All-State Medicaid and CHIP Call

August 13, 2024

Agenda

- Update on Fall Vaccines
- 2025 Outpatient Prospective Payment System (OPPS) Notice of Proposed Rulemaking
  - Four Walls Provision
  - Continuous Eligibility Provision
- Open Mic Q and A

Preparing for Fall and Winter Respiratory Illness Season

- Current Issues in Immunizations

- *August 13, 2024*

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WHY IMMUNIZE: Best defense against viruses that can cause serious illness

Viruses cause many hospitalizations.

- **Thousands of people are hospitalized** for COVID-19, flu and RSV every week during the respiratory virus season
- **RSV is the #1 reason babies are hospitalized** in the US

While some people at higher risk, cannot predict who will get severely ill.

- **Adults 65+ are 4–9 times more likely to be hospitalized** for COVID, flu and RSV than those under age 65
- Half of children under 18 years hospitalized with COVID-19 had **NO underlying conditions**

Immunizations are our best defense.

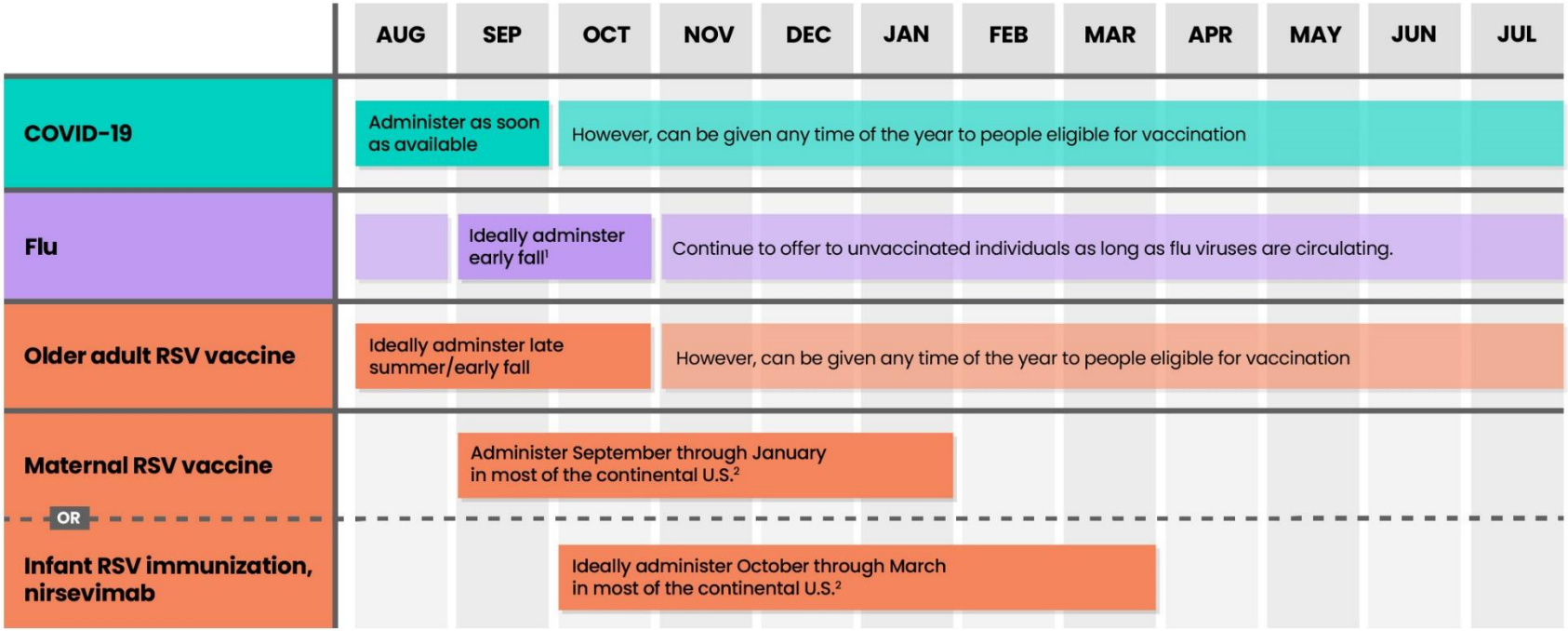
- COVID-19 & flu **vaccines cut risk of hospitalization in half** in all ages
- RSV vaccines **>70% effective in preventing older adult hospitalizations**
- **Nirsevimab prevented >90% of infant RSV hospitalizations** in 2023-24

Who should get COVID-19, flu, and RSV Immunizations in the 2024-2025 respiratory season?

