Residential and long-term care facility call

Jan. 14, 2026

All LTCF facilities

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RLTCF calls and newsletters

- 2026 residential and long-term care facility calls are on a quarterly cadence.
    - Next call is **April 8, noon - 1 p.m.**
- The newsletter is sent out **one month after the quarterly call**.
- Sign up to receive our newsletters and call slides.
- Infection prevention and control topic survey is available.

Agenda

- **Following your manufacturer's Instructions for Use (IFU)**
  Pam Fricke, CDPHE HAI/AR Program, Infection Preventionist

- **Invasive group A *Streptococcus* in LTCFs**
  Cayla Mayle, HAI Prevention and Response Epidemiologist

- **Viral respiratory disease updates**
  Deborah Aragon, FluSurv-NET and Response Unit Manager

Following your manufacturer's Instructions for Use (IFU)

Jan. 14, 2026

Pamela Fricke
CDPHE HAI/AR Program
Infection Preventionist

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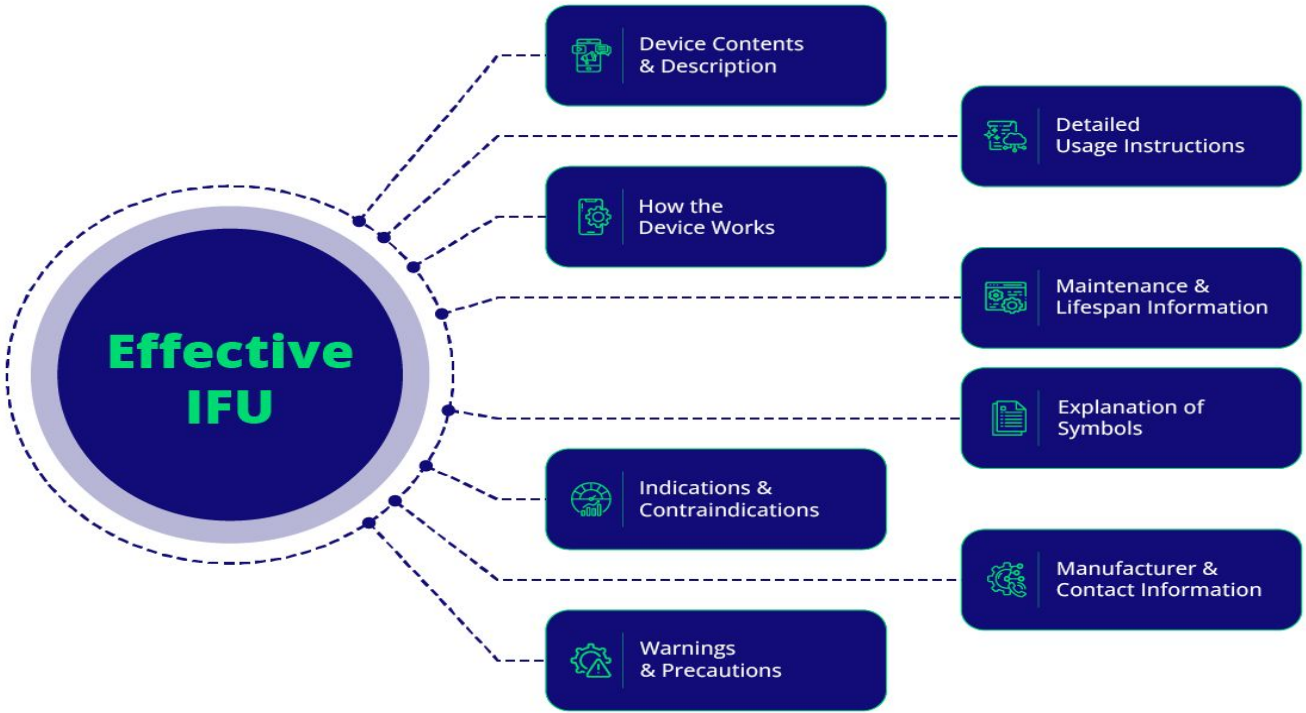
Objectives

- Define IFUs and why they are important.
- Identify risk factors of not following IFUs.
- Describe how to find and interpret IFUs.

What is an IFU?

- IFU = manufacturer's Instructions for Use
- Detailed, action-oriented, step-by-step, visual instructions
- Outline: prep, admin, handling, storage, and disposal

FDA requirements and processes



https://rookqs.com/hubfs/Rook_Quality_Systems_January2025/images/rookqs-elements-of-an-effective-ifu.webp
https://rookqs.com/glossary/instruction-for-use

Why are IFUs important?

- IFUs help reduce the risk of errors and accidents.
- Provide intended use for products/equipment
- Using products/equipment effectively
- Setup, maintenance, and storage instructions
- Cleaning, disinfection, and sterilization cycles
- Prevents infection control gaps
- Failure to follow instructions can lead to various risks.

Which medical devices/products have IFUs?

- **All** medical devices, equipment, and products have IFUs (whether a symbol on a box, package, or form).
- Organizations are expected to follow those instructions.

Risk factors to not following IFUs

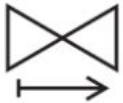
- Safety issues
  - Risk of infections
  - Products not effective
- Equipment not maintained
  - Breakdown or malfunction
  - Unneeded costs/delays in procedures
- Voided warranty

Where to find IFUs

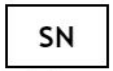
- Packaging
- Packaging inserts
- Boxes
- Labels on bottles
- On some devices or equipment

*If you are unable to find an IFU, it is important to contact the manufacturer to get a copy before putting the items into use.

