**Questions and Answers – Mandatory Vaccination Survey process and Updated Guidance 2/2022**

**Follow up questions to CMS Stakeholder call:**

**RE: Use of CMP monies for purchase of portable fans and portable room air cleaners with HEPA filters to increase or improve air quality**

The Visitation FAQs (updated 2/2/22) address in question 15, page 7, the use of $3,000 per facility including shipping cost may be requested. What will be the process for these requests? Can facilities purchase in advance and expect to receive the requested funding, or must they wait for IDOH approval?

When will the process be announced and can you have the announcement related to the process ready for February 10th weekly update call?

**Answer:** Details are being discussed and the information will be provided via the LTC Newsletter when available.

**RE: Requiring a visitor to test as a condition of entering the facility**

The Visitation FAQs (updated 2/2/22) address in question 16, page 7, “States can require visitors to test upon entry if the facility is able to provide a rapid antigen test.” Is this decision at the discretion of the individual facility, or must it be a “state” wide decision that this practice is acceptable? On the call, CMS referenced the state’s stance. What is the IDOH stance on testing visitors?

**Answer:** The department of health will not require facilities to test visitors. It will be a facility decision. Facilities can offer to test visitors if they have the resources.

If a visitor refuses to be tested, it should not be a barrier to permitting their entry if they meet the screening protocol.

Will COVID-19 positive tests from a visitor need to be reported to anyone? If yes, explain.

**ANSWER**: Yes, any testing the facilities do on their POC machine, whether positive or negative, must be reported either via the POC REDcap or NHSN POC Module or an ELR feed (some larger LTCs utilize this method).

Will Indiana State Department of Health Surveyors be required to be vaccinated and or request an exemption? If a surveyor is exempted from vaccination, will they be required, by you to wear or take additional precautions while on the job?

**ANSWER:** QSO-22-10-ALL directs state agencies to have a process to ensure surveyors who are not fully vaccinated do not participate as part of the onsite survey team performing federal oversight of certified providers and suppliers. Exemptions will be considered. Additional safeguards will be determined by the state. This is effective 2/24/2022.

**Questions regarding Surveys beginning 2/14 assessing mandatory vaccination**

**RE: CMS 20054- Infection Prevention, Control & Immunizations (January 2022)**

As there are instructions for use of this document for surveyors when conducting a COVID-19 Focused Infection Control (FIC) Survey (not associated with a recertification survey), is it accurate that this will be the only pathway used for either FIC, recertification, or complaint survey and the surveyor will use the portions applicable to the type of survey being conducted?

**ANSWER:** For a complaint survey, only Critical Element Pathway #s 13, 14 and 15 are evaluated.

**ANSWER:** A COVID-19 Focused Infection Control Survey not associated with a recertification survey would include this pathway except for CE #s 8 and 9.

Page 4, sixth bullet, states, “When COVID-19 is present in the facility, staff are wearing an N95 or equivalent or higher-level respirator instead of a facemask for aerosol generating procedures.” Is this not the expectation regardless of whether COVID-19 is present in the facility?

**ANSWER:** Yes, this is correct, our IDOH guidance requires N95 for all AGP in TBP and post 1 hour from procedure to allow air exchanges.

Will the STOP signs developed by the ISDH be changing? If yes, please explain the changes. There are no changes noted at this time.

Page 4, bottom of page, Transmission-Based Precautions (TBP), second bullet, “For a resident on droplet precautions: staff don a facemask and eye protection (goggles or face shield) within six feet of a resident and prior to room entry.” Does it remain acceptable to continue to wear the same facemask and face shield continuously unless soiled (i.e., new PPE does not have to be donned immediately prior to room entry)?

**ANSWER:** The same medical facemask with eye protection for green zone may be worn. N95 and eye protection may be worn between residents if within the yellow and red zone and should be doffed upon exit. If reuse is in place, only five donning’s for N 95 respirators. All masks, and N95 respirators should be discarded if soiled, damaged, or hard to breathe through before leaving the room. In option for TBP outside the red zone, N95 must be discarded before leaving the room. If adequate PPE is not available, then the red zone would be required for re-use of N 95.