	2024–2025 COVID-19[1]	2024–2025 Influenza[2]	RSV[3]
Infants & Children	**6 months – 17 years** Some children 6 months through 4 years may need multiple doses	**6 months – 17 years** Some children 6 months through 8 years may need multiple doses	**All infants <8 months and children 8 through 19 months with risk factors should get nirsevimab** Typically, October through March, if mom not vaccinated with maternal RSV vaccine
Adults 18–59	**All**	**All**	See pregnant people
Adults 60+	**All**	**All** Higher dose or adjuvanted flu vaccine for 65+, if available	**All adults 75+ and adults 60 through 74 years with risk factors should get one lifetime dose of RSV vaccine**
Pregnant People	**All**	**All**	**32–36 weeks gestation should get RSV vaccine (Pfizer, Abrysvo only)** Typically, September–January

[1] Immunocompromised may need to get additional dose(s) of COVID-19 vaccine regardless of age
[2] Solid organ transplant recipients on immunosuppressives may get high-dose or adjuvanted flu vaccine, if available
[3] All infants should be protected by either maternal RSV vaccine or nirsevimab. Both are not needed for most infants

Timing of administration for COVID-19, influenza, and RSV immunization



[1] Children who need 2 doses should receive their first dose as soon as possible (including during July and August). One dose of flu vaccine can be considered for pregnant people in their third trimester during July and August.

[2] In jurisdictions with RSV seasonality that differs from most of the continental United States, including Alaska, southern Florida, Guam, Hawaii, Puerto Rico, U.S.-affiliated Pacific Islands, and U.S. Virgin Islands, providers should follow state, local, or territorial guidance. However, nirsevimab may be administered outside of routine seasonal administration (i.e., October through March) based on local RSV activity and other special circumstances.

Adults aged 60-74 years at higher risk for RSV should get the RSV vaccine

Chronic cardiovascular disease

Severe obesity (body mass index ≥40 kg/m^2)

Diabetes mellitus complicated by chronic kidney disease, neuropathy, retinopathy or other end-organ damage

Chronic lung or respiratory disease

End stage renal disease/dialysis dependence

Chronic hematologic conditions

Chronic liver disease

Neurological or neuromuscular conditions causing impaired airway clearance or respiratory muscle weakness

Residence in a nursing home

Moderate or severe immunocompromise

Other factors that a provider determines would increase risk of severe disease due to viral respiratory infection (e.g., frailty)

Use of Respiratory Syncytial Virus Vaccines in Adults Aged ≥60 Years: Updated Recommendations of the Advisory Committee on Immunization Practices — United States, 2024 | MMWR (cdc.gov)

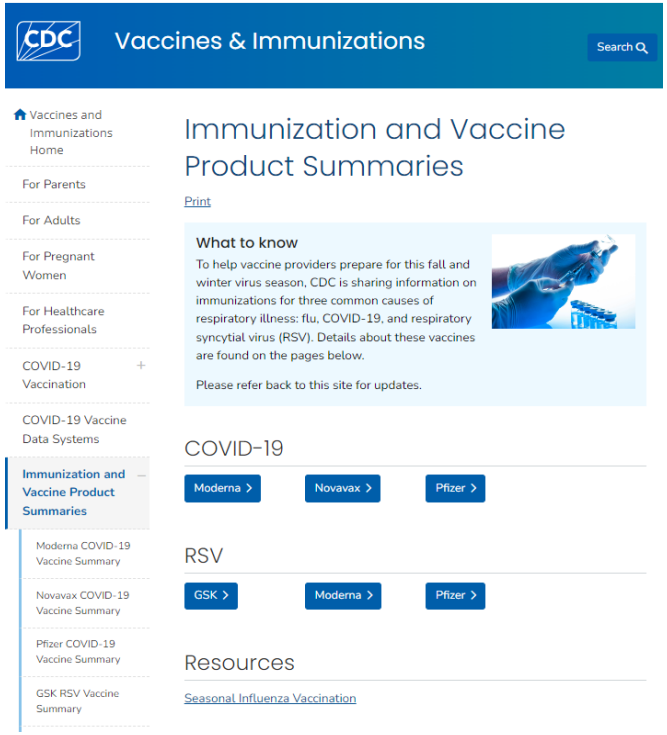
Clinics can order immunizations for respiratory virus season now