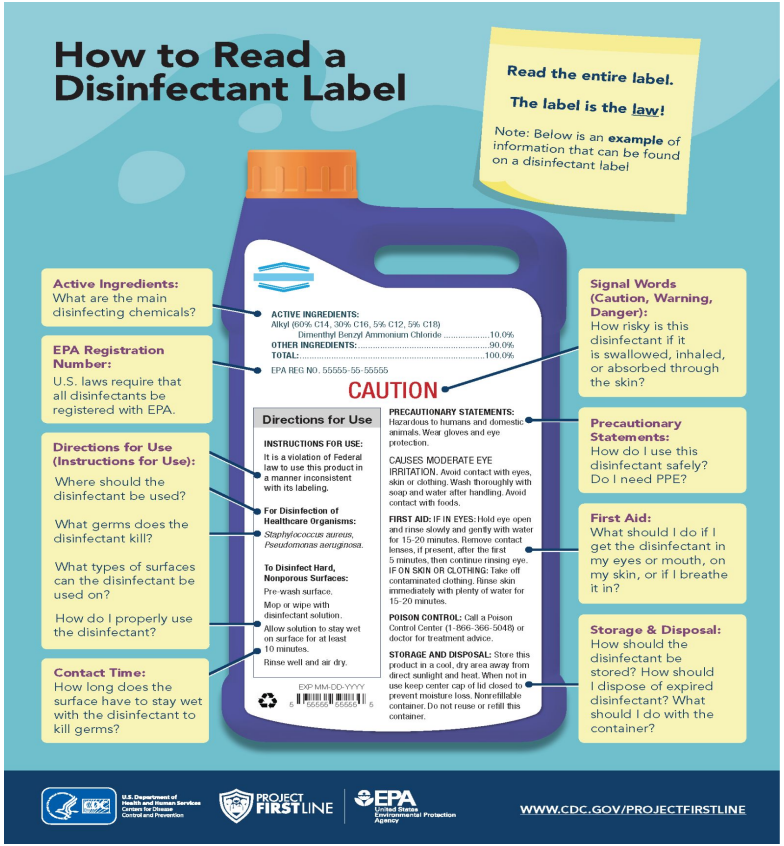
Manufacturer's packaging symbols

Manufacturer's Packaging Symbols					
 Caution	 Consult instructions for use	 Do not reuse and/or single use	 Single patient, multiple uses. Devices can be used multiple times on a single patient.	 Device must be kept dry.	 Do not sterilize more than once.
 Keep away from sunlight	 Keep away from heat & radiation	 Do not use if package is damaged	 One-way valve	 Presence of natural rubber latex	 Reference number or catalog number

Manufacturer's packaging symbols (cont.)

 Expiration date or use by date	 Lot number or batch code	 Date of manufacture	 Manufacturer	 Serial number	 Sterile
 Lower Limit of temperature range	 Temperature limitation	 Upper limit of temperature range	 Non-Sterile	 Sterilized using Aseptics	 Sterilized using irradiation
 Atmosphere pressure limitation	 Humidity limitation	 Instrument must be autoclaved	 Biological risks	 Do not use if package is damaged	 Sterilized using steam or dry heat

Reading disinfectant labels



CDC. https://www.cdc.gov/project-firstline/media/pdfs/HowToReadALabel-Infographic-508.pdf

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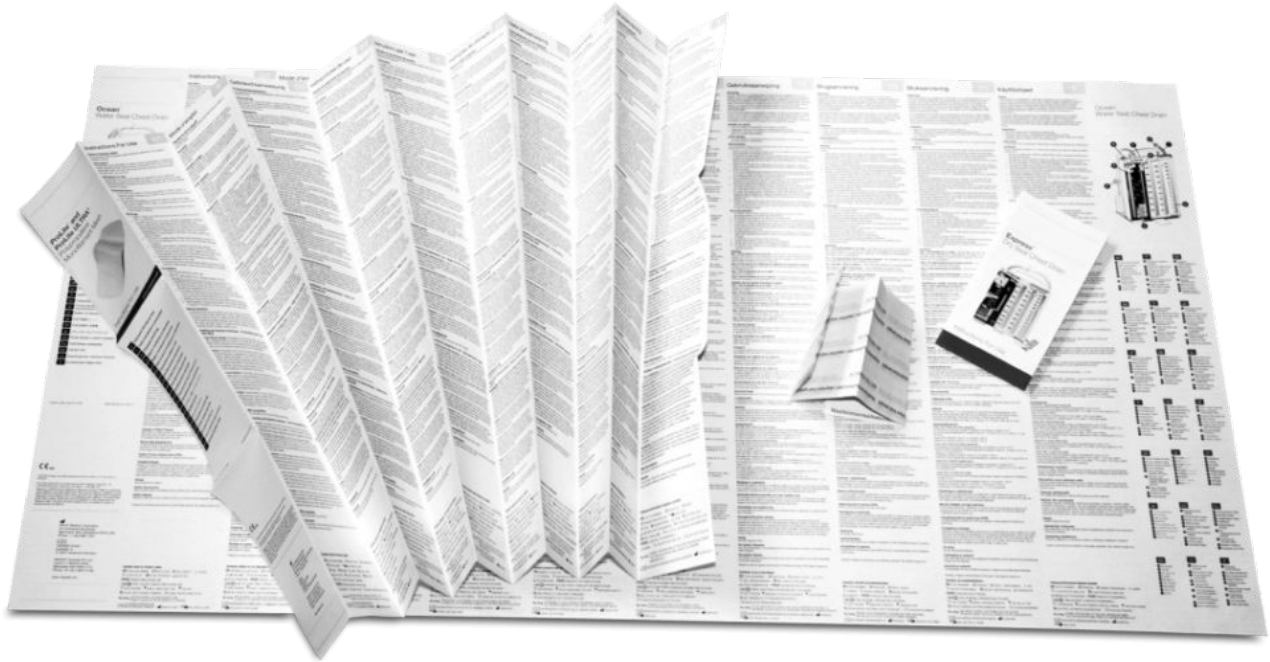
Example of a packaging insert



https://kaseprinting.com/wp-content/uploads/2024/11/medical-device-and-pharmaceutical-ifu-1024x567.png
https://kaseprinting.com/commercial-printing/instructions-for-use-ifu/

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Electronic and manual IFUs

Electronic IFUs

- Digital library
- Easier to keep track of IFUs
- Routine updates
- Staff can access them from anywhere in a facility.

Manual IFUs

- One area of the facility
- Keep all IFUs together
- Responsible for updating the IFUs

Thank you!

