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LTC COVID-19 Update

Presented by:

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Indiana Department of Health

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Today's Topics

- CMP Application and Process – Amy Kent
- Vaccine Mandate Survey process – Brenda Buroker and Tammy Alley
- NHSN Reporting Support – Kara Dawson
- CDC ISDH Updates and next weeks agenda – Lori Davenport
- Q&A

***Developing an Exceptional Infection Control & Prevention Program**, a webinar on Feb. 15, details HERE*

***Spring Conference: Recruitment & Retention**, April 18-20 in French Lick, registration opens Feb. 15, details HERE*

Indiana Department of Health

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2/9/22

OUR MISSION:

To promote, protect, and improve the health and safety of all Hoosiers.

OUR VISION:

Every Hoosier reaches optimal health regardless of where they live, learn, work, or play.

F-888 COVID-19 Facility Staff Vaccination

F-888

§483.80 Infection control §483.80(i) COVID-19 vaccination of facility staff.

The facility must develop and implement policies and procedures to ensure that all staff are fully vaccinated for COVID-19. For purposes of this section, staff are considered fully vaccinated if it has been 2 weeks or more since they completed a primary vaccination series for COVID-19. The completion of a primary vaccination series for COVID-19 is defined here as the administration of a single-dose vaccine, or the administration of all required doses of a multi-dose vaccine.

Healthcare Staff Vaccination

- COVID-19 vaccination requirements for healthcare providers and suppliers **do not** apply to residential care facilities
- We are clarifying if RCFs with Medicaid waiver are included
- The following information only applies to SNF/NF facilities

Who is Required?

(1) Regardless of clinical responsibility or resident contact, the policies and procedures must apply to the following facility staff, who provide any care, treatment, or other services for the facility and/or its residents:

(i) Facility employees;

(ii) Licensed practitioners;

(iii) Students, trainees, and volunteers; and

(iv) Individuals who provide care, treatment, or other services for the facility and/or its residents, under contract or by other arrangement.

(2) The policies and procedures of this section do not apply to the following facility staff: (i) Staff who exclusively provide telehealth or telemedicine services outside of the facility setting and who do not have any direct contact with residents and other staff specified in paragraph (i)(1) of this section; and (ii) Staff who provide support services for the facility that are performed exclusively outside of the facility setting and who do not have any direct contact with residents and other staff specified in paragraph (i)(1) of this section.

Policy and Procedure Requirements

1. A process for ensuring all staff (as prior slide), except for those with pending exemption or exemptions or those staff whose vaccine is delayed as recommended by the CDC due to clinical cautions and considerations, have received one dose of 2 dose primary series or the single dose vaccine prior to providing care, treatment or other services for the facility or residents
2. A process for ensuring all staff are fully vaccinated (not including booster) except those excluded above
3. A process for implementing additional precautions, intended to mitigate the spread of COVID-19 for all staff who are not fully vaccinated

Policy: Additional Precautions

CMS has not stated what these strategies must be, but did give some suggestions in the Infection Prevention, Control & Immunization Pathway (January 2022):

- Additional precautions that **may include but are not limited to:**
  - Reassigning staff who have not completed their primary vaccination series (including those who have pending requests or been granted an exemption, or who have a temporary delay) to non-resident areas, to duties that can be performed remotely (i.e., telework), or to duties that limit exposure to those most at risk (e.g., assigning to residents who are not immunocompromised, unvaccinated).
  - Requiring staff who have not completed their primary vaccination series (including those who have pending requests or been granted an exemption, or who have a temporary delay) to follow additional, CDC-recommended precautions, such as adhering to universal source control and physical distancing measures in areas that are restricted from resident access (e.g., staff meeting rooms, kitchen), even if the facility or service site is in a county with low to moderate community transmission.

Additional Precautions

- Requiring at least weekly testing for staff who have not completed their primary vaccination series (including those who have pending requests or been granted an exemption, or a temporary delay) or until the regulatory requirement is met. Weekly testing should be conducted in the facility or services site regardless of the level of community transmission.

