

**NACDS** NATIONAL ASSOCIATION OF  
CHAIN DRUG STORES



**PHARMACY-BASED  
IMMUNIZATION WEBINAR SERIES:**  
INNOVATIONS IN PRACTICE, ADVOCACY, & SCIENCE

# Federal and State Regulatory Update: Increasing Opportunities for Pharmacist-Provided Immunizations

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# Learning Objectives

- Describe distinctions between prescription and collaborative practice model requirements for immunization services
- Discuss the current landscape of state regulations impacting pharmacist-provided immunizations
- Explain how to obtain payment for Medicare-covered vaccines and their administration as well as beneficiary cost-sharing requirements

# Polling Question

- Which description best matches your role in a pharmacy immunization program?
  - A. Student pharmacist
  - B. Immunization educator and/or advocate
  - C. Immunizing pharmacist
  - D. Immunizing pharmacist and program coordinator/manager

# States Where Pharmacists Can Immunize

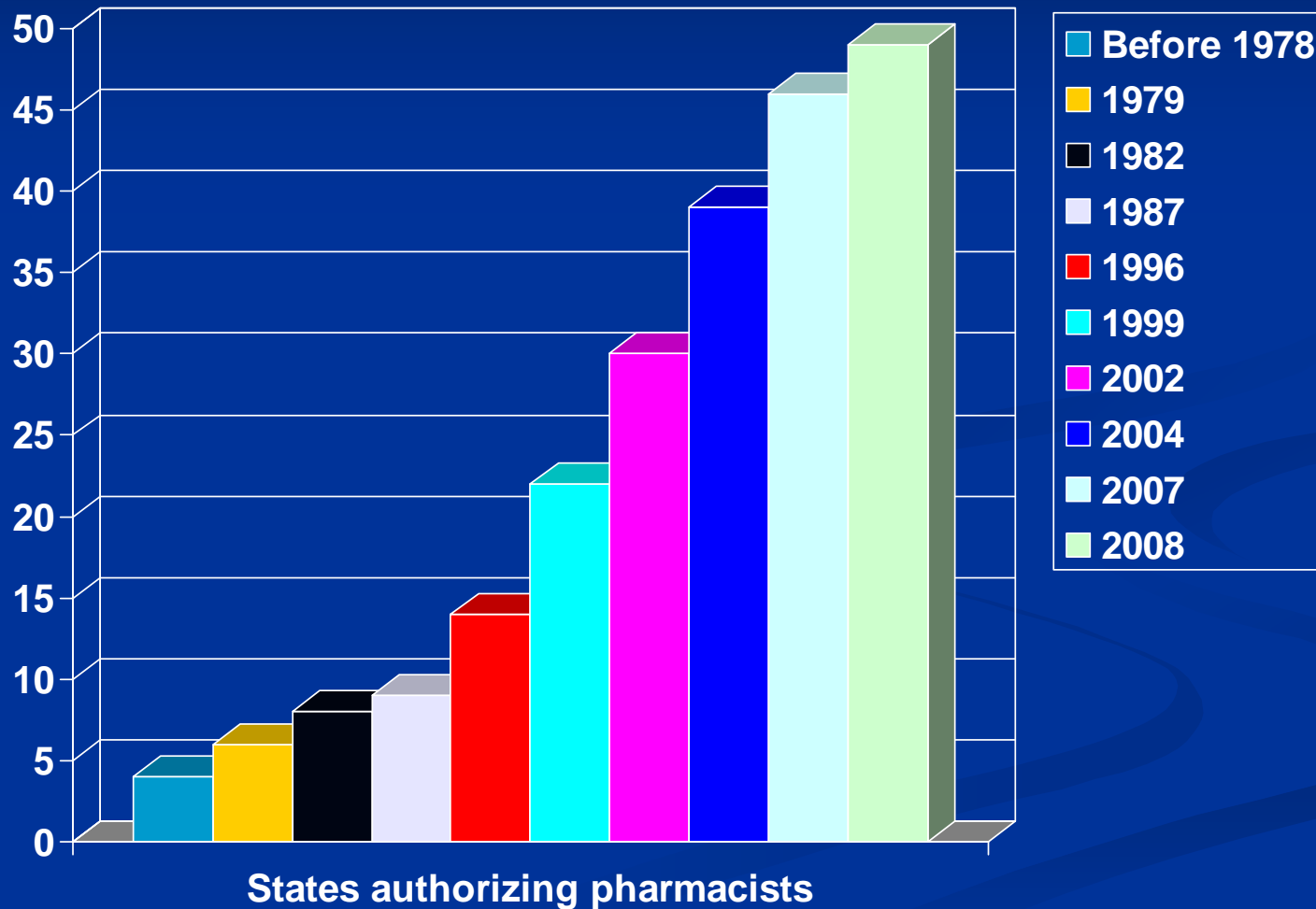
- As of December 2008, pharmacists in 49 states have legislative or regulatory authority to administer immunizations

