listed above, contact your designated fee-for-service contractor before you submit this application.
Medicare Form 855b (Section 1, page 3)

SECTION 1: BASIC INFORMATION
ALL APPLICANTS MUST COMPLETE THIS SECTION (See instructions for details.)

A. Check one box and complete the required sections.

<table>
<thead>
<tr>
<th>REASON FOR APPLICATION</th>
<th>BILLING NUMBER INFORMATION</th>
<th>REQUIRED SECTIONS</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐ You are a new enrollee in Medicare</td>
<td>Enter your Medicare Identification Number (if issued) and the NPI you would like to link to this number in Section 4.</td>
<td>Complete all sections</td>
</tr>
<tr>
<td>☐ You are enrolling in another fee-for-service contractor’s jurisdiction</td>
<td>Enter your Medicare Identification Number (if issued) and the NPI you would like to link to this number in Section 4.</td>
<td>Complete all sections</td>
</tr>
</tbody>
</table>

Medicare Form 855b (Section 2, page 7)

SECTION 2: IDENTIFYING INFORMATION

A. TYPE OF SUPPLIER
Check the appropriate box to identify the type of supplier you are enrolling as with Medicare. If you are more than one type of supplier, submit a separate application for each type. If you change the type of service that you provide (i.e., become a different supplier type), submit a new application.

Your organization must meet all Federal and State requirements for the type of supplier checked below. If you are a single specialty clinic/group practice, the specialty must be reported.

TYPE OF SUPPLIER (check one only)
- Ambulance Service Supplier
- Ambulatory Surgical Center
- Clinic/Group Practice
  - Single Specialty Clinic
  - Multi-Specialty Clinic
- Hospital Department(s)
  - Emergency Care
  - Rehabilitation
- Public Health/Welfare Agency
- Physical/Occupational Therapy Group in Private Practice
- Rehabilitation/Physician Assistant Program
- Competitive Acquisition Program (CAP) Part B Drug Vendor
- Independent Clinical Laboratory
- Independent Diagnostic Testing Facility
- Independent Radiation Therapy Center
- Independent Pharmacy
- Portable X-ray Supplier
- Slide Preparation Facility
- Other (Specify):__________

Mass Immunization (Roster Biller Only)
Medicare Form 855b
(Section 2b, page 8)

SECTION 2: IDENTIFYING INFORMATION (Continued)

2. STATE LICENSE INFORMATION/CERTIFICATION INFORMATION
Provide the following information if the supplier has a State license/certification to operate as the supplier type for which you are enrolling.

State License Information
☐ License Not Applicable

<table>
<thead>
<tr>
<th>License Number</th>
<th>State Where Issued</th>
</tr>
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<tbody>
<tr>
<td></td>
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</tbody>
</table>

Effective Date (mm/dd/yyyy) | Expiration/Renewal Date (mm/dd/yyyy)

Certification Information
☐ Certification Not Applicable

<table>
<thead>
<tr>
<th>Certification Number</th>
<th>State Where Issued</th>
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</tr>
</tbody>
</table>

Effective Date (mm/dd/yyyy) | Expiration/Renewal Date (mm/dd/yyyy)

Medicare Form 855b
(Section 3, page 11)

SECTION 3: ADVERSE LEGAL ACTIONS/CONVICTIONS (Continued)

ADVERSE LEGAL HISTORY

1. Has your organization, under any current or former name or business identity, ever had an adverse legal action listed on page 11 of this application imposed against it?

☐ YES—Continue Below  ☐ NO—Skip to Section 4

2. If yes, report each adverse legal action, when it occurred, the Federal or State agency or the court/administrative body that imposed the action, and the resolution, if any. Attach a copy of the adverse legal action documentation and resolution.

<table>
<thead>
<tr>
<th>Adverse Legal Action</th>
<th>Date</th>
<th>Taken By</th>
<th>Resolution</th>
</tr>
</thead>
<tbody>
<tr>
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</tbody>
</table>
Medicare Form 855b (Section 4, page 13)

SECTION 4: PRACTICE LOCATION INFORMATION (Continued)

A. PRACTICE LOCATION INFORMATION

If you see patients in more than one practice location, copy and complete Section 4A for each location. To ensure that CMS establishes the correct association between your Medicare legacy number and your NPI, providers and suppliers must list a Medicare legacy number—NPI combination for each practice location. If you have multiple NPIs associated with both a single legacy number and a single practice location, please list below all NPIs and associated legacy numbers for that practice location. If you are changing, adding, or deleting information, check the applicable box, furnish the effective date, and complete the appropriate fields in this section.