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Questions

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(direct HAI/AR email)

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(to reach me directly)

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Resources

Joint Commission

- Manufacturers Instructions for Use - Expectations Regarding Access To IFUs for Medical Instruments and Devices | Joint Commission

EPA

- Why Read Labels | EPA
- Why Read Labels? | US EPA
- EPA How To Read A Label

Additional resources

- IFU for Medical Devices, a Definitive Guide (EU & US)
- Instruction for Use (IFU) | Rook Quality Systems

Invasive group A *Streptococcus* in LTCFs

Cayla Mayle – CDPHE HAI/AR Program

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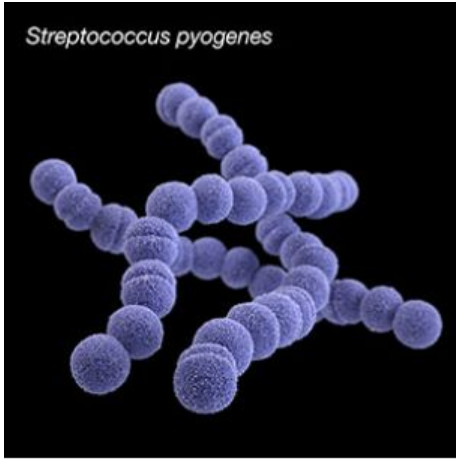
Objectives

- Overview
- Surveillance
- Risk factors
- Prevention measures
- Response activities
  - Single case
  - Outbreak
- Resources

Overview: *Streptococcus pyogenes*

- Commonly referred to as “group A strep” or “GAS”
- Bacteria often found in the throat and on the skin
- Diseases caused by GAS:
  - Pharyngitis (strep throat)
  - Scarlet fever
  - Impetigo
  - Cellulitis
  - Rheumatic fever
  - Post-streptococcal glomerulonephritis
  - Streptococcal toxic shock syndrome (STSS)
  - Necrotizing fasciitis



Source: CDC

Source: CDC Group A Streptococcal (GAS) Disease

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Overview: infection types

- Symptomatic infection:
  - **Invasive GAS (iGAS):** isolation of GAS from a normally sterile site (e.g., blood, muscle) or from a non-sterile site (e.g., wound) in the presence of STSS or necrotizing fasciitis
  - **Noninvasive GAS:** isolation of GAS from a non-sterile site (e.g., throat, wound) with symptomatic infection (e.g., pharyngitis, wound infection) that does not meet the invasive definition
- Colonization: isolation of GAS bacteria on the skin or in the throat of an individual with no signs or symptoms of infection

Source: CDC Group A Streptococcal (GAS) Disease

Overview: routes of transmission

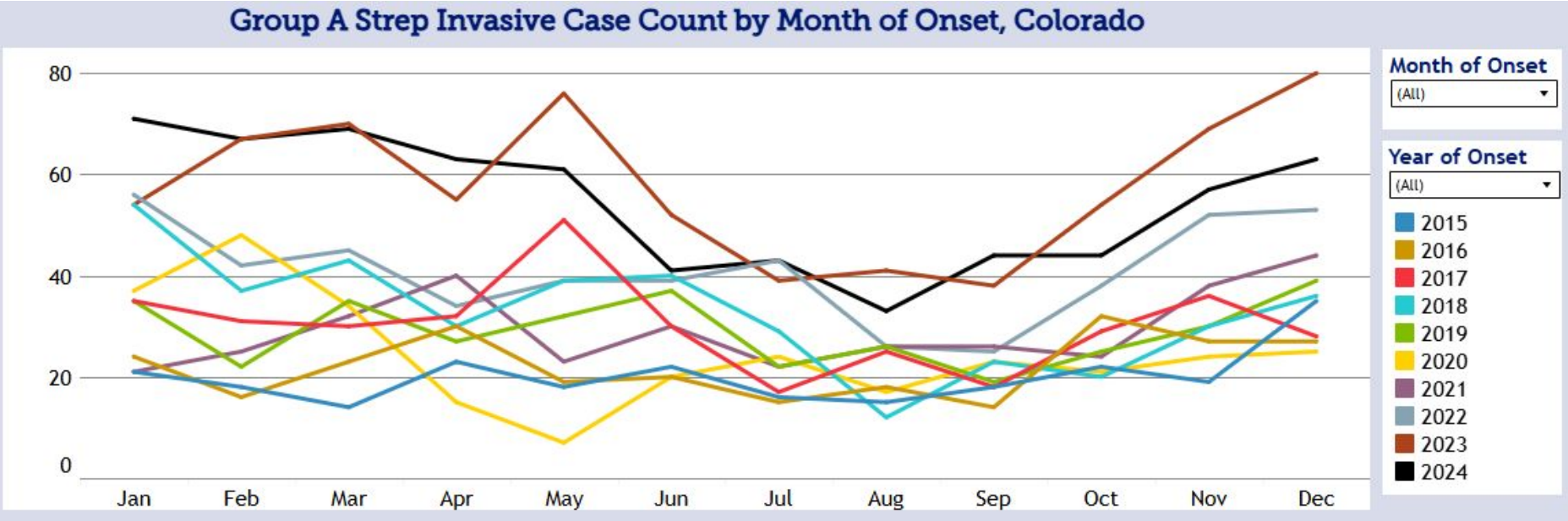
- Humans are the primary reservoir of GAS.
- Can be transmitted from an infected or colonized person
- Direct transmission (person to person)
  - Respiratory droplets
  - Contact with saliva, nasal secretions, wound discharge, skin lesions
- Indirect transmission (environmental)
  - Contaminated equipment or surfaces

Source: CDC Group A Streptococcal (GAS) Disease

Surveillance: reporting

- Invasive GAS (iGAS) is a laboratory reportable condition in the five-county Denver metro area.
- All outbreaks (known or suspected) are reportable statewide.
- CDPHE HAI/AR Program conducts routine surveillance of reported iGAS cases to identify and respond to cases with exposure to a long-term care facility (LTCF) in the 14 days prior to positive culture.