# States Where Pharmacists Can Immunize



As of July 2008

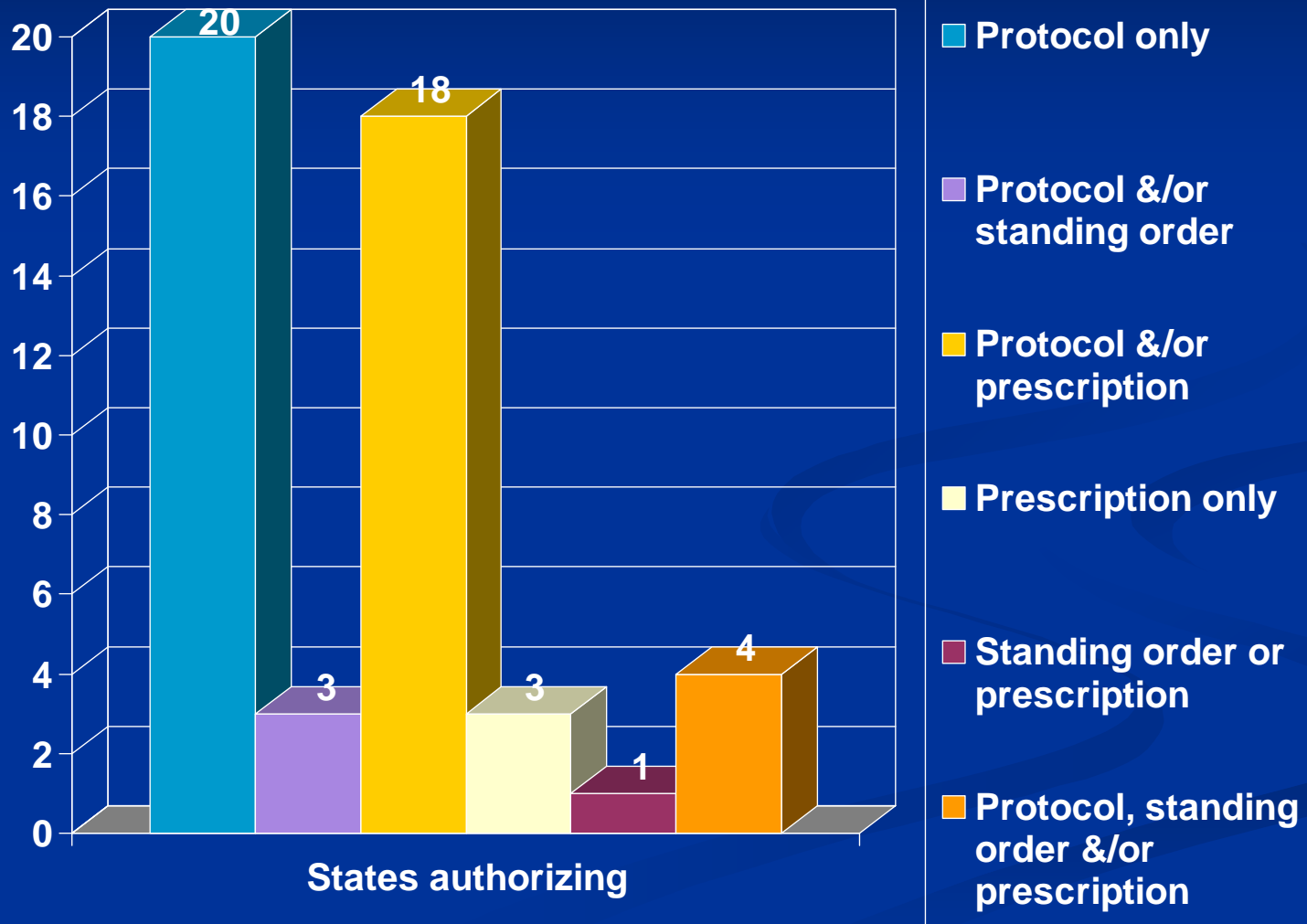
# Pharmacist Authority to Administer Immunizations