<table>
<thead>
<tr>
<th>CHECK ONE</th>
<th>CHANGE</th>
<th>ADD</th>
<th>DELETE</th>
</tr>
</thead>
<tbody>
<tr>
<td>DATE (mm/dd/yyyy)</td>
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<td></td>
</tr>
</tbody>
</table>

Medicare Form 855b (Section 5, page 20)

SECTION 5: OWNERSHIP INTEREST AND/OR MANAGING CONTROL INFORMATION (ORGANIZATIONS)

NOTE: ONLY REPORT ORGANIZATIONS IN THIS SECTION. INDIVIDUALS MUST BE REPORTED IN SECTION 6.

Complete this section with information about all organizations that have 5 percent or more (direct or indirect) ownership interest in, any partnership interest in, and/or managing control of, the supplier identified in Section 2, as well as information on any adverse legal actions that have been imposed against that organization. For examples of organizations that should be reported here, visit our Web site: www.cms.hhs.gov/MedicareProviderSupEnroll. If there is more than one organization that should be reported, copy and complete this section for each.

MANAGING CONTROL (ORGANIZATIONS)

Any organization that exercises operational or managerial control over the supplier, or conducts the day-to-day operations of the supplier, is a managing organization and must be reported. The organization need not have an ownership interest in the supplier in order to qualify as a managing organization. For instance, it could be a management services organization under contract with the supplier to furnish management services for the business.
Medicare Form 855b
(Section 6, page 23)

SECTION 6: OWNERSHIP INTEREST AND/OR MANAGING CONTROL INFORMATION (INDIVIDUALS) (continued)

Any information on adverse legal actions that have been imposed against the individuals reported in this section must be furnished. If there is more than one individual, copy and complete this section for each individual.

A. INDIVIDUALS WITH OWNERSHIP INTEREST AND/OR MANAGING CONTROL — IDENTIFICATION INFORMATION

If you are changing, adding, or deleting information, check the applicable box, furnish the effective date, and complete the appropriate fields in this section. The name, date of birth, and social security number of each person listed in this section must coincide with the individual's information as listed with the Social Security Administration.

<table>
<thead>
<tr>
<th>CHECK ONE</th>
<th>CHANGE</th>
<th>ADD</th>
<th>DELETE</th>
</tr>
</thead>
<tbody>
<tr>
<td>DATE (mm/dd/yyyy)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

1. First Name | Middle Initial | Last Name | Jr., Sr., etc.
Social Security Number (Required) | Date of Birth (mm/dd/yyyy) | Medicare Identification Number (if issued) | NPI (if issued)

2. What is the above individual’s relationship with the supplier in Section 281? (Check all that apply.)

Medicare Form 855b
(Section 8, page 25)

SECTION 8: BILLING AGENCY INFORMATION

A billing agency is a company or individual that you contract with to prepare and submit your claims. If you use a billing agency, you are responsible for the claims submitted on your behalf.

☐ Check here if this section does not apply and skip to Section 13.

BILLING AGENCY NAME AND ADDRESS

If you are changing, adding, or deleting information, check the applicable box, furnish the effective date, and complete the appropriate fields in this section.

<table>
<thead>
<tr>
<th>CHECK ONE</th>
<th>CHANGE</th>
<th>ADD</th>
<th>DELETE</th>
</tr>
</thead>
<tbody>
<tr>
<td>DATE (mm/dd/yyyy)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Medicare Form 855b Tips

1. Submit 2006 version of Form 855b
2. Submit correct application – immunization roster biller
3. Submit complete application
4. Request and obtain national provider identifier (NPI)
5. Submit EFT authorization agreement
6. Submit all supporting documentation
7. Sign and date the application
8. Respond to fee-for-service contractor requests promptly and fully

SECTION 17: SUPPORTING DOCUMENTS

This section lists the documents that, if applicable, must be submitted with this enrollment application. If you are newly enrolling, or are reactivating or revalidating your enrollment, you must provide all applicable documents. For changes, only submit documents that are applicable to that change. You may submit a notarized Certificate of Good Standing from your State licensing/certification board or other medical associations in lieu of copies of business licenses, certifications, and/or registrations as required in your State. This certification cannot be more than 30 days old.

The fee-for-service contractor may request, at any time during the enrollment process, documentation to support or validate information reported on the application.