Ordering and offering immunizations in your clinics is one of the most powerful ways to improve vaccine confidence and increase immunization rates

- Convenience is a top reason for patient acceptance
- Reduces missed opportunities for immunization

NEW tool to make ordering immunizations easier!

- Provides estimated launch dates
- Links to pre-ordering and early reservation programs
- Details on product type (single or multidose vial, pre-filled syringe) / Return policies for unused product



Source: https://www.cdc.gov/vaccines/php/info-by-product/index.html

Vaccines for Children (VFC) Updates

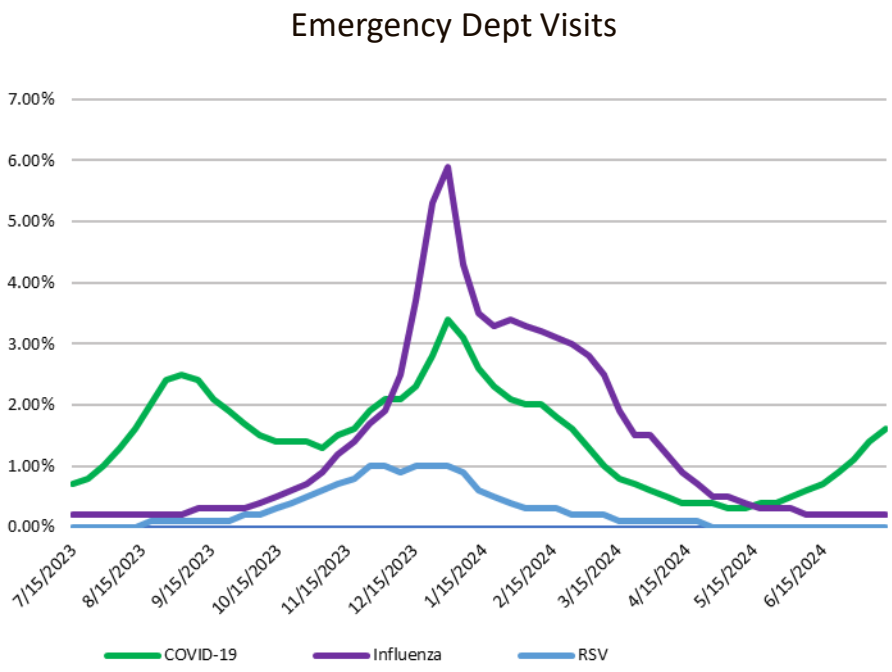
- **Increasing access to nirsevimab in birthing hospitals**
  - **Benefit**: Immunizing infants prior to discharge – critical opportunity to ensure protection for uninsured or publicly insured infants, who have a higher odds of missing well child visits.
  - **Current status**: ~25% birthing hospitals in VFC, accounting for ~30% of in-hospital births.
  - **Opportunity:**
    - Birthing hospitals, nurseries, and NICUs may enroll in the VFC program as **'Specialty Providers,'** if approved by their jurisdiction's VFC program.
      - Only offer nirsevimab and hepatitis B vaccination birth dose.
      - **Virtual enrollment** with a jurisdiction's VFC program is allowed
    - Allowing **"Vaccine Order Replacement Model"** - not required to maintain separate stocks of public & private vaccines; can electronically account for public/private vaccine inventories
    - VFC providers are **NOT currently required to meet private inventory requirement for COVID-19 vaccine and/or Nirsevimab** while operations for these products are expanded. Note: All VFC providers will be required to meet all private stock requirements by August 31, 2025.