- Requiring staff who have not completed their primary vaccination series (including those who have a pending request or been granted an exemption or who have a temporary delay) to use a NIOSH-approved N95 or equivalent or higher-level respirator for source control, regardless of whether they are providing direct care to or otherwise interacting with residents.

Policy: Tracking and Documenting

4. Process for tracking and securely documenting the COVID-19 vaccination status of all staff, including:
   - Staff who are fully vaccinated
   - Staff who have received the booster
   - Staff who have requested an exemption based on applicable State and Federal Laws and those who have been granted an exemption.
     - Medical exemptions must contain recognized clinical contraindications (for which vaccine of the authorized COVID-19 vaccines) and must be signed and dated by a licensed practitioner, with a statement authenticating that the exemption is based on the recognized clinical contraindications.

   In general, CDC considers a history of a severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a component of the COVID-19 vaccine, an immediate allergic reaction of any severity to a previous dose, or known allergy to a component of the vaccine, to be a contraindication to COVID-19 vaccination.

Policy: Tracking and Documenting

Requests for non-medical exemptions, such as religious in accordance with Title VII, must be evaluated and documented according to federal law. **Surveyors will NOT evaluate acceptance or denial of non-medical exemptions but ensure there is a process for requesting such exemption.**

- Staff whose vaccination must be temporarily delayed, as recommended by CDC (website under medical exemptions)
- Secure Documents: CMS has indicated vaccine documentation does not have to be stored onsite but must be presented upon request

Policy: Tracking and Documenting

5. Contingency plans for staff who are not fully vaccinated for COVID-19: Plans should address staff who are not fully vaccinated due to an exemption

   IC pathway questions:

   - What are the actions the facility will take when staff indicate they will not get vaccinated and do not qualify for an exemption?
   - Review the facility's plan to ensure it addresses staff who are not fully vaccinated due to an exemption or temporary delay in vaccination. The plan should prioritize those staff that have obtained no doses of any vaccine over staff that have received a single dose of a multi-dose vaccine.
   - Does the contingency plan include a deadline for staff to have obtained the COVID-19 vaccine?
   - Does the plan indicate the action taken if the deadline is not met?

Survey Process: Off-site prep

- **Surveyors will investigate for compliance of these requirements as part of initial, standard recertifications, and ALL complaint surveys**
- **Off-site prep:**
  - Obtain NHSN COVID-19 vaccination data.
  - Link provided in IC pathway: this link
  - Once the link is opened, go to the task bar and click sort and filter, and double click filter in the drop down. The filter arrows will then be on the spreadsheet. Click the arrow and you can put in the facility name. Then scroll over to "Recent Percentage of Staff who are Fully Vaccinated." Place the percentage on the IC Pathway.

Survey Process: Entrance

Entrance Conference

- Request COVID-19 policy and procedures for staff vaccination.
- A numbered list of resident and staff COVID-19 cases over the last 4 weeks and indicate if any of these cases resulted in hospitalization or death.
- A list of all staff and their vaccination status including, title, position, and assigned work area.
- The percentage of staff vaccinated.
- Providers may use the COVID-19 Staff Vaccination Matrix Instructions for Providers: Matrix instructions for providers can be found in the survey resource folder on CMS website, or this resource was sent out in LTC Newsletter 2022-08 Feb. 3, 2022.

Investigation Process

- Compare NHSH data with facility provided information (matrix data) to see if this data is reasonably consistent. If there is more than a 10% disparity, determine the source and explanation for this difference.
- There are variables that could be related NHSH coding of exemptions for staff.

A difference will not automatically result in a F888 finding

Investigation

Surveys conducted at 30–59 day threshold: beginning Feb. 14 and ending on March 14, 2022

Compliant if:

- Can demonstrate that policy and procedures are developed and implemented
- 100% of staff have received at least one vaccine (does not have to 14 days after to count) or
- Have a pending request for/and or granted an exemption or has temporarily delayed vaccination.
- If the percent vaccinated is less than 100% of all staff have received at least **one dose** of COVID-19 vaccine, or have a **pending** request for, or have been granted a qualifying exemption, or identified as having a temporary delay as recommended by the CDC, cite F888.
- Formula to determine percentage of vaccinated staff is in Section III of the Matrix.