MANDATORY FOR ALL PROVIDER/SUPPLIER TYPES

- Licenses, certifications and registrations required by Medicare or State law.
- Federal, State, and/or local (city/county) business licenses, certifications and/or registrations required to operate a health care facility.
- Written confirmation from the IRS confirming your Tax Identification Number with the Legal Business Name (e.g., IRS CP 575) provided in Section 2.
- Completed Form CMS-588, Authorization Agreement for Electronic Funds Transfer. Note: If a supplier already receives payments electronically and is not making a change to its banking information, the CMS-588 is not required.
Information Needed to Complete CMS 1500

- Patient’s medical insurance information
- ICD-10 code(s)
- CPT code
- NPI
Influenza Coverage Under Medicare

- Medicare pays for **one influenza immunization each influenza season** for all beneficiaries
- Separate rates for the administration and cost of the influenza vaccine
- Cost reimbursement rate is $13.22

Pneumococcal Coverage Under Medicare

- Medicare pays for **pneumococcal vaccination for all beneficiaries**
- Medicare will also pay for the booster vaccination for high risk persons if 5 years have passed since their last vaccination
- Separate rates for the administration and cost of the pneumococcal vaccine
- Cost reimbursement rate is $29.73
Medicare Reimbursement

<table>
<thead>
<tr>
<th>Description</th>
<th>Diag. Code</th>
<th>CPT, HCPCS</th>
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</thead>
<tbody>
<tr>
<td>Influenza vaccine</td>
<td>V04.8</td>
<td>90657, G0008</td>
</tr>
<tr>
<td>-children 6-35 mo</td>
<td>V04.8</td>
<td>90658, G0008</td>
</tr>
<tr>
<td>-split, &gt; 3 y/o</td>
<td>V04.8</td>
<td>90659, G0008</td>
</tr>
<tr>
<td>-whole, &gt; 3 y/o</td>
<td>V04.8</td>
<td></td>
</tr>
<tr>
<td>Pnuemococcal vaccine</td>
<td>V03.82</td>
<td>90732, G0009</td>
</tr>
<tr>
<td>Hepatitis B vaccine</td>
<td>V05.3</td>
<td>90746, G0010</td>
</tr>
</tbody>
</table>

Place of service code = 60;  specialty code = 87

Completing the CMS 1500

• Fields 1-11
  – Patient and insured’s information
• Field 12: Patient’s or Authorized Representative’s Signature
  – Authorizes provider to collect or release medical info to file claim
  – Can use “signature on file”
• Field 13: Assignment of Benefits
  – Patient authorizes payment for services
  – Can use “signature on file”
Completing the CMS 1500

• Field 14: Date of Current Illness
  – Enter date of service
• Fields 15, 16, 18, 19, 20, 22
  – Leave blank
• Field 17, 17a: Name & ID of Referring Physician
  – Enter MD and UPIN/NPI if patient was referred

Completing the CMS 1500

• Field 21: Diagnosis or Nature of Illness
  – Enter ICD-10 code from MD
• Field 23: Prior Authorization Number
  – Enter prior authorization number if required by payer
• Field 24A: Dates of Services
  – List actual dates of service
• Field 24B: Place of Service
  – Location where service performed
  – Use 01 (pharmacy) unless providing at a different site
Completing the CMS 1500

• Field 24C: Type of Service
  – Many payers do not require – check with payer

• Field 24D: Procedures, Services, or Supplies
  – CPT / HCPCS codes & modifier

• Field 24E: Diagnosis Code
  – Common source of error
  – Enter reference # (1,2,3 or 4) from field 21
  – NOT ICD-10 code

Completing the CMS 1500

• Field 24F: $ Charges
  – List charge for service being billed

• Field 24G: Days or Units
  – When billing multiple days of service, indicate total days
  – If only one service, enter “1”
Completing the CMS 1500

- Fields 25 – 33
  - Self-explanatory
  - Field 33b
    - Enter your NPI
Medicare Billing Reimbursement

- Individual billings
- “Roster” billings
- Centralized billings

<table>
<thead>
<tr>
<th>Provider Name</th>
<th>Provider Number</th>
<th>Date of Service</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient’s Health Insurance Number</td>
<td>Patient’s Name</td>
<td>M/F</td>
</tr>
<tr>
<td>Last</td>
<td>First</td>
<td>MI</td>
</tr>
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<td></td>
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</table>
### PNEUMOCOCCAL PNEUMONIA VACCINE ROSTER