Conventional isolation by resident room instead of COVID-19 RED, YELLOW and GREEN Zones would certainly promote resident centered care (stay in your own home), and relieve staffing demands while providing more capacity to admit individuals from the outside and more importantly care for the resident residing in the nursing home. When can Indiana expect to see this change – Go back to managing isolation like we did pre- pandemic?

We are not at the same place as we were 2 years ago. PPE is now readily available, but staff is not readily available.

**ANSWER:** CDC Guidance has not changed for the ideally recommending a red zone, however we have provided options in our updated guidance for those facilities that have private rooms or semi-private rooms when both residents are positive for COVID 19 to remain in TBP if the facility can meet the IC requirements.

Page 4, bottom of page, Transmission-Based Precautions (TBP), third bullet states, “For a resident on airborne precautions: staff don a fit-tested N95 or higher-level respirator prior to room entry of a resident.” As fit-testing is under the OSHA standard, will surveyors be requesting to review the documentation for fit-testing? The Respiratory Protection Program?

**ANSWER:** Surveyors will not review for fit testing or the Respiratory Protection Program.

Page 11, Infection Preventionist, second box, states, “The Infection Preventionist(s) works at least part-time at the facility.” Per the CDC guidance, “Interim Infection Prevention and Control Recommendations to Prevent SARS-CoV-2 Spread in Nursing Homes” Page 2, states, *“Assign one or more individuals with training in infection prevention and control to provide on-site management of the IPC Program. This should be a full-time role for at least one person in facilities that have more than one hundred residents or that provide on-site ventilator or hemodialysis services. Smaller facilities should consider staffing the IPC program based on the resident population and facility service needs identified in the IPC risk assessment.”* As this is different than F882, what will be the expectation? If the CDC guidance is used as standard, can the full-time IP also fill other roles during that full-time position?

Providers would ideally have an IP designated to the position full-time, however, resident care comes first, and it is rare not to be called upon while working in healthcare to stretch and cross cover items outside of the traditional job description. – this is reality.

**ANSWER:** Surveyors would only cite F882 if the facility did not have an IP at least part time.

Page 12, Policy and Procedure for Staff COVID-19 Vaccinations, 3rd bullet, states, “Additional precautions **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 which limit exposure to those most at risk (e.g., assigning to residents who are not immunocompromised, unvaccinated). Will this be viewed as restricting employees with an approved exemption from providing resident care? Or would the word “may” leave it at the discretion of the facility?

Leaving at the discretion of the facility will take into consideration contingency and crisis staffing models being used by the facility. Will the surveyors view compliance differently under different staffing plans? Such as, a provider using conventional staffing plan vs a provider under a crisis staffing plan.

**ANSWER:** The “may” means that they are additional precautions that the facility could put into their policy. It does not mean the staff would be taken off resident care only that staff should be using the additional safeguards. If the facility chooses to use different safeguards for different staffing models, they need to make that clear in the policy.

Page 13, first three bullets: Again, are these at the discretion of the facility due to the preceding “may” on page 12? The third bullet addresses “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.” **ANSWER:** Yes

This is again addressed on page 15 (third sub-bullet under the NOTE), which states, “Observe staff to determine whether they are using additional CDC-recommended precautions, including universal source control (use a NIOSH approved N95 or equivalent or higher-level respirator for source control).” **ANSWER:** Surveyors will observe to see if the facility policy is being followed.

It was stated on the CMS stakeholder call (2/2) that the expectation of CMS was NOT to “require” the wearing of an N95 at all times. Thus, this would appear to be at the discretion of the facility and as outlined in its policy as to the additional precautions to be taken.

How will the ISDH surveyors be trained to observe staff and how will they determine compliance with additional CDC precautions? Is this objective and/or subjective observations?

