

# **Recommendations for Using Pneumococcal Vaccines among Adults**

**IHS Webinar**

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## **Disclosure**

- The presenters have no financial relationships to this program.**

# Objectives

**At the end of this presentation, participants will be able to:**

- ❑ Describe the burden of pneumococcal disease among adults 65 years and older.**
- ❑ Describe the potential impact of PCV13 on invasive pneumococcal disease and non-invasive pneumococcal pneumonia.**
- ❑ Evaluate patients 65 years and older for pneumococcal vaccination in accordance with the ACIP recommendations.**

## Burden of pneumococcal disease among adults $\geq 65$ years of age

- ❑ Adults  $\geq 65$  years at increased risk for pneumococcal disease and serious illness from the major clinical syndromes associated with it
- ❑ Case-fatality rate for pneumococcal bacteremia is  $\sim 15\%$  overall, but as high as 60% among adults  $\geq 65$  years
- ❑  $\sim 18,000$  fatal cases of pneumococcal disease among adults  $\geq 65$  years each year in the United States

# ACIP Recommendations through 2012: Pneumococcal Polysaccharide Vaccine (PPSV23)

- All adults 65 yrs and older
- Adults 19-64 years old with the following conditions

Risk group	Underlying medical condition or other indication
Immunocompetent persons	Chronic heart disease (excluding hypertension)* Chronic lung disease† Diabetes mellitus Cerebrospinal fluid leaks Cochlear implant Alcoholism Chronic liver disease, including cirrhosis Cigarette smoking
Persons with functional or anatomic asplenia <sup>§</sup>	Sickle cell disease and other hemoglobinopathies Congenital or acquired asplenia, splenic dysfunction, or splenectomy
Immunocompromised persons <sup>§</sup>	Congenital or acquired immunodeficiencies <sup>¶</sup> HIV infection Chronic renal failure Nephrotic syndrome Leukemias Lymphomas Hodgkin disease Generalized malignancy Diseases requiring treatment with immunosuppressive drugs, including long-term systemic corticosteroids or radiation therapy Solid organ transplantation Multiple myeloma

\* Including congestive heart failure and cardiomyopathies.

† Including chronic obstructive pulmonary disease, emphysema, and asthma.

§ A second dose of PPSV23 is recommended 5 years after the first dose for persons with functional or anatomic asplenia and for immunocompromised persons.

¶ Includes B- (humoral) or T-lymphocyte deficiency, complement deficiencies (particularly C1, C2, C3, and C4 deficiencies), and phagocytic disorders (excluding chronic granulomatous disease).

# 13-valent Pneumococcal Conjugate Vaccine (PCV13) for Adults

- Licensed for use among adults  $\geq 50$  years old on 12/30/11
- FDA approved under the Accelerated Approval Pathway
- Based on non-inferior immunogenicity compared to PPSV23
- Indications
  - Prevention of pneumococcal disease (including pneumonia and invasive disease) in adults 50 years of age and older
  - Prevention of disease caused by *Streptococcus pneumoniae* serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F and 23F
- Post-approval condition of licensure: Randomized controlled trial of PCV13 against pneumococcal pneumonia among adults  $\geq 65$  years old in the Netherlands (CAPiTA)

# ACIP Recommendations in 2012

- Deferred recommendation for adults  $\geq 65$  years old until more data available
  - Efficacy against pneumonia (CAPiTA)
  - Indirect (herd) effects of PCV13 use in children
- Recommended a dose of PCV13 in sequence with PPSV23 for adults with immunocompromising conditions (highest risk for pneumococcal disease)

## New Evidence Supporting PCV13 use among adults, CAPiTA results

Study/population	Endpoint	Vaccine Efficacy (95% CI)
CAPITA ~85,000 Adults 65+ Netherlands	PCV13-serotype IPD	75% (41%, 91%)
	PCV13-serotype non-bacteremic pneumonia	45% (14%, 65%)

# Summary of evidence supporting PCV13 use among adults $\geq 65$ years of age

- ❑ **Prevents IPD and non-bacteremic pneumonia<sup>1</sup>**
  - 75% reduction in vaccine type IPD
  - 45% reduction in vaccine type non-bacteremic pneumonia
- ❑ **Immune response non-inferior or improved (for some serotypes) for PCV13 (or PCV7) vs. PPSV23<sup>2,3</sup>**
- ❑ **Safety demonstrated in clinical trials**