<table>
<thead>
<tr>
<th>Region</th>
<th>Insurance Company</th>
<th>Region Coverage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Region A</td>
<td>NHIC</td>
<td>CT, DE, ME, MA, NY, NH, NJ, PA, RI, VT</td>
</tr>
<tr>
<td></td>
<td><a href="http://www.medicarenhic.com">www.medicarenhic.com</a></td>
<td>866-419-9458</td>
</tr>
<tr>
<td>Region B</td>
<td>AdminaStar Federal Inc.</td>
<td>DC, IL, IN, MD, MI, MN, OH, VA, WV, WI</td>
</tr>
<tr>
<td></td>
<td><a href="http://www.adminastar.com">www.adminastar.com</a></td>
<td>877-299-7900</td>
</tr>
<tr>
<td>Region C</td>
<td>Palmetto GBA</td>
<td>AL, AR, CO, FL, GA, KY, LA, MS, NM, NC, OK, PR, SC, TN, TX, Virgin Islands</td>
</tr>
<tr>
<td></td>
<td><a href="http://www.pgba.com">www.pgba.com</a></td>
<td>866-238-9650</td>
</tr>
<tr>
<td>Region D</td>
<td>Noridian Medicare</td>
<td>AK, AZ, CA, Guam/American Samoa, HI, ID, IA, KS, Marianna Islands, MO, MN, NE, NV, ND, OR, SD, UT, WA, WY</td>
</tr>
<tr>
<td></td>
<td><a href="http://www.noridianmedicare.com">www.noridianmedicare.com</a></td>
<td>866-243-7272</td>
</tr>
</tbody>
</table>

**WARNING:**

- Ask beneficiaries if they have been vaccinated with PPV.
- Rely on patient's memory to determine prior vaccination status.
- If patients are uncertain whether they have been vaccinated within the past 5 years, administer the vaccine.
- If patients are certain that they have been vaccinated within the past 5 years, do not vaccinate.
Medicare Billing Documentation

• Documentation is critical for any reimbursement program
• Medicare has strict guidelines and the time you spend to familiarize yourself and your staff will be time well spent

Electronic Part B Billing

• Electronic billing is faster, fewer errors
• Many options
  – Contact software vendor
Medicare Part D

• As of January 2008, all vaccinations not included in Medicare B coverage should be covered under Medicare Part D
• If your pharmacy has contracts with Part D plans, you should be able to bill via the prescription claims processing systems for both the vaccine and the administration and receive reimbursement

Sample Medicare Part D Billing

• Preferred approach is a **combination claim** on a prescription billing claim (NCPDP 5.1)
• Here are a few examples on how to achieve this result
  1. Your pharmacy dispenses and administers a Part D covered vaccine
  2. Your pharmacy dispenses a Part D vaccine to an out-of-network provider who then administers the vaccine
  3. Your pharmacy dispenses a Part D vaccine to the beneficiary. The beneficiary takes the vaccine to his/her out-of-network provider who then administers the vaccine
Medicare Part D MA-PDs

• Medicare Advantage (MA-PDs) are Medicare managed care plans – comprehensive health coverage
• Participation with MA-PD plans to offer their immunizations
  – Contact your local MA-PD plans and set up a meeting to discuss your thoughts and ideas

Billing Third Parties

• Many prescription plans provide for immunization coverage
• Commonly reimbursement allows the pharmacist to administer the vaccine by physician’s standing order or new prescription and electronically submit a claim
• Insurance company reimburses the pharmacist, patient not involved in reimbursement
• Reimbursement for vaccine NOT administration
• Charge the patient a separate fee for pharmacist care
Patient Self Pay

- No Insurance
- Insurance with a higher co-pay than the charge for service
- Flexible Spending or Health Savings

Important note: Medicare regulations prohibit charging Medicare more than you charge your self-pay patients

Employer Groups

- Taking the vaccination program outside the four walls of the pharmacy
  - Generally lump sum billing
  - Employer bills insurance
  - Reduced paper work for pharmacy
Reimbursement Help

• Consider using leading vaccine manufacturers for reimbursement assistance questions
  – Offer free advice on billing options and provide up-to-date billing codes

Interactive Checkpoint

• When completing the Medicare 855b form, it is vital that you complete the application with what NPI number?