Please share how the surveyors are trained in this observation. **ANSWER:** The survey process is an objective review of facility practice. The surveyors first review the policy and then make observations of the practice of the facility staff. If there are differences noted, there will be follow-up interviews.

Page 13 addresses surveyor review of the documentation for the “medical exemption” but is silent as to a religious exemption. Should facilities anticipate any questions as to the documentation for the religious exemption, other than providing to the surveyor their policy in which such a request is addressed? Page 16 addresses staff “interview” of someone who has been granted a non-medical exemption to determine the “process.” Does this mean interview of staff and review of policy will be the extent of review of the granted non-medical exemption? **ANSWER:**  Yes, that is the intent.

What proof will surveyors need for vaccination exemptions for non-facility employees (not on the payroll) but are contacted or under arrangement? **ANSWER:** The sample is to include a non-facility employee who is vaccinated so there would be no exemptions reviewed or proof requested.

How long will surveyors give the facility to produce the vaccination information (documentation) for employees and/or employees not on payroll but under contact or other arrangement? ANSWER: By the end of the first day if needed. The Entrance Conference Checklist directs the facility to have the COVID-19 Staff Vaccination Status for Providers completed within 4 hours of survey entry.

Will surveyors be contacting vendors or interviewing contacted or arranged employees providing services, or treatments to residents? **ANSWER:** Not unless there would be a complaint requiring additional investigation into a specific person.

Do surveys have access to CHIRP and if so, how are they authorized to use it? no

**Questions/Clarifications that may be needed due to language in the new CDC guidance:**

RE: Interim Infection Prevention and Control Recommendations to Prevent SARS-CoV-2 Spread in Nursing Homes (Updated February 2, 2022)

Page 2- As previously questioned, please clarify as to the “full-time” role of the facility IP for applicable facilities. **ANSWER:** If facilities have greater than one hundred residents **it is recommended** to have a full time Infection Preventionist. F882 is the requirement that the facility must have an IP at least part time

Page3- Notification of the health department promptly of: Resident with severe respiratory infection resulting in hospitalization or death. Is this severe respiratory infection of any type? Yes

Is this a self-reportable event for any severe respiratory infection resulting in hospitalization or death using the gateway with a 5-day follow-up? **ANSWER:** Yes

Has Indiana changed any reportable requirements? **ANSWER:** No

Page 4- There is potential for question when the new testing guidance references a series of two “viral” tests for SARS COV-2 infection, and then later refers to the antigen for asymptomatic or recovered. Facilities may simply want to be assured antigen testing is acceptable viral testing for the series of two tests. **ANSWER:** A viral test is either an antigen or a PCR test. The antigen test may be preferred in those with a COVID-19 infection in the past 90 days.

Page 4- Addresses HCP who work infrequently being tested within the 3 days before their shift (including the day of the shift). There will be questions due to use of agency and not knowing “who” will be sent to the facility to the fill the shift- thus, an inability to accomplish/require testing 3 days prior. Does this only apply to the facility-employed infrequent (i.e., PRN) staff?

Is COVID-19 testing a requirement (three days before their shift including the day of the shift) when a facility is under contingency staffing plan or crisis staffing plan?

**ANSWER:** Follow QSO 20-38, revised 9/10/21.

Page 5- Regarding dedicated areas to care for confirmed COVID infection: This section addresses “if possible” HCP should avoid working on both the COVID unit and other units during the same shift. As staffing continues to become increasingly challenging, facilities will want to know if crossing zone “must” occur, this is still acceptable and they should use the practices that have been discussed in the past (i.e., batching tasks, performing non-time sensitive tasks to the red zone after completing duties on the green zone, etc..)

If a facility needs to transfer residents to a hospital or other setting because of staffing and the requirements under the vaccine mandate ----- who should they notify from the ISDH?