#partially vac + #completely vac + #pending exemptions + #granted exemptions + #temporally delayed

divided by total staff x 100

Enforcement at the 30-59 day threshold

CMS expects all staff to receive the appropriate doses by the timeframes specified in QSO-22-07-All.

- For facilities who demonstrate 80-99% of staff received at least one dose of COVID-19 vaccine, have pending exemption, exempted, or a temporary delay, the facility is non-complaint and will be cited for F888.
- If the facility is above 80% with plans in place to achieve 100% staff vaccination rate within the 60 days, they will not be subject to CMS enforcement.
- If the facility is below the 80% of staff having received at least one dose of COVID-19 vaccine, have pending exemption, exempted, or a temporary delay, the facility is non-compliant, will be cited at F888, and COULD be subject to additional enforcement actions.

Investigation

- Surveys conducted 60-89 days; the facility is compliant if:
  - All policies and procedures have been developed and implemented, and
  - 100% of staff have received necessary doses to complete the vaccine series, or have been granted an exemption, or identified as having a temporary delay for vaccination.
- 60 days and thereafter staff vaccination formula:

 # completely vaccinated + # granted exemptions + Temporary delayed

Divided by total staff x 100 = % Vaccinated

- Remember the 14-day waiting period does not have to occur to include staff in the vaccination rate

Enforcement at 60-89 days and 90 days and after threshold

During this time frame, if the facility is not 100% complaint with all staff having received the first dose of multi-dose series or single dose vaccine, has been granted an exemption or a temporary delay, then the facility is noncompliant as previous slide will be cited at F888.

- If the facility is above 90% and has a plan to achieve 100% vaccination rate within 30 days, the facility would not be subject to enforcement.
- If the facility is below the 90% of staff completed the primary series (multi-dose of single) or have been granted an exemption or a temporary delay, the facility is non complaint and will be cited at F888 and COULD be subject to additional enforcement actions.

Enforcement at 90 days and after

- Facilities are expected to be 100% complaint with the requirement. If not F888 will be cited, and the facility COULD be subject to enforcement actions

Surveying on site: Follow IC pathway

- Focus investigation regularly on staff who provide services (e.g., weekly)
- Review policies and procedures
- Select 8 staff from the matrix or facility list
  - 2 vaccinated staff: One CNA and one contracted staff (e.g., hospice, dialysis, therapists, licensed practitioners …) this list is not all inclusive
  - 6 unvaccinated staff (if any exist): 3 (two CNAs) without exemption or delay, one with a non-medical exemption, one with a medical exemption (if there are more than 2 staff with a medical exemption, review 50% of this category), and one whose primary series is delayed.
  - If no staff meet one of the unvaccinated criteria, DO NOT increase the sample size for another area to make the total 6.
  - If surveyor identifies an unvaccinated staff, without exemption or delay, that were not on Matrix, add this individual to the matrix.

Surveying on Site

- Observe and interview SAMPLED unvaccinated staff, to determine if additional precautions are in place. (discussed in previous slide)
- Review documentation to verify staff vaccination status: a single dose of COVID-19 vaccine, all required doses for multi-dose series and any boosters received. (If this data cannot be identified then look at F887 for additional information)

Surveying on Site: Medical Exemptions

Review documentation of medical exemptions to determine if secure, tracked and contain:

- Which vaccine is clinically contraindicated
- The recognized reason for the contraindication (CDC link or previous slide)
- A statement recommending the exemption
- A signature and date by a licensed practitioner who is not the individual requesting the exemption.

Surveying on Site: Non- Medical Exemption

- Review documentation for staff who requested non-medical exemption to determine if the requests are secure and tracked.
- Interview staff to see if they know the process to request a non-medical exemption and how they are informed about the process.

Surveyors will not evaluate details of requests for non-medical exemptions or the rational of the facilities acceptance or declination of the request.

Surveying on Site: Unvaccinated without exemption or delay

Interview staff and review documentation for unvaccinated staff without exemption or temporary delay.