A. Pharmacist NPI
B. Pharmacy NPI
Interactive Checkpoint

• Pharmacy NPI
  – When apply as a mass immunizer, it is recommended that you include your pharmacy NPI, not your pharmacist NPI
  – This ensures that all reimbursements are attributable to your store, not your personal income

Legal Considerations
Legal Considerations

• Legal issues vary state by state and are very complex in nature
• Be aware of your state requirements and make sure you have adequate liability insurance
• Ensure that insurance covers professional acts of the pharmacist and drug administration

Most Common Causes of Litigation

• Negligence
• Failure to Warn
Best Way to Avoid Legal Problems

1. Receive specialized training
2. Act prudently within your scope of practice
3. Mimic local standards and safeguards
4. Inform patients of risks and benefits

5. Always distribute Vaccine Information Statements (available @ www.cdc.gov)
6. Ask patient to remain in store for at least 15-20 minutes after immunization
7. Have a checklist for entire procedure and require patient to sign
8. Have proper staff training
9. Keep accurate records
Special Considerations for Pharmacy Owners

• If a pharmacist owner is working as an employee in a pharmacy, consider purchasing an individual liability policy for added protection, especially if they are involved in a vaccination program

Legal Considerations - OSHA

• OSHA Requirements
  – Blood-borne pathogen control plan
  – Sharps containers
  – Hepatitis vaccination requirements
  www.osha.gov
OSHA - Exposure Control Plan

• Employers must have a bloodborne pathogen control plan
• Sample control plan can be found here: http://www.osha.gov/Publications/osha3186.pdf

OSHA - Hepatitis B Requirement

• Employers must offer hepatitis B vaccination free of charge to employees
• Employees can decline but must sign a declination statement (available in toolkit)
Interactive Checkpoint

• Does a physician’s liability encompass the pharmacist scope of practice during immunizations?

A. Yes
B. No

Interactive Checkpoint

• No!
  – A physician’s liability does not encompass a pharmacist’s scope of practice
  – Consequently, their liability insurance will not go up as a result of partnering with your pharmacy.
Resources Needed to Start an Immunization Program

What Do I Need to Get Started in Immunization?

- Space and workflow modifications
- Vaccine supplier
- Equipment/storage
- Supplies
- Disposal
- Practice agreements
- Training
- Immunization records
Workflow Modifications/
Vaccine Supplier

Workflow Modifications

• Not much space is required
  – Small, private area for administration
• Incorporate vaccines into standard prescription workflow
Vaccine Supply Issues

• Some people have thought that if you were a small purchaser, you automatically go back to the end of the line of the distributors. That's not the case. They have a fair process for making decisions about who gets vaccine when. But if it's not coming out of the factory they can't distribute it. And that's just one of those things that until we have an even more robust supply we'll always have this mismatch during the early part of the season."

--DR. JULIE GERBERDING, Director of the Centers for Disease Control and Prevention (Oct. 4, NFID Press Conference)

Vaccine Supplier

• Three ways to obtain vaccines for the community pharmacy
  – Wholesaler
  – Vaccine Distributor
  – Direct from manufacturer
Wholesaler Pros and Cons

• Easy
• Quick delivery
• Availability may be limited by manufacturer programs

Vaccine Distributor Pros and Cons

• Examples include: FFF Enterprises, VaxServe
• Good for hard-to-get or late in season vaccines
• Price and billing advantages
• Hard to establish a relationship
Manufacturer Pros and Cons

• Special programs
• Marketing material
• Shorter payment window

Influenza Vaccine Availability Tracking System (IVATS)

• http://www.preventinfluenza.org/ivats/
• The purpose of IVATS is to enable health care providers to find influenza vaccine to purchase, especially during the critical vaccination period
### Storage/Handling

<table>
<thead>
<tr>
<th>Company</th>
<th>Fax</th>
<th>Email</th>
<th>Contact Person</th>
<th>Phone</th>
</tr>
</thead>
<tbody>
<tr>
<td>ARI Pharmaceuticals</td>
<td>(555) 123-4567</td>
<td><a href="mailto:sales@ari.com">sales@ari.com</a></td>
<td>Sally Smith</td>
<td>(555) 123-4568</td>
</tr>
<tr>
<td>ABC Healthcare</td>
<td>(555) 234-5678</td>
<td><a href="mailto:info@abc.com">info@abc.com</a></td>
<td>John Doe</td>
<td>(555) 234-5679</td>
</tr>
<tr>
<td>XYZ Biotech</td>
<td>(555) 345-6789</td>
<td><a href="mailto:support@xyz.com">support@xyz.com</a></td>
<td>Jane Jones</td>
<td>(555) 345-6790</td>
</tr>
</tbody>
</table>

For example, product availability status for vaccines or other products can be included in the table above.
Equipment/Storage

• Vaccines are fragile and must be kept at recommended temperatures at all times
• Vaccines are expensive
• It is better to NOT VACCINATE than to administer a dose of vaccine that has been mishandled

Vaccine Storage & Handling

• Apparent vs. inapparent damage
• Is the drug working?
  -Furosemide - urine output
  -Albuterol - respiration
  -Vaccines - NOT obvious!
Is the Vaccine Working?