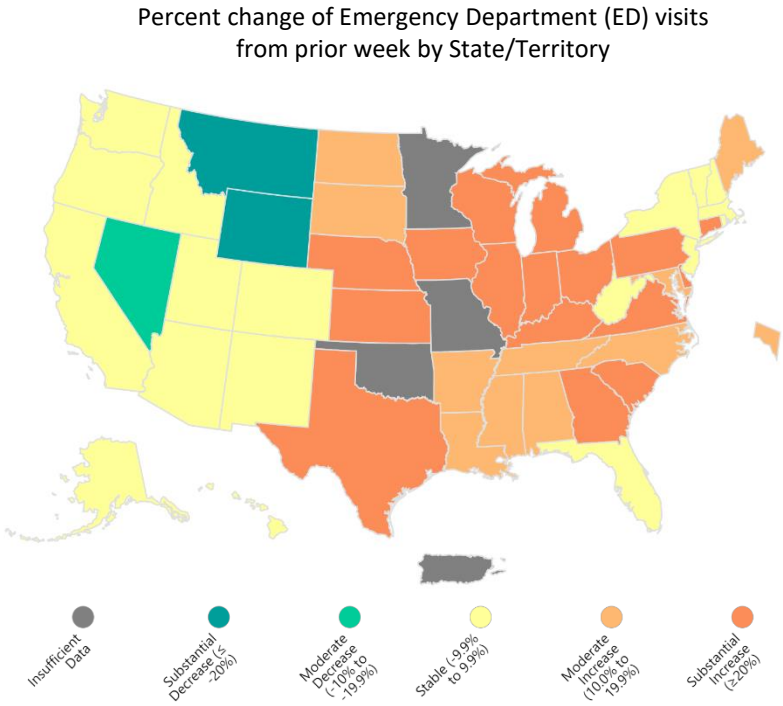
Increasing Immunization Access: Pharmacies

- **Pharmacies are critical** in national vaccination efforts
  - **Common**: >60% of adults get their fall/winter vaccines in pharmacies
  - **Convenient**: ~90% of U.S. residents live within 5 miles of a pharmacy; people appreciate evenings, weekends, and walk-in access.
  - **Variability and opportunities**
    - Pharmacies participation in VFC
    - Pharmacist scope of practice

Remind patients to get vaccinated at an in-network provider or pharmacy

COVID-19 Emergency department visits increasing across the United States





https://www.cdc.gov/respiratory-viruses/data-research/dashboard/activity-levels.html
https://covid.cdc.gov/covid-data-tracker/#maps_percent-covid-ed-change

Treat people at high risk for severe COVID-19 with antivirals

Paxlovid cuts risk of hospitalization due to COVID-19 by more than 60% and death by 75%

Ritonavir-boosted nirmatrelvir (Paxlovid)

- For people ≥12 years of age
- No liver function or creatinine testing needed
- Review drug-drug interactions and adjust dosing/stop other meds as needed

Remdesivir

- For people ≥ 28 days old
- Liver function and prothrombin testing needed
- Requires IV administration

Alternate if above not available: molnupiravir

Early treatment important for people at high risk for severe COVID-19

- Adults aged 65 years or older
- Pregnant people
- People with weakened immune systems
- People of any age with underlying conditions such as chronic lung disease and heart disease

https://www.cdc.gov/respiratory-viruses/guidance/background.html

Campaign Overview

The ***Risk Less. Do More.*** Public Education Campaign is a national integrated effort to increase awareness of, confidence in, and uptake of vaccines that reduce severe illness from influenza (flu), COVID-19, and RSV in at-risk populations.

Primary Audiences:

- Older adults (65+)
- Long-term care facility (LTCF) residents, including adults 65+ and adults with disabilities
- Health navigators (people who influence primary audiences and help them make health care decisions)

Secondary Audiences:

- Pregnant people
- Adults 18+ (special focus on Black, Latino, and rural audiences)
- Health care providers

Medicaid Opportunities to Increase Vaccine Access

Encourage providers to order and offer vaccines in clinic

Help increase awareness and confidence in vaccines!