Surveillance: iGAS data



Source: [CDPHE Colorado Reportable Disease Data]

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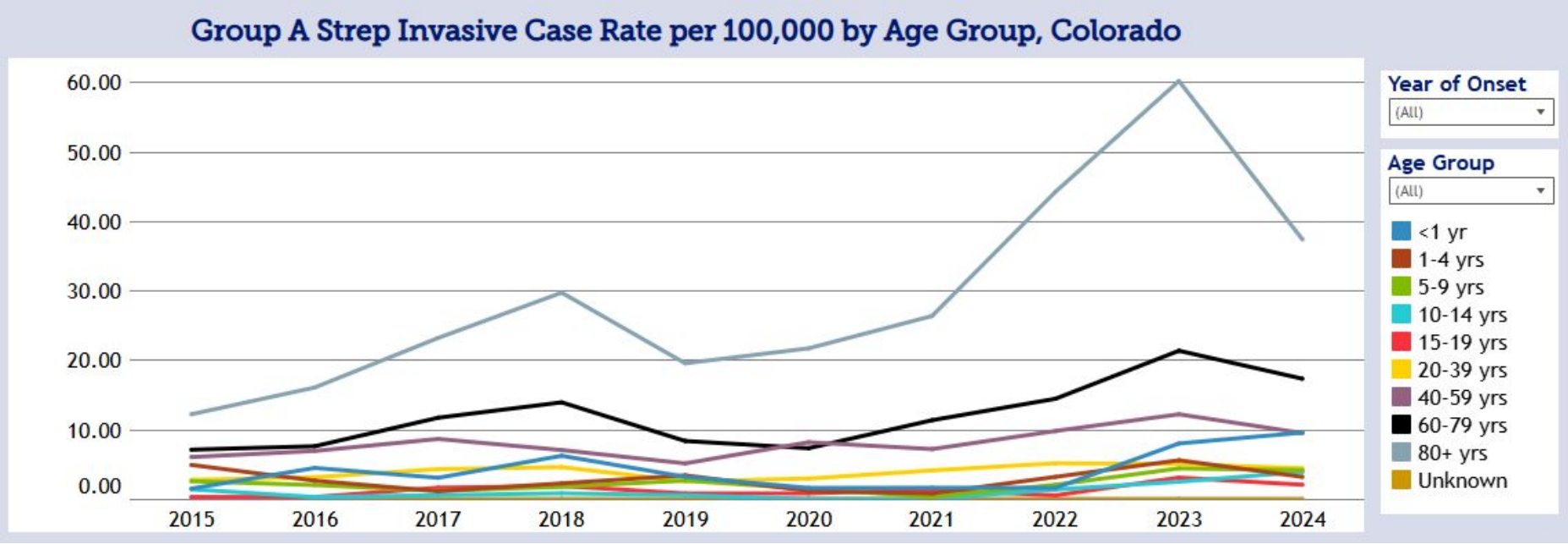
Surveillance: iGAS data



Source: [CDPHE Colorado Reportable Disease Data]

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Risk factors: LTCF population

- Rates of iGAS infection and death increase with age.
- Older adults living in LTCFs compared to age-matched adults in community
  - 3- to 8-fold higher incidence of iGAS infections
  - 1.5 times more likely to die from iGAS infections
- Underlying medical conditions
  - Cancer
  - Chronic heart, kidney, or lung disease
  - Diabetes
  - Immunocompromising conditions
  - Wounds or skin disease

Source: CDC Group A Streptococcal (GAS) Disease

Risk factors: transmission within LTCFs

- Transmitted by residents, visitors and/or health care personnel (HCP)
- Transmission has been associated with:
  - Having a roommate infected or colonized with GAS
  - Residing on the same unit as a resident infected or colonized with GAS
  - Being cared for by the same HCP as a resident infected or colonized with GAS
  - Being cared for by staff infected or colonized with GAS
- Lapses in infection prevention and control practices allow spread.
  - Hand hygiene and glove use
  - Wound care
  - Supplies/equipment

Source: CDC Group A Streptococcal (GAS) Disease

Prevention: identify cases

- Educate staff on signs and symptoms of GAS infection.
  - Pharyngitis
  - Skin and wound infections (e.g., impetigo, cellulitis)
  - Necrotizing fasciitis
  - Streptococcal toxic shock syndrome

- Test symptomatic residents and staff.
  - Implement transmission-based precautions for residents and exclude staff.
  - Treat as clinically indicated.

- Cases of iGAS are often identified and reported by acute care hospitals.
  - Review medical records, transfer notes, laboratory reports, and discharge summaries to rule out GAS infection in hospitalized residents.

Prevention: infection prevention and control

- Staff education and continued observations
- Focus areas
  - Hand hygiene
  - Wound care
  - Supplies and medication storage and preparation
    - Separation of clean and dirty
    - Dedicate supplies to individual residents.
    - Limit supplies going room to room.
  - Environmental services
  - Enhanced barrier precautions
    - When TBP, do not otherwise apply

Source: CDC

Response: single case

- Retrospective and prospective surveillance
- Survey residents and staff for signs and symptoms.
  - Test, isolate, and treat positives as clinically indicated.
- Screen roommates and close social contacts.
  - Treat positives with a regimen for clearing carriage.
  - Rescreen positives 7-10 days after completion of antibiotics.
- Visual assessments of staff infection control practices
  - Hand hygiene and personal protective equipment use
  - Cleaning and disinfection of environmental surfaces and shared medical equipment
  - Direct care activities based on the site(s) of infection (e.g., wound care, device care, respiratory care)

Source: CDPHE GAS Toolkit for LTCFs

Response: outbreak

Definition: Two or more symptomatic cases among LTCF residents, where at least one specimen is invasive GAS, with symptom onset in a four-month period

- Notify CDPHE.
- Investigate potential links between cases.
- Perform additional screening of residents and health care personnel.
  - Geographical location (units, hallways, etc.)
  - Epidemiological links (short stay vs. long stay, wound care, respiratory care, etc.)
- HAI/AR infection prevention onsite assessment
- *Emm* typing and whole genome sequencing to determine relatedness
- Prospective surveillance for four months following most recent GAS case

Resources

CDPHE Group A *Streptococcus* (GAS) Toolkit for LTCFs

CDC Decision Tool for Investigating Group A *Streptococcus* Infections in Long-Term Care Facilities

CDPHE Wound Care Assessment Tool

CDPHE healthcare-associated infections (HAIs)

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- Report cases and outbreaks
- Questions and concerns

Viral respiratory disease updates

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Respiratory disease surveillance components