• DTaP  Baby cries
• OPV    Baby swallows
• Influenza Patient winces

• Same reactions whether vaccine is fresh and potent or degraded by extreme temperature
• But mishandled vaccines won’t protect

Key Storage Principles

• Keep your refrigerator at proper temperature
  – Use signs, charts, logs, thermometers, and thermal buffers
• Keep your vaccines cold
  – Refrigerate right after receipt
  – Consider cooling trays
• Check expiration dates
  – Rotate stock
  – Don’t use expired vaccine
• Discourage pre-filling syringes, for identity, sterility, and stability reasons
• Protect MMR from light
• Keep OPV and varicella vaccines frozen
The Effect of "Thermotrauma" on Vaccines

- Live vaccines
  - Tolerate freezing
  - Live viruses deteriorate rapidly after removal from refrigeration
- Inactivated vaccines
  - Inactivated by freezing
  - Tolerate short times out of refrigeration

Vaccine Storage Requirements

- Maintain required temperature range year-round
- Large enough to hold year’s largest inventory
- Dedicated to biologics
Refrigerator

• A refrigerator is required for most vaccines
• Maintain refrigerator temperature at 35–46°F (2–8°C) or colder

Freezer

• A freezer is required for the following vaccinations
  – MMR
  – Varicella
  – Zoster
• Maintain freezer temperature at 5°F (-15°C) or colder
Vaccine Storage Requirements

Tips for Storage

- Refrigerate or freeze immediately upon receiving shipment
- Do not store vaccine in the door of the refrigerator or freezer
- Inactivated vaccines should always be placed in the middle of the refrigerator
- Always use the vaccine with the earliest expiration date first
Temperature Log

- Pharmacy should keep a temperature log to ensure stable refrigeration temperature
- Place thermometer inside refrigeration unit and record temperature regularly
## Temperature Monitoring

### Protect Your Vaccines: Check Temperatures Twice a Day!

**Mo./Yr.:** __________  
**Days 1–15**

**Instructions:** Place an "X" in the box that corresponds with the temperature. The boxed zones represent acceptable temperature ranges. If the temperature recorded is in the boxed zone, 1. Store the vaccines under proper conditions as quickly as possible. 2. Call the vaccine manufacturer to determine whether the primary of the vaccine(s) has been affected. 3. Call the immunization program at your local health department for further assistance.

4. Document the action taken on the reverse side of this log.

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| Free Zones   |   |   |   |   |   |   |   |   |   |    |    |    |    |    |    |

Adapted by the Immunization Action Coalition courtesy of the Michigan Department of Community Health

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Temperature Monitoring

### Protect Your Vaccines: Check Temperatures Twice a Day!

**Mo./Yr.:** __________  
**Days 1–15**

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Adapted by the Immunization Action Coalition courtesy of the Michigan Department of Community Health

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Temperature Monitoring

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46
### Temperature Monitoring

#### Protect Your Vaccines: Check Temperatures Twice a Day!

**Instructions:** Place an "X" in the box that corresponds with the temperature. The hatched zones represent acceptable temperature ranges. If the temperature recorded is in the hatched zone: 1. Store the vaccines under proper conditions as quickly as possible. 2. Call the vaccine manufacturer to determine whether the potency of the vaccine(s) has been affected. 3. Call your local health department for further assistance.

**Days 1–15**

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**Immediate Action:**

1. Document the action taken on the reverse side of this log.

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**Adapted from the Immunization Action Coalition courtesy of the Michigan Department of Community Health**

[Immunization Action Coalition](https://www.immunize.org) - [admin@immunize.org](mailto:admin@immunize.org)
Certified Calibrated Thermometers

Certified Calibrated Thermometers

[Image of a calibration certificate]
Thermometer Placement

Refrigerator

Freezer

Preventive Measures

• Use a plug guard or safety-lock plug
• Post a warning sign at the plug and on the refrigerator
• Label fuses and circuit breakers
• Install a temperature alarm

WARNING
Do not unplug the refrigerator/freezer or break circuit.
Expensive vaccine in storage.
In event of electrical problem, immediately contact:
Tips for Stabilizing Temperature

• Store ice packs in the freezer and large jugs of water in the refrigerator along with the vaccine
• Do not store food or beverages in the refrigerator or freezer
• Make sure the refrigerator is plugged into an outlet in a protected area where it cannot be disconnected accidentally
• Mark plugs and circuit breakers