- Public education - HHS campaign launching mid Aug
- Remind your own teams about vaccine benefits

Consider coverage and reimbursement policies to increase access to vaccines and treatment

Centers for Disease Control and Prevention
National Center for Immunization and Respiratory Diseases

For more information, contact CDC
1-800-CDC-INFO (232-4636)
TTY: 1-888-232-6348 www.cdc.gov

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.

Brought to you by the U.S. Department of Health and Human Services

2025 Outpatient Prospective Payment System (OPPS) Notice of Proposed Rulemaking: Four Walls Provision

Medicaid and CHIP All State Call

August 2024

Note: The policies presented in this deck are not final and are subject to change in the final rule. All comments must be received using the instructions in the published Federal Register document 89 FR 59186 by September 9, 2024.

Background (1/4)

- The Medicaid clinic services benefit is **an optional benefit** category.
- Clinic services are defined at **section 1905(a)(9) of the Social Security Act (the Act)** and implementing regulations at **42 CFR § 440.90**.
- The clinic services benefit is **a separate benefit** category from the **federally qualified health center (FQHC) services, rural health clinic (RHC) services, and outpatient hospital services benefit categories**.
- Under the current regulation, clinic services:
  - Are **preventive, diagnostic, therapeutic, rehabilitative, or palliative services** furnished by a **facility that is not part of a hospital** but is **organized and operated** to provide medical care to **outpatients**;
  - Must be furnished **by or under the direction of a physician**; and
  - Must be furnished **within the four walls of the clinic** except for services furnished to an **individual who is unhoused**.

Background (2/4)

- Congress **amended section 1905(a)(9) of the Act** in 1987 to **create an exception** to the clinic services four walls requirement **for individuals who are unhoused**.
- In 1991 rulemaking, CMS explained that **clinic services have always been limited to the four walls** of the clinic (or satellite location) and that:
  - The exception added by Congress for individuals who are unhoused **represents an exception to the four walls general coverage requirement**; and
  - CMS **interpreted** this legislative change as **ratifying the four walls requirement by establishing an explicit exception** for individuals who are unhoused.

Background (3/4)

- CMS recognized in 2017 that **Indian Health Service (IHS) and Tribal clinics were providing services outside of the four walls**, including to individuals to whom the existing statutory and regulatory exception does not apply, and that states were paying for these services at the clinic services rate.
- In a 2017 frequently asked questions (FAQ) document, **CMS announced a four-year grace period** to January 30, 2021, to allow states and IHS/Tribal clinics to come into compliance with the four walls requirement.
- CMS issued CMCS Informational Bulletins (CIBs) on January 15, 2021, October 4, 2021, and September 8, 2023, to **announce further extensions of the grace period**.
- The grace period is currently scheduled to **end on February 11, 2025**.

Background (4/4)

- CMS has heard from **Tribes, the CMS Tribal Technical Advisory Group (TTAG), and the HHS Secretary's Tribal Advisory Committee (STAC)** that the four walls requirement will **create barriers in access** for beneficiaries who receive care from IHS/Tribal clinics after the grace period ends.
- Tribes, the TTAG, and the STAC have asked CMS to **eliminate the four walls requirement for IHS/Tribal clinics**.
- CMS has also received requests from some states to **allow exceptions to the four walls requirement for clinics that serve vulnerable populations**, such as behavioral health clinics.

Proposed Clinic Services Four Walls Exceptions

- CMS has **included a proposal to add exceptions to the Medicaid clinic services four walls requirement** as part of the calendar year (CY) 2025 Hospital Outpatient Prospective Payment System (OPPS) and Ambulatory Surgical Center (ASC) Payment System proposed rule (CMS-1809-P).
- CMS is proposing a mandatory exception for **IHS/Tribal clinics**, and optional exceptions for **behavioral health clinics** and **clinics located in rural areas**.
- Comments are **due by September 9, 2024**.
- CMS is proposing these exceptions:
  - To **address the concerns we have heard** from Tribes, the TTAG, the STAC, states, and other interested parties;
  - To **fulfill Executive Orders 13175, 14009, and 14070**; and
  - To be consistent with our **strategies, goals, and objectives to advance health equity and improve health care access** for Tribal, behavioral health, and rural populations.