<sup>1</sup>CAPITA, June 2014 ACIP

<sup>2</sup>Phase III trials, Pfizer, ACIP 2011, 2012

<sup>3</sup>DeRoux et al. CID 2008, Goldblatt et al 2009

# Summary of evidence supporting PCV13 use among adults $\geq 65$ years of age

- **Vaccine preventable disease burden remaining among adults  $\geq 65$  years**
  - Estimated 2,600 PCV13 type IPD cases in 2013<sup>1</sup>
  - Over 50,000 PCV13-type inpatient CAP<sup>2</sup>
  
- **In the short-term, PCV13 likely provides adequate coverage of disease causing serotypes**
  - 20-25% IPD due to PCV13 types<sup>1</sup>
  - ~10% of all CAP due to PCV13 types<sup>2</sup>

<sup>1</sup>Active Bacterial Core Surveillance, 2013

<sup>2</sup> Estimate based on studies using serotype-specific urine antigen test, Pfizer

# Expected public health impact and cost-effectiveness

- **Various strategies considered and evaluated for expected public health impact and cost-effectiveness**
  - Vaccination at ages 50, 60, and 65 years
  - PCV13 instead of PPSV23
  - PCV13 in sequence with PPSV23
  
- **Adding PCV13 at age 65 years to existing PPSV23 recommendations likely the optimal strategy**
  - Health benefits for all outcomes
  - Cost-effectiveness comparable to other adult interventions accepted as cost-effective (base case)

## Expected public health impact of adding PCV13 at age 65 years to existing PPSV23 recommendations (base case)

<b>Health Outcomes</b>	<b>Change in outcome compared to existing PPSV23 recommendation</b>
IPD	-226
Inpatient NBP	-4,961
Outpatient NBP	-7,252
Deaths (IPD)	-33
Deaths (NBP)	-332
QALYs	3,053
Life-years	4,627

## Cost-effectiveness of adding PCV13 at age 65 years to existing PPSV23 recommendations (base case)

<b>Outcomes</b>	<b>Change in outcome compared to existing PPSV23 recommendation</b>
Total Cost (Millions)	\$189
Medical (Millions)	-\$132
Vaccine total cost (Millions)	\$321
Cost/QALY gained	\$62,065
Cost/Life-year gained	\$40,949

**PCV13 now recommended in series with  
PPSV23 for all adults  $\geq 65$  years**

**Adults  $\geq 65$  years of age with  
no previous pneumococcal vaccine  
(PCV13 or PPSV23) or  
unknown vaccination history**

**Recommendation**

- ❑ Administer a dose of PCV13 first, followed by a dose of PPSV23

**Guidance on intervals for sequential use**

- ❑ A dose of PPSV23 should be given **at least 1year\*** following a dose of PCV13. The two vaccines should not be co-administered. **If a dose of PPSV23 was inadvertently given earlier than the recommended interval, the dose need not be repeated.**