- Is the staff scheduled for a vaccine or have they requested an exemption?
- When was the facility aware the staff did not have an exemption or temporary delay?
- What has the facility done to educate and offer the vaccine?
- What actions has the facility taken when staff indicated they will not get vaccinated or qualify for an exemption?

The facility should follow their policies and procedures.

Severity Compliance Determination

Severity will be based on the following criteria:

- **Level 4 - Immediate Jeopardy (IJ)**
  - **Noncompliance resulting in serious harm or death:**
    - Did not meet the requirement of staff vaccinated or has no policies and procedures developed or implemented; **and**
    - 3 or more resident infections in the last 4 weeks resulting in at least one resident experiencing hospitalization (i.e., serious harm) or death.
  - **OR, Noncompliance resulting in a likelihood for serious harm or death:**
    - Did not meet the requirement of staff vaccinated; **and**
    - 3 or more resident infections in the last 4 weeks that did not result in serious harm or death; **and**
    - One of the following: Any observations of noncompliant infection control practices by staff, (e.g., staff failed to properly don PPE so F880 would also be cited); or 1 or more components of the policies and procedures to ensure staff vaccination were not developed or implemented. **OR,**
    - More than 40% of staff are unvaccinated and there is evidence of a lack of effort to increase staff vaccination rates.

Severity Compliance Decision

- **Level 3: Actual Harm that is not IJ**
  - Did not meet the requirement of staff vaccinated; **and**
  - 3 or more resident infections in the last 4 weeks which did not result in hospitalization (i.e., serious harm) or death, or the likelihood for IJ for one or more residents; **and**
  - 1 or more components of the policies and procedures were not developed and implemented.
- **Level 2: No actual harm w/potential for more than minimal harm that is not IJ**
  - Did not meet the requirement of staff vaccinated; **and**
  - No resident outbreaks **OR,**
  - Did not meet the requirement of staff vaccinated; **and**
  - 1 or more components of the policies and procedures not developed and implemented

Severity Compliance Decision

- **Level 1:**
  - Met the requirement of staff vaccinated; and
  - 1 or more components of the policies and procedures to ensure staff vaccination were not developed and implemented (must be cited as widespread (“C”).

Scope

Isolated: 1% or more, but fewer than 25% of staff are unvaccinated (76% – 99% of staff are vaccinated).

Pattern: 25% or more, but fewer than 40% of staff are unvaccinated (61% – 75% of staff are vaccinated).

Widespread: 40% or more of staff are unvaccinated (0% - 60% of staff are vaccinated), OR 1 or more components of the policies and procedures listed above were not developed and implemented.

Components of Plan of Correction Or IJ Removal

- Correcting any gaps in the facility's policies and procedures.
- Implementation of the facility's contingency plan, that should include a deadline for each unvaccinated staff to have received their first dose of a vaccine.
- Implementation of additional precautions (see §483.80(i)(3)(iii)) to mitigate the spread of COVID-19 by unvaccinated staff.

Plan of Correction

To Qualify for Substantial Compliance and Clear the Citation:

- The facility has met the requirement of staff vaccinated (either by staff obtaining additional doses, or replacing unvaccinated staff with vaccinated staff); **or**
- The combined number of staff that are vaccinated (have received a single dose of a single-dose vaccine, or all doses of a multiple vaccine series) or have received at least one dose of a multiple vaccine series meet the requirement of staff vaccinated.
  - Staff that have received at least one dose of a multiple vaccine series must also have their second dose scheduled.

Plan of Correction

To Qualify for Substantial Compliance, but the Citation Remains at Level 1 (“C”):

The facility has not met the requirement of staff vaccinated but has provided evidence that some of the unvaccinated staff have obtained their first dose, **and** other unvaccinated staff are scheduled for their first dose. For example, the citation at Level 1 would continue if there is evidence that 50% of staff who were identified as unvaccinated have received one dose of a multiple vaccine series with their second dose scheduled or are scheduled to receive one dose of a single-dose vaccine series.

Good Faith Effort

Surveyors and CMS may lower the scope and severity of a citation and/or enforcement action if they identify that any of the following **have occurred prior to the survey** (note: noncompliance is still cited, only the scope, severity, and/or enforcement is adjusted).