# Vaccine Administration Authorization

- Prescription
- Collaborative practice agreement/protocol
- Vaccines listed in statute
- Not authorized

# Pharmacist Immunization Administration Protocol/Standing Order vs Rx



# Age Limitations and Route of Administration

- Age limitations
  - No age limitations (17 states)
  - Patients  $\geq 14$  years old with parental consent,  $\geq 18$ ,  $\geq 19$
  - Variable depending on antigen
    - Influenza, no restriction
    - Prescription required (for certain age or antigen)
- Route of administration
  - Injection
  - Oral
  - Intranasal
  - Some states allow one, combination, or all

# What Can Be Administered?

- Identified within protocol, prescription, or collaborative agreement
  - Disease-state specific
    - Influenza only
- Vaccines/antigens by state law
- All vaccines/antigens
- All medications including vaccines

# Specialized State Training Requirements

- None
- APhA programs
- State-specific courses
- Certificate programs
- Training may be required but with no clear guidelines

# Additional Training Requirements

- CPR certification requirements
  - Not required but recommended
  - CPR required
  - CPR plus American Heart Association (AHA) Cardiac Basic Life Support
- Continuing education requirements
  - None
  - Specific time frames
    - 2, 3, 6 hours every 2 years
    - 1 hour every year
  - Required with no specific guidelines

# Can Student Pharmacist Interns/Externs Administer Vaccines?

- Varies by state
  - 27 states allow interns to give immunizations
  - 4 additional states list as “to be determined”
- Which students can administer?
  - Many allow any student under trained/certified pharmacist
    - 1 state requires the pharmacist to have a PharmD
  - State may further restrict to only 3rd- and 4th-year students
- Disease-state specific
  - Influenza only (1 state)
- Requirements for training
  - Training only or immunization certification

# Record Keeping Requirements

- May be same as prescription requirements
- Specific time frame
  - 2,7,10 years – up to 30 years for hospitals
- Determined by specific protocol
- Patient informed consent
  - No specific requirements
  - Informed consent required
  - Determined by specific protocol
- Provision of Vaccine Information Statements (VIS)

# Polling Question

- Do you or your pharmacy currently participate in a collaborative practice agreement that allows you to provide one or more immunizations?
  - A. Yes
  - B. No

# Which Pharmacists Are Eligible to Participate?

- Any licensed pharmacist
- Any licensed pharmacist having met training requirements
- Must meet state criteria for clinical practitioners
- May require postgraduate education or BPS certification
- May need to meet specific insurance requirements

# Which Medical Practitioners Are Eligible to Participate?

- Anyone licensed to prescribe
- Physicians only
- Some states disallow medical residents
- May require specialty certification

# Who Needs to Be Named in the Agreement?

- Usually at least the participating pharmacist and physician
- Some states may require an alternate physician
- Some states require the agreement to be patient specific

# Who Must Approve the Agreement?

- The Board of Pharmacy
- The Board of Medicine and/or Board of Nursing may be involved
- The patient may need to be included in the process
- If administered in an institution or pharmacy corporation, the institution/corporate management may need to approve the agreement
- Some states have no specific rules

# What Pharmacy Practice Settings Are Authorized?

- Some states set no limitations
- Some states set criteria for “licensed health care facility” status
- Some states set requirements for privacy and available resources for optimal care

# Written Protocol: General or Specific?

- Usually at least physician and pharmacist specific
- May encompass any patient or be patient specific
- May be specific to immunization
- Encompass vaccinations and handling adverse reactions/anaphylaxis

# What Documentation Requirements Exist?

- Required records may include copy of agreement, patient consent, documentation of any therapy modifications, patient progress, etc.