- Sentinel lab positivity
- Syndromic surveillance (via emergency department and outpatient visit data)
- Wastewater data
- Sentinel lab specimen submission (e.g., subtyping, variants)
- Cases
- Outbreaks
- Hospitalizations
- Mortality

2025-2026 viral respiratory season update

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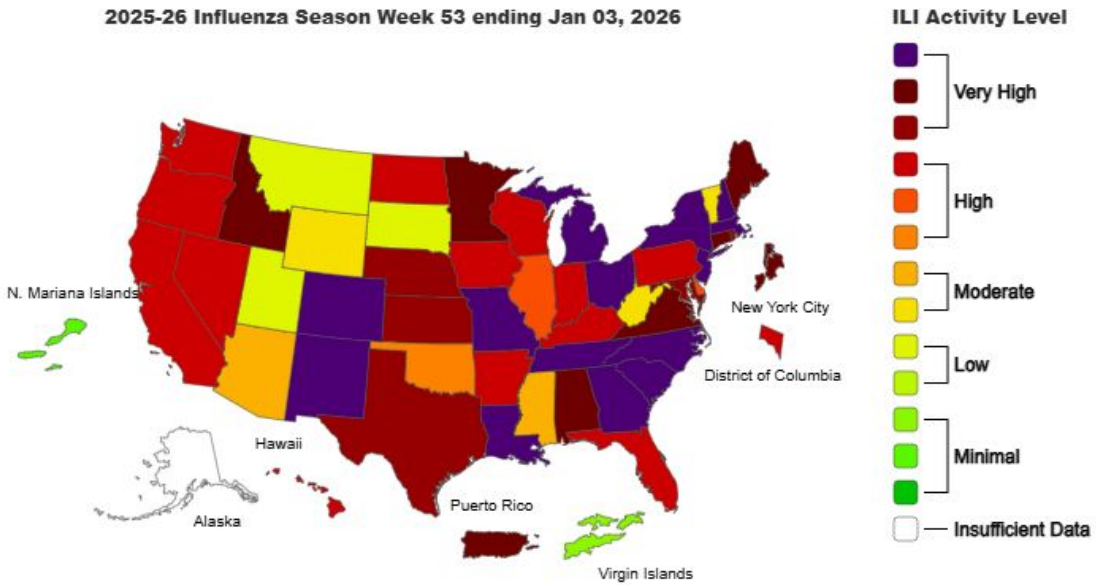
Current activity in Colorado

- National: [Seasonal flu activity remains elevated across the country]



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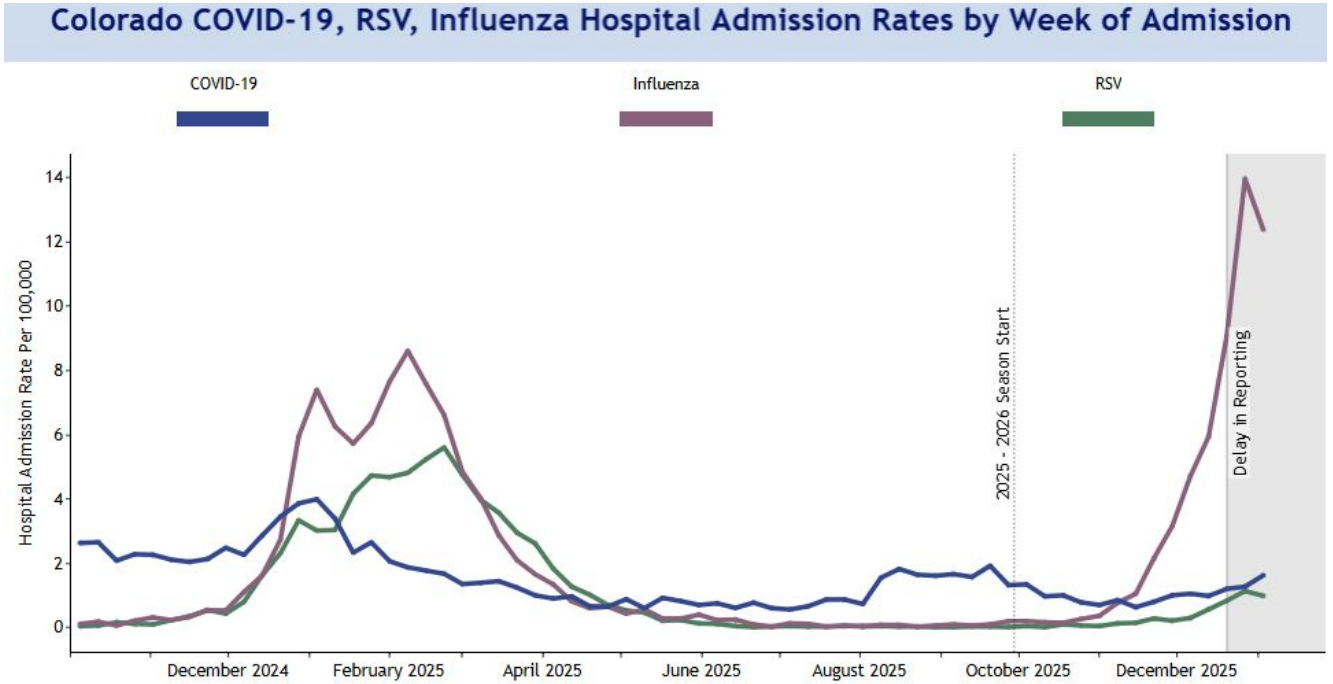
Current activity in Colorado (cont.)

- Colorado: cdphe.colorado.gov/viral-respiratory-diseases-report



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Current activity in Colorado (cont.)