\*June 2015 ACIP vote

# PCV13-naïve adults $\geq 65$ years of age **previously vaccinated with PPSV23**

## Recommendation

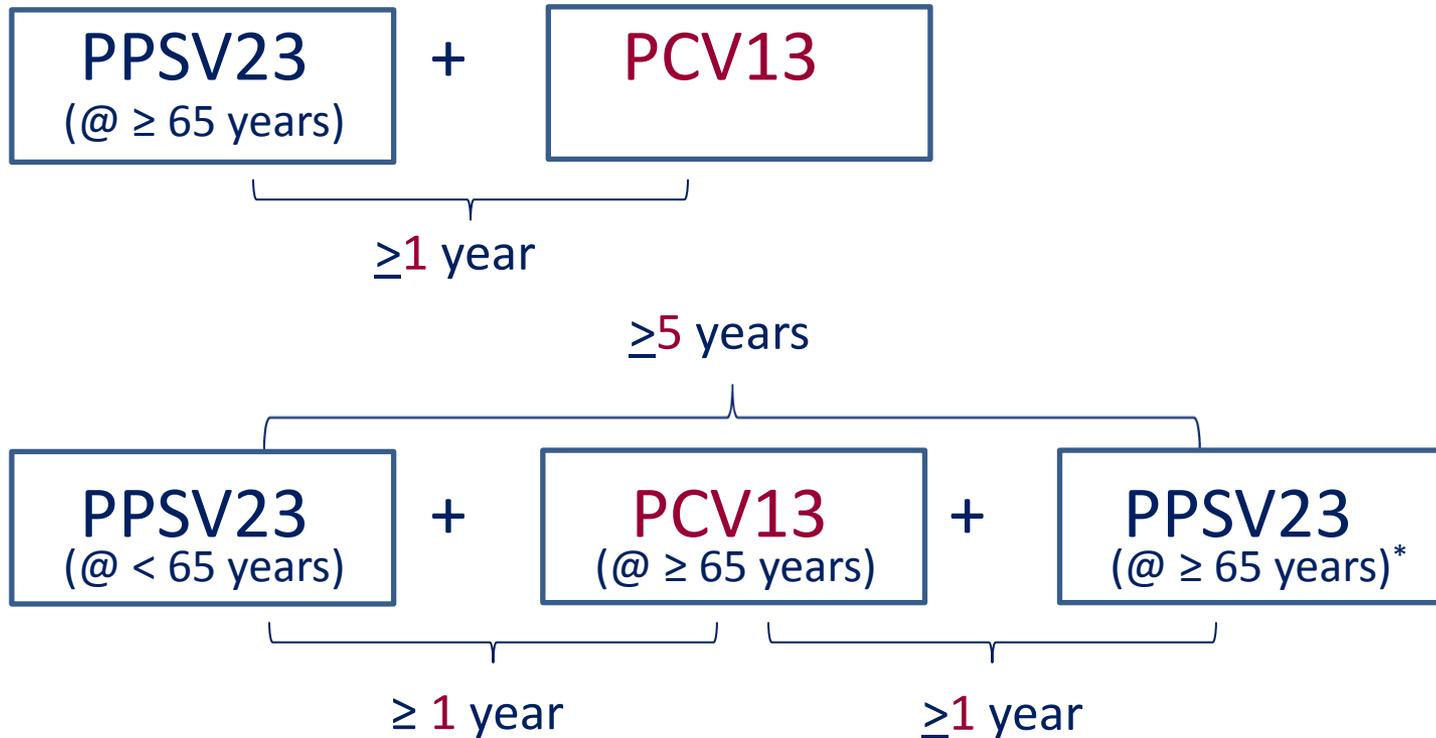
- ❑ Administer a dose of PCV13

## Guidance on intervals for sequential use

- ❑ Administer PCV13 at least 1 year after the receipt of the most recent PPSV23 dose
- ❑ For those for whom an additional dose of PPSV23 is indicated, administer it **at least 1 year\*** after PCV13 and at least 5 years after the most recent dose of PPSV23