Vaccine Shipments

• Examine shipment on arrival
• Check contents against packing slip
• Check vaccine expiration dates
• Examine contents for damage
• Ensure shipping time <48 hours
Vaccine Storage After Opening or Reconstitution

• Multidose vials
  – Contain a bacteriostatic agent
  – Can be used until the expiration date unless contaminated
Vaccine Storage After Opening or Reconstitution

• Single dose vials
  – Do NOT contain a bacteriostatic agent
  – Once opened use or discard at the end of the clinic day

• Reconstituted vials
  – Consult package insert for life of vaccine once reconstituted

Pre-filling Syringes

• Pre-filling is generally not recommended
• May result in vaccine administration errors, vaccine wastage, possible bacterial growth
• May be appropriate for single vaccine clinics
• Only for use within specified time period
  – Follow manufacturer/CDC recommendations
“Pre-filling” Syringes

- Use same lot of vaccine for all pre-filled syringes
- Must maintain “cold chain”
- Mimic or surpass local health department standards
- Consider using manufacturer-supplied prefilled syringes for large immunization clinics (e.g., annual influenza clinics)
- Syringes other than those filled by manufacturer should be discarded at end of clinic day

Vaccine Inventory Control

- Conduct a monthly vaccine inventory
- Avoid stocking excessive vaccine supplies
- Monitor expiration dates and rotate stock to avoid waste
- Never use expired vaccine or diluents
- Limit access to authorized personnel
Vaccine Inventory Log

• Name of each vaccine
• Number of doses of each vaccine received
• Date received
• Condition upon arrival
• Vaccine manufacturers
• Lot numbers
• Expiration date for each vaccine

Responsibility for Vaccine Potency

• Keep the “cold-chain” intact !!
• Vaccine potency is a shared responsibility, step by step:
  – Manufacturer: production, initial shipment
  – Wholesaler: storage, later shipment
  – Pharmacy/Clinic: receiving, storage, ultimate handling up to administration
  – Involves professionals and technicians
Storage and Handling
Take-Home Messages

• Colder is NOT better for inactivated vaccines
• Out of range temperature readings require IMMEDIATE action
• It is estimated that >$100 million worth of vaccine is exposed to freezing temperatures each year in the US

Storage Considerations for the Pharmacy Owner

• Detailed written protocol
• Assign storage responsibilities to 1 person
• Designate a back-up
• Training on vaccine storage and handling
Interactive Checkpoint

- Should a pharmacist avoid using a multi-dose vial for immunizations due to potential bacterial growth and other considerations?

A. Yes  
B. No
Interactive Checkpoint

• No
  – However, it is unadvisable to pre-fill syringes using a multi-dose vial
  – The concern in this situation is with syringe itself, not the multi-dose vial
Disposal

- Proper disposal is required
- Follow OSHA guidelines
- Contract with a biowaste hazard company

Sharps Containers

- Use “sharps” containers for used syringes and other biowaste
  - Do not reuse
  - Replace when 2/3 full
- Move full containers to isolated area
- Hire a contractor for disposal
Other Supplies

- Syringes
  - Generally 1 inch, 22-25 gauge
- Needles
- Latex Gloves
- Cotton balls/gauze pads
- Alcohol swabs
- Band-aids (spot and rectangular)

- Oral thermometer
- Probe covers for thermometer
- Towel
- Paper towels
- Disinfecting cleanser
- Epinephrine
- (2) Sharps Container
- Bleach Solution in spray bottle

Practice Agreements

- Prescriptions
- Standing orders
- Collaborative practice agreements
Practice Agreements

- Prescriptions

Practice Agreements

- Standing orders programs
  - Allows nurses and pharmacists to administer vaccinations without the need for a physician examination or direct order
Practice Agreements

• Collaborative practice agreement

Training

• Immunization training
• Emergency response training
• Staff training
Immunization Training

• To be become an immunizer, you must undergo hands-on practical training
• Sources for training
  – Schools of Pharmacy
  – Centers for Disease Control and Prevention (CDC)
  – American Pharmacists Association (APhA)
• Areas of focus
  – Disease characteristics
  – Characteristics of vaccines, storage requirements
  – Contraindications, side effects of vaccines
  – Practicum for administering vaccinations

Emergency Resources
Emergency Response Training

• Immunizers and staff should be trained in proper protocol in the event of an emergency.
• After vaccinating, competent care-giver must observe patient for a suitable period of time.
• Emergency plan:
  – 911 (EMS) + epinephrine + CPR
• Mimic procedures in your community