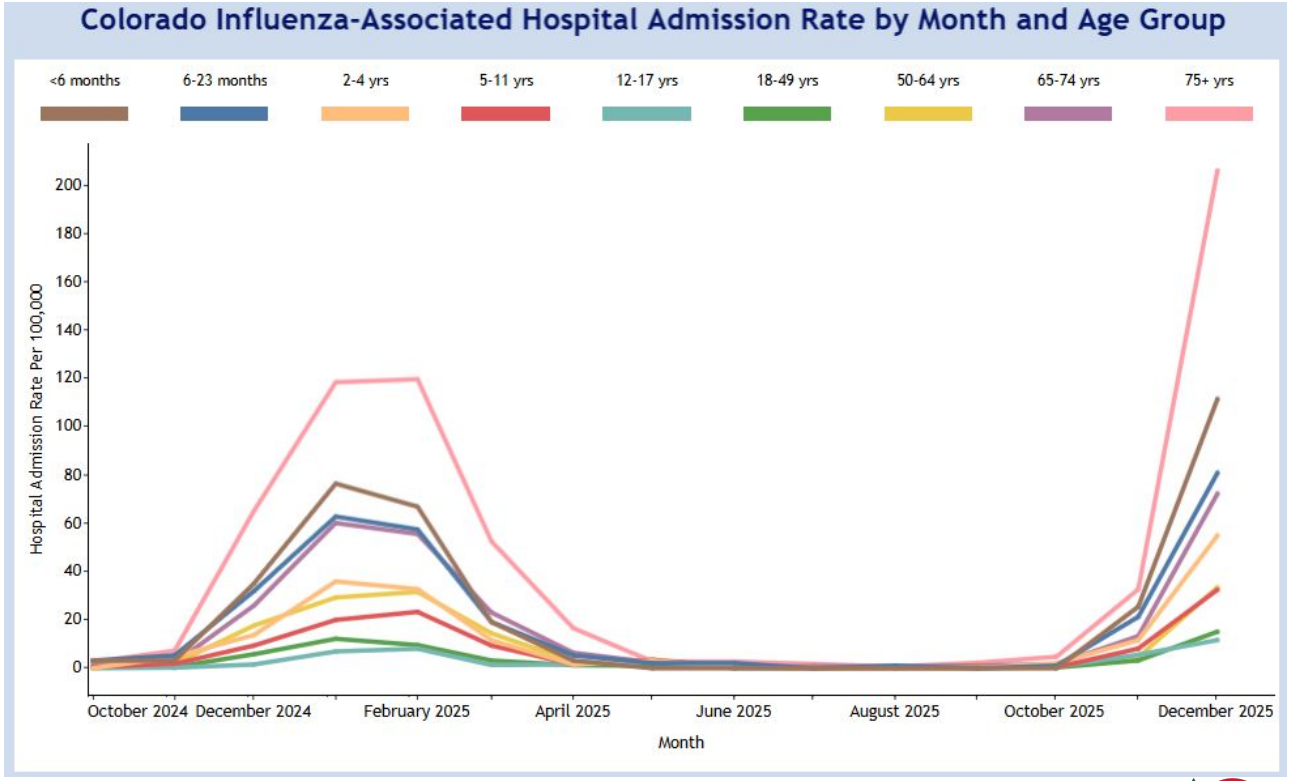
- Record no. of hospitalizations reported in the week ending Dec. 27 (831)
  - Previous high occurred during the same week in the 2014-15 season (582)
  - Indicators dipped slightly over the holiday weeks, still watching
- Season began ~four weeks earlier than a typical season, although early starts have been observed before (e.g., 2022-23 season)
- Emergence of new strain of type A/subtype H3N2 called subclade K likely explains the early and sharp increase in activity
  - Not included in this season's vaccine
  - Of specimens tested at our lab in December, ~90% have been identified as subclade K.

Current activity in Colorado (cont.)

Key Metric Changes This Week Compared to Last Week

Pathogen	ED Visits Diagnosed	Weekly Sentinel Positivity Rate
COVID-19	0.88% (▲0.17)	3.91% (▲0.62)
Influenza*	7.35% (▼2.29)	24.85% (▼8.24)
RSV	0.18% (▲0.01)	4.42% (▲2.58)

Current activity in Colorado (cont.)



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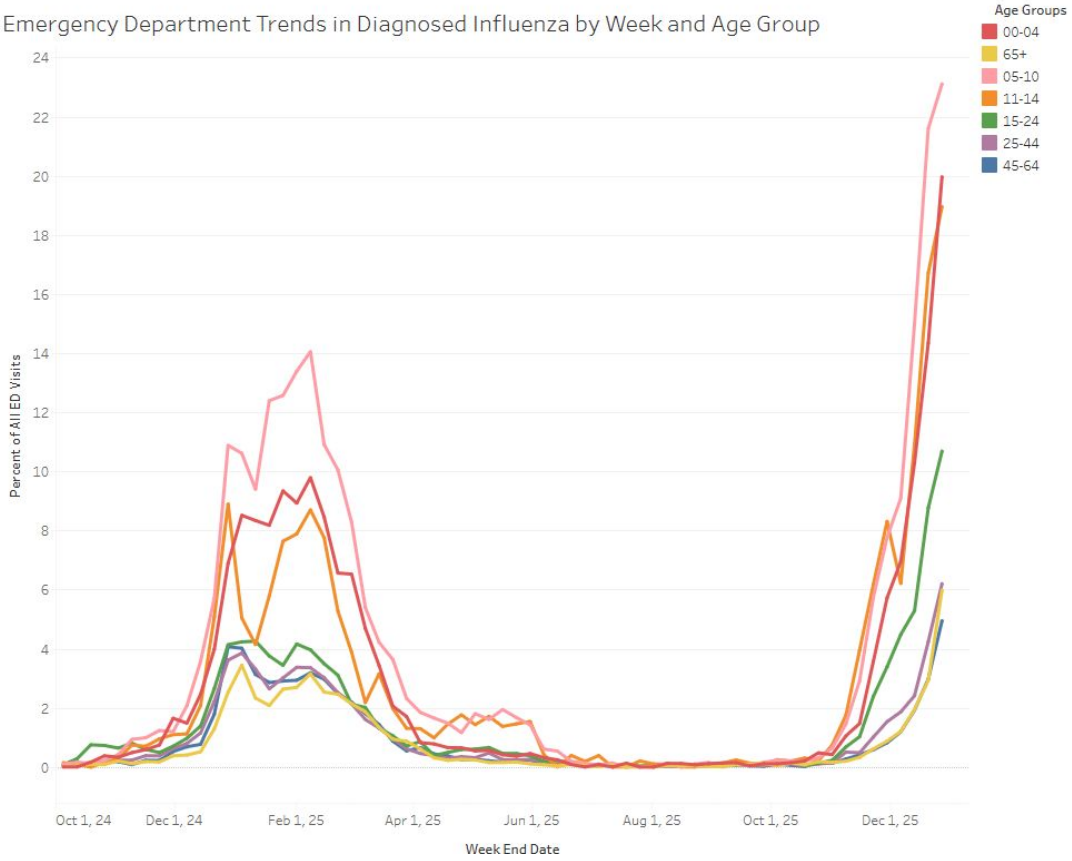
Current activity in Colorado (cont.)