\*June 2015 ACIP vote

# PCV13-naïve adults $\geq 65$ years of age **previously vaccinated with PPSV23**



# Intervals Between the Two Pneumococcal Vaccines Incorporating June 2015 Changes

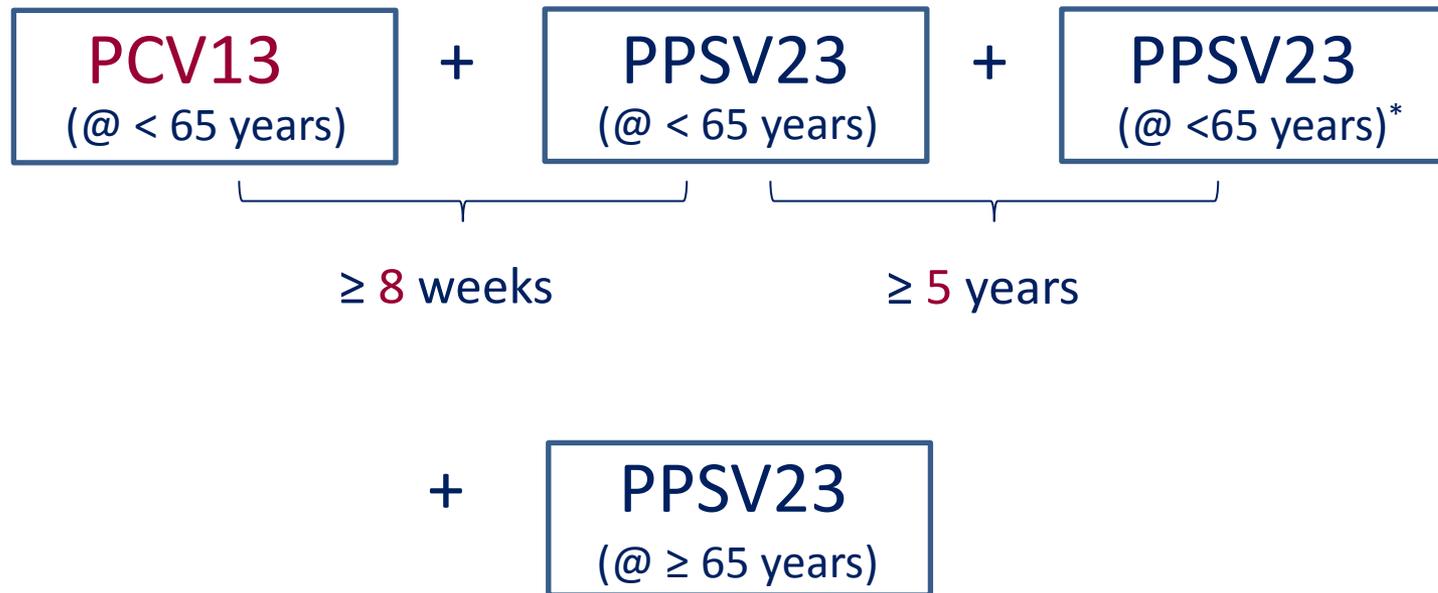
Age groups	Underlying conditions	PCV13→ PPSV23	PPSV23→ PCV13
≥19 years	<ul style="list-style-type: none"> <li>• High-risk immunocompetent (CSF leak, cochlear implants)</li> <li>• Functional or anatomic asplenia</li> <li>• Immunocompromised</li> </ul>	≥8 weeks	≥1 year
≥65 years	NA	≥1 year	≥1 year

# Prevention of pneumococcal disease among adults $\geq 19$ years with **high risk conditions**

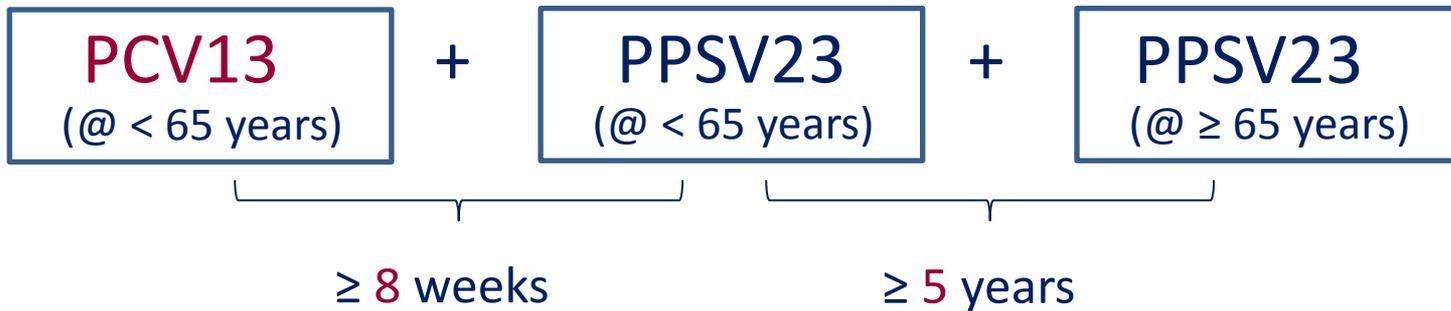
## Current guidelines

- ❑ “Use of PCV13 and PPSV23 for Adults with Immunocompromising Conditions: Recommendations of the Advisory Committee on Immunization Practices (ACIP)” remain unchanged
- ❑ <http://www.medscape.com/viewarticle/772339>
- ❑ <http://www.cdc.gov/mmwr/preview/mmwrhtml/m6140a4.htm>