# How Long Is the Term of the Agreement?

- Some states set no limitations
- May need to be reviewed, renewed, or modified within 1 or 2 years

# Do Any Termination Guidelines Exist?

- Usually either practitioner or pharmacist can terminate agreement at any time
- Notification of the Board of Pharmacy and/or Board of Medicine may be required within a certain amount of time
- Requirements may exist for patient notification

# Miscellaneous Requirements

- Check with your state Board of Pharmacy to determine additional requirements

# Medicare Vaccine Coverage

# Polling Question

- What percentage of your current influenza vaccines are billed to Medicare Part B?
  - A. 0%–30%
  - B. 31%–60%
  - C. Greater than 60%
  - D. Unsure/not applicable

# Polling Question

- Which of the following vaccines are covered by Medicare Part D?
  - A. Influenza
  - B. Pneumococcal
  - C. Zoster
  - D. A and B

# Medicare Part B vs Part D Vaccine Coverage

- Medicare Part B vaccine coverage (three covered by statute)
  - Influenza (one per flu season)
  - Pneumonia (once per lifetime or risk-based)
  - Hep B (for intermediate to high risk patients)
- Other vaccines also covered to treat illness, injury or post-exposure (e.g. rabies)
- Pharmacy provider must be enrolled with Medicare

# Medicare Part B vs Part D Vaccine Coverage (cont.)

- Medicare Part D
  - All other approved preventative vaccines
- Prior to 2008, vaccine product was covered by Part D, while administration was through Part B.
- Medicare Part D changes effective 2008
  - The Tax Relief and Health Care Act of 2006 (PL 109-432)
  - Modified the law to cover vaccine administration (for covered Part D vaccines) under Part D starting January 1, 2008.

# Medicare Part B vs Part D Vaccine Coverage (cont.)

- What does all this mean?
  - Previously covered under Part B, then coverage stays with Part B (Influenza, pneumococcal, hepatitis B)
  - Previously not covered through Part B, then may be covered through Part D
  - 2008 Call Letter— All formularies must contain all commercially available vaccines unless excluded due to B coverage.
    - E.g. – zoster vaccine live (Zostavax)

# Claims Processing

- As of January 2008, Part D covers administration costs for Part D-covered vaccine
- Part D vaccine administration is a component of the negotiated price, which includes the ingredient costs, dispensing fee (if applicable), and administration fee

# Claims Processing (cont.)

- Pharmacist dispenses and administers vaccine
  - Submit one claim to Part D plan for both in- and out-of-network situations
    - Single claim includes ingredient cost, dispensing fee, and administration fee
    - Collect applicable beneficiary cost-sharing
  
- Pharmacist only dispenses
  - Submit one claim to plan for ingredient cost and dispensing fee
  - Collect applicable beneficiary cost-sharing
  - Physician who administers vaccine bills beneficiary directly for administration fee
    - Beneficiary submits reimbursement claim to plan

# Claims Processing (cont.)

- Physician supplies and administers vaccine
  - Physician bills beneficiary for entire amount of ingredient cost and administration fee
  - Beneficiary submits paper reimbursement claim to plan
  - Processed as out-of-network claim
  - Physician online processing options

# Zoster Vaccine Live (Zostavax)

- Because of storage requirements:
  - Pharmacists are discouraged from dispensing vaccine to patients for administration by physician

# Vaccine Coverage Information

- NCPDP
  - Instructions on single claim billing
  - Contact specific vendor with questions
- CMS Part D Call Letter guidance to plans
- Coverage options for in-network vs out-of-network situation
- Coverage for new vaccines during plan year

# Helpful Resources

- CMS Medicare Learning Network (MLN)
  - *MLN Matters* Article Number SE0727:  
Reimbursement for Vaccines and Vaccine  
Administration Under Medicare Part D
    - <http://www.cms.hhs.gov/ContractorLearningResources/downloads/JA0727.pdf>

# Helpful Resources

- Medicare Parts B/D Coverage Issues
  - <http://www.cms.hhs.gov/pharmacy/downloads/partsbdcoverageissues.pdf>
  - <http://www.cms.hhs.gov/mlnmattersarticles/downloads/se0727.pdf>

# Questions





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