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Viral respiratory disease outbreaks

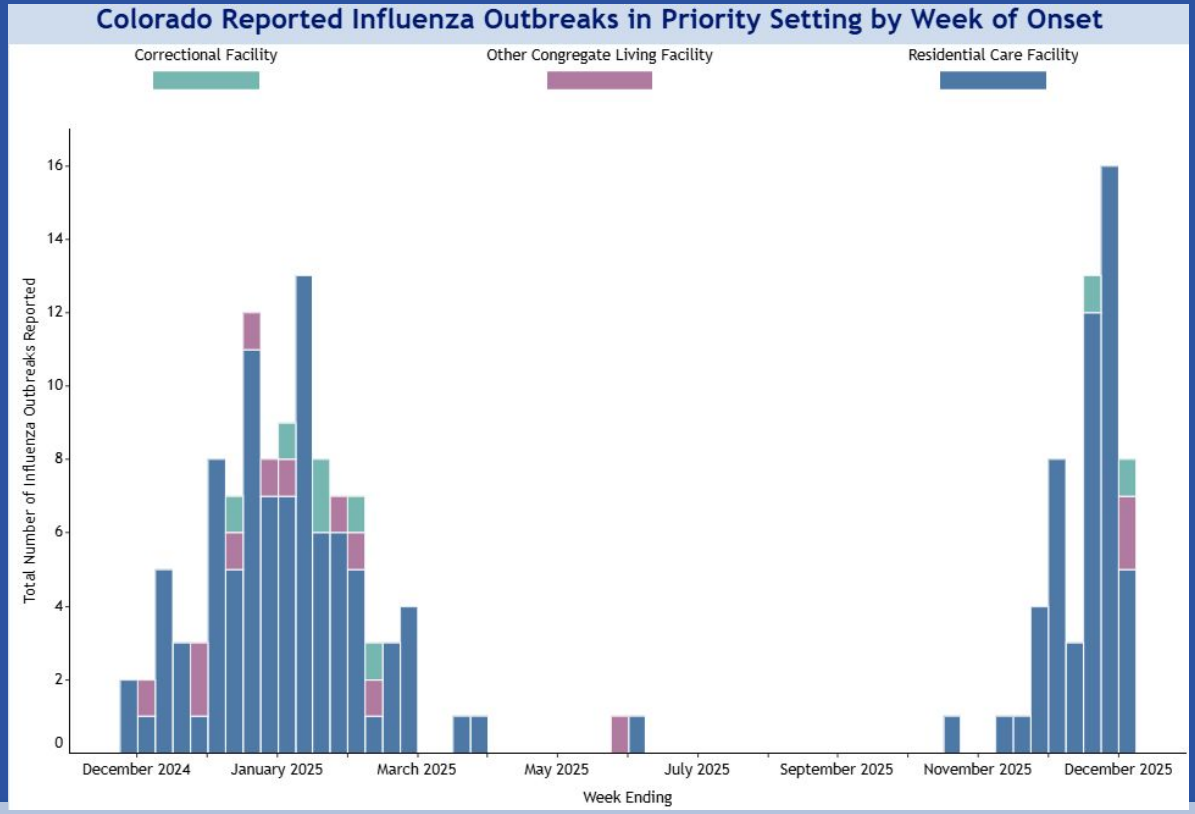
Reportable outbreaks

- All communicable disease outbreaks are reportable to CDPHE.
- Priority settings captured in outbreak counts on our dashboard:
  - Flu and COVID-19 in LTCFs/residential care/congregate settings, correctional facilities
  - RSV in LTCFs/residential care/congregate settings and schools/child care facilities
- Other viral respiratory etiologies that might be investigated:
  - Increased severity of symptoms
  - High levels of reported school absenteeism
  - High transmission levels of illness in the community
  - E.g., croup, pneumonia, bronchitis

Clinical presentation of viral respiratory illness

- Symptoms associated with respiratory illness caused by viruses like influenza, RSV, and SARS-CoV-2 can be similar.
  - Examples: fever, cough, congestion, fatigue, shortness of breath
- Determining which virus is causing illness can be difficult based on symptoms alone.
  - Diagnostic testing is helpful for determining the cause(s) of illness.
  - Informs need for isolation precautions.