Proposed Exception Criteria (1/2)

- CMS continues to believe that the statute **does not authorize broad exceptions to the four walls requirement that have no relationship to the current exception** or **a complete elimination** of the four walls requirement.
- CMS is **reinterpreting section 1905(a)(9) of the Act as permitting additional exceptions** to the four walls requirement for populations served by clinics **if those populations have similar health care access issues as the unhoused population**.
- The exceptions outlined in the proposed rule **follow four criteria that mirror the needs and barriers to access** experienced by **individuals who are unhoused**:

    1. The population **experiences high rates of behavioral health diagnoses or difficulty accessing behavioral health services**;
    2. The population **experiences issues accessing services due to lack of transportation**;

Proposed Exception Criteria (2/2)

3. The population **experiences a historical mistrust of the health care system**; and
4. The population **experiences high rates of poor health outcomes and mortality**.

- CMS **expects the proposed exceptions to the clinic services four walls requirement to improve access to care** for the populations targeted by the exceptions.
- If finalized, the exceptions would **authorize states to pay for services** furnished under the exceptions at **facility-based clinic services payment rates**.

Proposed IHS/Tribal Clinic Exception (1/2)

- CMS **proposes to add an exception** to the four walls requirement for **IHS/Tribal clinics** at a new 42 CFR 440.90(c).
- This exception would:
  - Be **mandatory for all states** that cover the clinic services benefit.
  - Only apply to clinics that are **owned and operated by IHS, clinics that are owned by IHS and Tribally-operated as authorized by the Indian Self-Determination and Education Assistance Act of 1975 (ISDEAA), or by Tribes and Tribal organizations** as authorized by the ISDEAA; and
  - Apply to **any Medicaid beneficiary who receives services from an IHS/Tribal clinic**.
- CMS is **not proposing to include facilities operated by urban Indian organizations (UIOs)** in this proposed exception.

Proposed IHS/Tribal Clinic Exception (2/2)

- CMS is proposing this exception **based on advice and input received through Tribal consultation** and **evidence that the population served by IHS/Tribal clinics tends to meet the four criteria** more than other populations.
- CMS is proposing that the IHS/Tribal clinics would be **a proxy for the patient population they serve** because:
  - The entire patient population **is likely to meet some or all of the four criteria** described in the proposed rule; and
  - They serve **a clearly identifiable group of Medicaid beneficiaries** under IHS statutes and regulations.

Proposed Behavioral Health Clinic Exception (1/2)

- CMS **proposes to add an exception** to the four walls requirement for **behavioral health clinics** at a new 42 CFR 440.90(d).
- This exception would:
  - Be **optional for states** that cover the clinic services benefit;
  - Apply to clinics that are **primarily organized for the care and treatment of outpatients with behavioral health disorders** (including mental health and substance use disorders);
  - Apply to **any services furnished outside of the four walls by a behavioral health clinic** (including non-behavioral health services);
  - Include behavioral health clinic types that are **recognized nationally, such as Community Mental Health Centers, and other behavioral health clinics organized in a state; and**
  - If this proposal is finalized as described, states that choose to adopt this exception would **describe the types of behavioral health clinics such exception applies to in their Medicaid state plan**.

Proposed Behavioral Health Clinic Exception (2/2)

- CMS is proposing this exception **based on evidence** that indicates that an exception to the clinic services four walls requirement could be warranted, based on state-specific circumstances, for behavioral health clinics, as these clinics might primarily serve a patient population that **may be more likely than other groups to meet more of the four criteria**.
- CMS is proposing that the behavioral health clinics would be **a proxy for the patient population they serve** because:
  - We believe it would be **too operationally burdensome** to require that, to qualify for the exception, clinic services be provided specifically to individuals with a behavioral health disorder; and
  - It is our understanding that behavioral health clinics **generally serve a patient population that consists primarily of individuals with behavioral health disorders**.