- If the facility has no or has limited access to the vaccine, and the facility has documented attempts to obtain vaccine access (e.g., contact with health department and pharmacies).
- If the facility provides evidence that they have taken aggressive steps to have all staff vaccinated, such as advertising for new staff, hosting vaccine clinics, etc.

Surveyor Vaccination

- QSO-22-10-ALL – Effective within 30 days of memo, Feb. 24, 2022
- COVID-19 vaccination status of surveyors performing onsite surveys for federal oversight of certified providers and suppliers. Per this guidance, surveyors performing this role are expected to be fully vaccinated against COVID-19.
- Leadership is aware of the memo and requirement and policies are being discussed.

Questions?

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What's New in February
CDC Updates and Revisions

Next week – ISDH will discuss the updated Clinical Guidance, Visitation and Activities Guidance and Infection Control Guidance
Highlighted Summary – next slides

ISDH Updates to Clinical Guidance, Infection Control Guidance, and visitation and Activities Guidance Newsletter

https://www.coronavirus.in.gov/professional-resources/

ISDH -- Red Zone vs Conventional Isolation

IF facilities have private rooms, there is **an option** to place COVID-19 residents throughout the facility provided **ALL** the following could be followed with full diligence without having a red zone. **If the facility is not confident of its ability to follow this guidance, they should continue to maintain a red zone for COVID-19 positive residents:**

Must Do All of the Following:

✓ COVID-19 positive resident in a private room with door closed.

✓2 residents in semi-private room and both positive for COVID-19 they may remain in the room together with TBP.

✓Don PPE before entering the room, doff and perform hand hygiene before exiting the room.

✓N95 respirator masks discarded upon exit.

This is conventional isolation

ISDH Visitation

✓ Facilities must instruct all visitors entering the TBP room to wear proper PPE – follow stop signs

✓IDOH has made PPE available for LTC facilities to order specifically for visitors thru the Langham portal.

CDC Updates and Revisions Highlights

CDC - Vaccination Status

Vaccination Status

Definition of vaccination status added – **“Up to date”**

A person that has received vaccination they are eligible for.

“Not up to date” – A person that has not received vaccinations they are eligible for.

CDC - Use of N95's – Stop and think

Follow the STOP signs for Yellow (suspected/unknown) and Red folks (confirmed COVID-19) and with aerosol-generating procedures. – we already do this regardless of county transmission rates.

Consider wearing:

Caring for a person who is not up to date with all recommended vaccines or unable to wear source control and in poorly ventilated areas.

CDC - Testing

Asymptomatic – close contact – regardless of vaccination status

Test immediately but not earlier than 24 hours after exposure.

If negative – test again 5-7 days after exposure.

COVID-19 positive within 90 days – testing is not necessary. If you test – use an antigen test.

CDC - Criteria to End Isolation for Patients with COVID-19

✓Asymptomatic

✓Mild to moderate illness

✓Not immunocompromised

TBP for 10 days after symptoms first appeared

CDC - Criteria to End Isolation for Patients with COVID-19

✓Severe to critical illness

✓Not severely immunocompromised

TBP for 10 days and up to 20 days since symptoms first appeared.

CDC - Criteria to End Isolation for Patients with COVID-19

✓Symptomatic and asymptomatic

✓Moderately to severely immunocompromised

A test-based strategy and if available consultation with an infectious disease specialist or other expert is recommended to determine when these patients can be released from isolation.

CDC - Quarantine for Residents

- ✓Resident with identified close contact
- ✓Not up to date with recommended vaccines
- ✓10 days minimum

CDC - No Quarantine for Residents…

✓Close contact and;

✓Asymptomatic and;

✓Up to date on all recommended vaccines and/or;

✓Recovered from COVID-19 infection in the prior 90 days

CDC - Visitation – not same as general population

✓Visitation should be delayed, if possible, when the following exists:

✓A positive viral test for SARS CoV2 infection

✓Symptoms of COVID-19

✓Close contact with someone with SARS CoV2 infection

Typically, until 10 days after last exposure or onset of symptoms has passed.

Q & A

Indiana Department of Health

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THANK YOU!