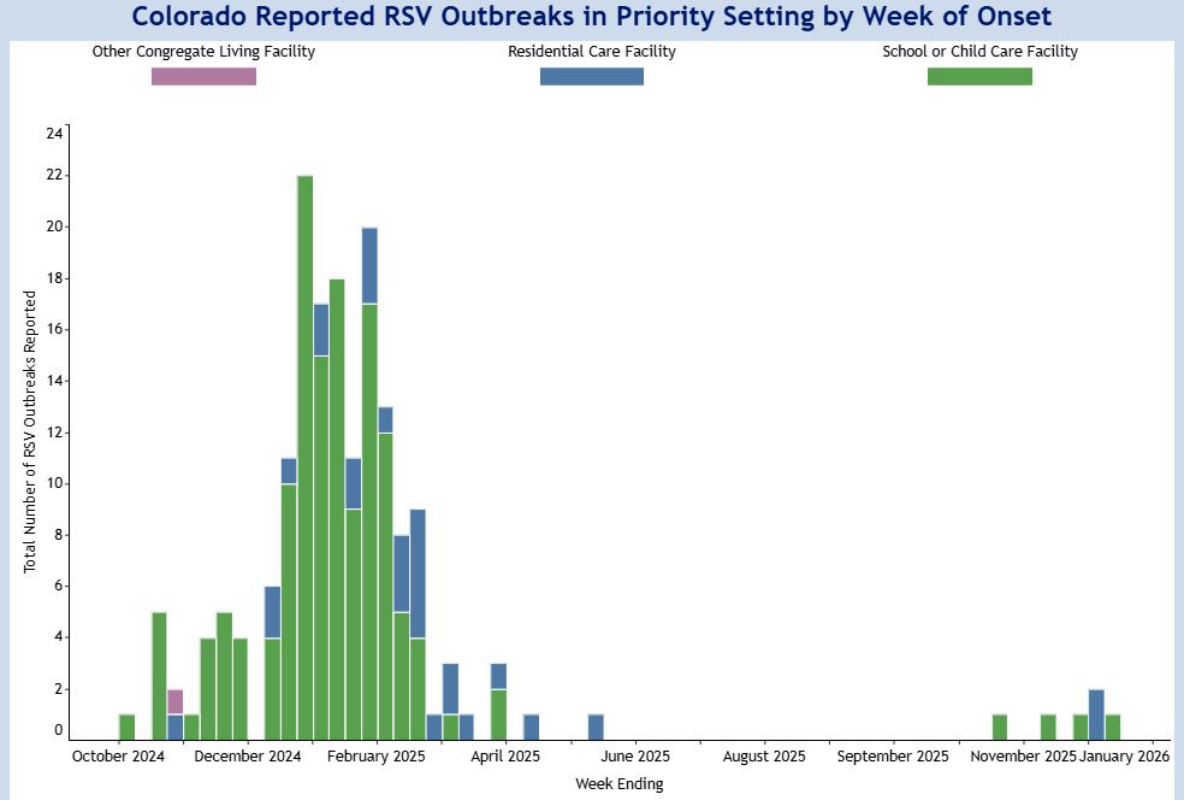
Influenza outbreak surveillance



Influenza outbreaks reported by setting type by season:

Season	RLTCFs	Correctional facilities
2022-2023	53	3
2023-2024	54	7
2024-2025	95	6
2025-2026	52	2

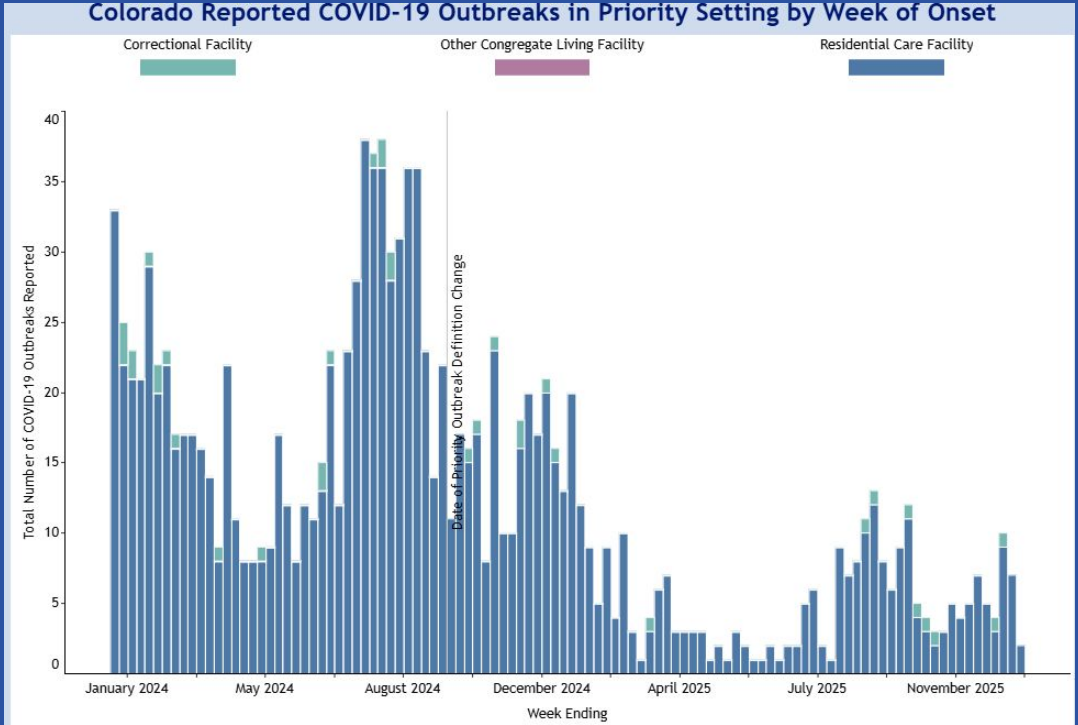
RSV outbreak surveillance



RSV outbreaks reported by setting type by season:

Season	School/child care settings	RLTCFs
2022-2023	458	29
2023-2024	141	41
2024-2025	139	28
2025-2026	4	2

COVID outbreak surveillance



COVID outbreaks reported by setting type by season:

Season	Schools/child care	RLTCFs	Corrections
2022-2023	17	1348	49
2023-2024	15	1377	35
2024-2025	N/A	405	10
2025-2026	N/A	79	6

Outbreak stuff

- **Chemoprophylaxis guidance has not changed**: “Once an influenza outbreak is confirmed, antiviral chemoprophylaxis is recommended for all medically eligible asymptomatic residents (regardless of whether they received an influenza vaccine).”
- COVID tests: Much of federal COVID-19 resources/funding ended with the end of the federal public health emergency in 2023; responsibility for purchasing tests/supplies transitioned back to facilities as part of routine care/operations.
    - LPHAs may be able to provide test kits.

Viral respiratory guidance/resources

Viral respiratory disease surveillance data

- Colorado viral respiratory diseases report

Guidance documents

- Outbreak guidelines for nursing facilities and intermediate care facilities
- Outbreak guidelines for assisted living residences and group homes
- Companion document for 2025-2026 outbreak guidelines for residential and long-term care facilities

Additional resource:

- Communicable disease manual pages for influenza and RSV can be found at cdphe.colorado.gov/communicable-disease-manual

Team email: cdphe_flu_rsv@state.co.us

Thank you!

Email: cdphe_flu_rsv@state.co.us or deborah.aragon@state.co.us

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Thank you!

Additional questions?

Email: cdphe_hai_ar@state.co.us

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