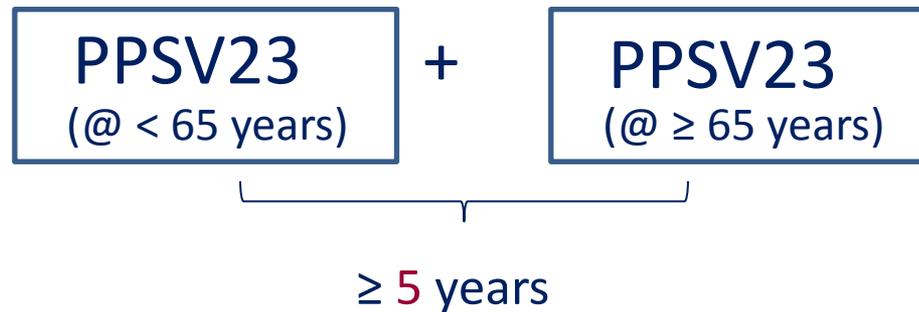
# Prevention of pneumococcal disease among adults $\geq 19$ years with **functional or anatomic asplenia or immunocompromising conditions**



# Prevention of pneumococcal disease among adults $\geq 19$ years with **cochlear implants or CSF leaks**



# Prevention of pneumococcal disease among adults $\geq 19$ years with **chronic medical conditions**



**PATIENT SCENARIOS FOR ADULTS  
≥65 YEARS OF AGE**

# Patient scenario #1

A 65 year old female patient with no underlying medical conditions and no previous pneumococcal vaccinations

❑ Administer vaccines as follows:

- ❑ 1 dose of PCV13 now
- ❑ 1 dose of PPSV23 1 year after administering PCV13

❑ Rationale:

- ❑ She is  $\geq 65$  years old and has no history of pneumococcal vaccination, so she is recommended both pneumococcal vaccines

## Patient scenario #2

A 67 year old male patient with no underlying medical conditions who received a dose of PPSV23 at age 65 years

- ❑ Administer vaccines as follows:

- ❑ 1 dose of PCV13 now

- ❑ Rationale:

- ❑ He is  $\geq 65$  years old
  - ❑ It has been  $\geq 1$  year since PPSV23
  - ❑ Only 1 dose of PPSV23 is recommended for adults  $\geq 65$  years

## Patient scenario #3

A 66 year old male patient with cochlear implants who received a dose of PPSV23 at age 55 years

- ❑ Administer vaccines as follows:
  - ❑ 1 dose of PCV13 now
  - ❑ 1 dose of PPSV23 1 year after administering PCV13
- ❑ Rationale:
  - ❑ He is  $\geq 65$  years old
  - ❑ At least 1 year has passed since he received PPSV23
  - ❑ It's been  $\geq 5$  years since his previous PPSV23 dose

## Patient scenario #4

A 66 year old female patient infection with HIV who received a dose of PPSV23 at ages 52, 57, and 65 years and a dose of PCV13 at 64 years

- ❑ Do not administer any vaccines
- ❑ Rationale:
  - ❑ Only 1 dose of PCV13 is recommended in an adult's lifetime
  - ❑ Only 1 dose of PPSV23 is recommended for adults  $\geq 65$  years

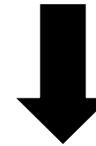
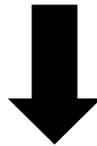
# Standards for Adult Immunization Practices

- ❑ Assess the immunization status of all your patients
- ❑ Strongly recommend vaccines that patients need
- ❑ Administer needed vaccines or refer patients to a vaccinating provider
- ❑ Document vaccines received by your patients



# CDC Resources

- ❑ Clinician: Adult immunization information/schedule
- ❑ Patient: Education materials on adult immunization  
The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.
- ❑ Implementation of Standards
- ❑ Pneumococcal disease and vaccine resources



[www.cdc.gov/vaccines/adults](http://www.cdc.gov/vaccines/adults)

[www.cdc.gov/vaccines/AdultStandards](http://www.cdc.gov/vaccines/AdultStandards)

[www.cdc.gov/pneumococcal/clinicians](http://www.cdc.gov/pneumococcal/clinicians)

[www.cdc.gov/vaccines/vpd-vac/pneumo](http://www.cdc.gov/vaccines/vpd-vac/pneumo)