Proposed Clinics Located in Rural Areas Exception (1/3)

- CMS **proposes to add an exception** to the four walls requirement for **clinics located in rural areas** at a new 42 CFR 440.90(e).
- This exception would:
  - Be **optional for states** that cover the clinic services benefit;
  - Apply to **clinics located in rural areas**; and
  - **Not apply to clinics that are RHCs.**

Proposed Clinics Located in Rural Areas Exception (2/3)

- CMS is proposing this exception **based on evidence** that indicates that an exception to the clinic services four walls requirement could be warranted, based on state-specific circumstances, for clinics located in rural areas, as these clinics might primarily serve a patient population that **may be more likely than other groups to meet more of the four criteria**.
- CMS is proposing that clinics located in rural areas would be **a proxy for the patient population they serve** because:
  - CMS believes it would be **too operationally burdensome** to require that, to qualify for the exception, clinic services be provided specifically to individuals who reside in rural areas; and
  - It is our understanding that clinics located in rural areas **generally serve a patient population that consists primarily of individuals who reside in rural areas**.

Proposed Clinics Located in Rural Areas Exception (3/3)

- There are **many federal and state definitions of rural** for various programs, and **no single definition precisely identifies all rural areas**.
- CMS **did not include a definition of rural in the proposed rule** but is considering defining the term in the final rule.
- CMS is **considering several approaches to defining rural** for the final rule:
  - **Census** definition;
  - **Office of Management and Budget** definition;
  - The **Federal Office of Rural Health Policy** definition;
  - A definition of rural that is **adopted and used by a Federal governmental agency for programmatic purposes**;
  - A definition of rural that is **adopted and used by a State governmental agency with a role in setting rural health policy**; or
  - **Not adopting any definition of rural**.

Additional Considerations in the Proposed Rule(1/2)

- CMS is also proposing to:
  - **Codify in regulation text** our longstanding interpretation that **the existing § 440.90(a) and (b) are mandatory components of the clinic services benefit** for states that cover the benefit; and
  - **Delete the word "eligible" from existing regulation text** at 42 CFR 440.90(b) because the word is unnecessary as Medicaid-covered services may only be provided to Medicaid-eligible individuals.
- CMS is proposing to make the **IHS/Tribal clinic exception mandatory** and the **exceptions for behavioral health clinics located in rural areas optional** because:
  - The population served by IHS/Tribal clinics **more consistently meets the four criteria**, both within and across states, **than the populations targeted by the optional exceptions, especially given the degree of state variability in whether the populations targeted by the optional exceptions meet those criteria**;

Additional Considerations in the Proposed Rule(2/2)

  - Medicaid is the largest source of third-party payment for services billed by IHS/Tribal facilities;
  - There **may be geographic variability** in the degree to which the populations served by behavioral health clinics and clinics located in rural areas **meet the four criteria**; and
  - It is our understanding that **Medicaid funding is less often the largest source of payment** for behavioral health clinics and clinics located in rural areas compared to IHS/Tribal clinics.

- CMS is **not proposing any additional exceptions** to the clinic services four walls requirement.
- CMS **welcomes comments** on our proposed rule. Comments are due **September 9, 2024**, please submit comments following instructions in the Federal Register notice.

2025 Outpatient Prospective Payment System (OPPS) Notice of Proposed Rulemaking: Continuous Eligibility Provision

Medicaid and CHIP All State Call

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Continuous Eligibility in Medicaid and CHIP

- Prior to the Consolidated Appropriations Act, 2023 (CAA, 2023), states had the option to provide up to 12-months continuous eligibility (CE) to children enrolled in Medicaid and CHIP. The CAA, 2023 made this previously optional policy mandatory, effective January 1, 2024.
- CMS is proposing updates to the Medicaid and CHIP regulations to codify the requirements of the CAA, 2023 related to continuous eligibility by:
  - Requiring that states provide 12-months CE under the state plan or waiver of a state plan for children enrolled in Medicaid and CHIP;
  - Removing the option to limit CE to a time period of less than 12-months or to a subgroup of Medicaid or CHIP enrollees; and,
  - For CHIP, removing the option to disenroll children during a CE period for failure to pay premiums.

Open Mic Q and A