Emergency Prevention

• Take a thorough history of allergies prior to administering vaccine.
Screening Questionnaire for Adult Immunizations

**Screening Questionnaire for Adult Immunization**

*For patients: The following questions will help us determine which vaccines you may be given today. If you answer “yes” to any question, it does not necessarily mean you should not be vaccinated. It just means additional questions must be asked. If a question is not clear, please ask your healthcare provider to explain it.*

1. Are you sick today?
   - [ ] Yes
   - [ ] No
   - [ ] Don’t know

2. Do you have allergies to medications, food, or any vaccine?
   - [ ] Yes
   - [ ] No
   - [ ] Don’t know

3. Have you previously had a serious reaction after receiving a vaccine?
   - [ ] Yes
   - [ ] No
   - [ ] Don’t know

4. Do you have a chronic health problem: heart disease, lung disease, asthma, kidney disease, metabolic disease (e.g., diabetes), anemia, or another blood disorder?
   - [ ] Yes
   - [ ] No
   - [ ] Don’t know

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**Suggested Supplies for an Emergency Kit**

- Standing orders for medical emergencies
- Aqueous epinephrine USP (1:1000), in ampules, vials of solution, or prefilled syringes
- Diphenhydramine injectable (50 mg/mL solution) and oral in 25 or 50 mg tablets
- One 3 cc syringes with 1", 1½", and 2" needles for epinephrine or diphenhydramine
- Adult airways masks (small, medium, large)
- Sphygmomanometer (adult & extra-large cuffs) and stethoscope
- Adult size pocket mask with one-way valve
- Alcohol swabs
- Tongue depressors
- Flashlight with extra batteries *(for examination of mouth and throat)*
- Wrist watch
- Tourniquet
- Cell phone or access to an on-site phone
It Looks Like the Patient Is Turning Blue…..

- Emergency responses
- Have a plan and practice it!

Epinephrine

- It is recommended to stock at least 4 adult doses of epinephrine for emergency situations
- Epinephrine has short shelf life
- Dosing schedule should be posted by emergency plan
Epinephrine Dosing

Epinephrine Dosage Forms

- 1mg/ml ampule
- AnaKit® - two 0.3 mg doses
- EpiPen® - one 0.3 mg dose
- EpiPen Jr.® - one 0.15 mg dose
Emergency Responses

- Epinephrine dosing based on body weight
- IM is more prompt than SC
- Repeat every 5 to 20 minutes, based on response
- Beta-adrenergic blockers antagonize epinephrine
  - May require higher epinephrine dose

Acute Responses

- Allow for fainting without injury
- Who will you refer patient to after an emergency?
- Remind patients & parents to report adverse reactions that happen at home
CPR Training

- CPR training is necessary in the event of cardiac arrest
- Sources of CPR Training
  - American Heart Association
  - Red Cross
  - Local Fire and Emergency Response Units
  - Hospitals

VAERS

- National adverse event reporting system for vaccines (vaers.hhs.gov)
- Provides a nationwide mechanism by which adverse events following immunization may be reported, analyzed and made available to the public
  - Similar to Medwatch for vaccines
- Remind patients & parents to report adverse reactions that happen at home
General Rule – Adverse Reactions

• *Inactivated* vaccines are expected to commonly produce reactions at the injection site
• *Live, attenuated* vaccines are expected to produce a mild form of the natural illness

Staff Training

• You can utilize staff for many aspects of the immunization program
  – Clerical: patient information intake, appointment scheduling
  – Expanded: vaccine preparation, post-vaccination monitoring
• Staff should be trained to ask for proper information prior to vaccination and to recognize warning signs
Immunization Records

• One major way to help reduce liability is to keep records
• Accurate records must be kept and maintained in any immunization program

Immunization Records

• Immunization records should provide:
  – Patient’s name, date of birth, address, telephone number, email address
  – Patient data such as medical history, reason for vaccination
  – Date of vaccination
  – Pharmacist’s name, address of the one administering the vaccine
  – Name of vaccine, manufacturer and lot number of vaccine
  – Release and/or consent form signed and dated by patient
**Conclusion**

- The community pharmacist is the ideal provider for immunization services to the community
- It is not difficult to modify your current practice to start an immunization clinic
- Many payers will compensate pharmacists for immunization services
- It is important that you and your staff are familiar with regulatory requirements to limit liability concerns
Please Proceed to the Post-Test