# Implementing PCV13 in IHS, Tribal and Urban Indian Healthcare Facility Settings

Amy V. Groom, MPH

IHS Immunization Program Manager

# Pneumococcal Disease

## AI/AN population

- Higher rates of invasive pneumococcal disease in some AI/AN populations compared to whites
  - Alaska, Southwest
- Pneumonia & Influenza one of the top 10 leading causes of death for AI/AN
  - Mortality rates 1.9 times higher for AI/AN vs. White
    - Range of 1.7 to 4.86, depending on age group
- High burden of underlying chronic conditions

Source: Groom et al. Pneumonia and Influenza Mortality Among American Indian and Alaska Native People, 1990–2009, AJP 2014 Jun;104 Suppl 3:S460-9.

# Clinical Decision Support In RPMS (Texas Children's Hospital Forecaster)

- TCH Forecaster Version 3.11.05 AND
- Immunization Package (BI) Path 10
  - PCV13 reminder for adults 65 years and older
  - Released May 19<sup>th</sup>, 2015
- Must update EHR Clinical Reminders for adult reminder to display

# TCH Forecast Logic for PCV13

- If no previous pneumococcal vaccine:
  - PCV13 at 65 years and older for all patients
  - PPSV23 forecast 6 months later (will change to 1 year)
  - Valid if given at least 8 weeks later (will change to no minimum interval)
- If previous PPSV23 given:
  - PCV13 forecast 1 year after PPSV23
  - If additional PPSV23 needed, will forecast 6 months after PCV13 (will change to 12 months) and 5 years after previous PPSV23
- If previous PCV13 given:
  - At 65 years, PPSV23 forecast
    - 6 months after PCV13 (change to 12 months)
  - No additional PCV13 dose forecast

# Funding for PCV13

- Cost
  - NSSC Pricing
    - PCV13 – \$88.50
    - PPSV23 – \$24.08
- PCV13 is covered by Medicare Part B
  - Reimbursement for both PCV13 and PPSV23
  - 1 year interval between pneumococcal doses required
  - <http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/MM9051.PDF>
- Pfizer RxPathways Vaccine Replacement Program
  - [http://pfizerrxpathways.com/sites/default/files/attachment/GroupCForm73114\\_Online.pdf](http://pfizerrxpathways.com/sites/default/files/attachment/GroupCForm73114_Online.pdf)
  - AI/AN patients whose only source of care is IHS are considered uninsured
  - Income requirements
  - Must seek approval before administering

# Medicare Coverage

- PCV13 is covered by Medicare Part B
- Outpatient encounters in hospital – based IHS facilities and Tribal 638 programs for patients with Medicare A and B coverage are reimbursed at the All Inclusive-Rate (AIR), which is the same for all states.
  - For 2015, the AIR is:
    - Lower 48: \$307
    - Alaska: \$564
    - *Q: If get AIR, can also bill part B for vaccine admin and vaccine?*
- Outpatient immunization encounters for flu, PPSV23 and PCV13 at non-hospital-based IHS and Tribal facilities are reimburseable under Medicare Part B
  - *What defines an encounter - physician visit? What about pharmacists? Nurses?*

# Medicaid Coverage

- Coverage for PCV13 and other adults vaccines varies by state.
- Outpatient encounters in IHS facilities and Tribal 638 programs for Medicaid patients are reimbursed at the All Inclusive-rate (AIR).
  - FY 2015 AIR for Medicaid:
    - Lower 48: is \$350
    - Alaska: \$601
- Reimbursable encounters are defined by the state. Sites should **seek advice from their Business Office Coordinator as to what constitutes an encounter for their respective states.**
- States determine the service providers for which the AIR is paid. For example, pharmacists are recognized as billable providers for the AIR in some states, but not in others.
- States determine the number of encounters they will pay for in one patient visit.
  - Many states will reimburse for multiple encounters during a patient's visit to an IHS or Tribal facility.

# Dual Eligible Patients

- For Dual Eligible patients (Medicare AND Medicaid)
  - Because Medicaid is covering some of the costs, Medicaid rules apply. Reimbursable encounters and service providers are defined by the state. Sites should seek advice from their Business Office Coordinator as to what constitutes an encounter for their respective states.