**ANSWER:** bburoker@isdh.in.gov

Page 6- “Residents should only be placed in a COVID-19 care unit if they have confirmed SARS-CoV-2 infection.” Thus, if a resident is symptomatic and antigen positive, or if the resident has been a close contact and tests antigen positive, the facility “can” leave them in TBP in place until the return of the PCR test? **ANSWER:** New guidance provides examples and options. If they are with a roommate, you are to follow the clinical guidance for exposures based on vaccination status for the roommate, and the symptomatic resident should be moved to the COVID red zone.

**RE: Interim Infection Prevention and Control Recommendations for Healthcare Personnel During the Coronavirus Disease 2019 Pandemic (updated 2/2/22)**

Page 5- “Performance of pre-procedure or pre-admission viral testing is at the discretion of the facility.” Does this imply facilities “can” require the hospital conduct viral testing prior to transfer to the facility? **ANSWER:** No, facilities cannot require the hospital conduct viral testing

2/8/22 Clinical Guidance - Testing: All new admissions and re-admissions regardless of vaccination status, should have a series of two viral tests for COVID-19 infection; immediately and, if negative, again 5-7 days after their admission.

The immediate testing is the responsibility of the facility.

From the Hospital to LTC transfer Guidance, dated 10/5/21 - LTCFs should not require a hospital to test a patient for COVID-19 before discharge if there is no clinical indication to test.

Page 6- References “Dedicated means that HCP are assigned to care only for these patients during their shifts.” Facilities are finding this difficult to accomplish and will want to know that IDOH concurs, if necessary, staff can cross zones, if done appropriately. **ANSWER:** Our guidance leaves room for staffing across the zones with proper IC practices, a dedicated staff is preferred if possible. HCP should work from green first to then yellow and red, bundling care.

Page 8- Environmental Control- “Once the patient has been discharged or transferred, HCP, including environmental service personnel, should refrain from entering the vacated room until sufficient time has elapsed for enough air changes to remove potentially infectious particles.” Is this 24 hour? Is there a timeframe? With facilities being bed-locked, there may not be the ability to leave a room vacated for an expanded period. Surveyors have monitored facilities during the transfer of residents to red zones and during the housekeeping/cleaning of vacated COVID positive rooms (from which the resident was transferred), thus, this will need clarification. **ANSWER:** IDOH has always supported facility policy for the room to have adequate full air exchanges or minimum 1 hour if the air exchanges are not clearly known based on clearance standard rates of resident rooms that are not negative air pressure.

Page 12- The issue of identifying residents who are moderate to severely immunocompromised will be a point of discussion due to staff assignment, etc.

The CDC provides the following at

<https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fvaccines%2Fcovid-19%2Finfo-by-product%2Fclinical-considerations.html#considerations-covid19-vax-immunocopromised>

*Moderate and severe immunocompromising conditions and treatments include but are not limited to:*

* *Active treatment for solid tumor and hematologic malignancies*
* *Receipt of solid-organ transplant and taking immunosuppressive therapy*
* *Receipt of CAR-T-cell therapy or hematopoietic cell transplant (HCT) (within 2 years of transplantation or taking immunosuppression therapy)*
* *Moderate or severe primary immunodeficiency (e.g., DiGeorge syndrome, Wiskott-Aldrich syndrome)*
* *Advanced or untreated HIV infection (people with HIV and CD4 cell counts <200/mm3, history of an AIDS-defining illness without immune reconstitution, or clinical manifestations of symptomatic HIV)*
* *Active treatment with high-dose corticosteroids (i.e., ≥20 mg prednisone or equivalent per day when administered for ≥2 weeks), alkylating agents, antimetabolites, transplant-related immunosuppressive drugs, cancer chemotherapeutic agents classified as severely immunosuppressive, tumor necrosis factor (TNF) blockers, and other biologic agents that are immunosuppressive or immunomodulatory.*

[*Factors to consider*](https://wwwnc.cdc.gov/travel/yellowbook/2020/travelers-with-additional-considerations/immunocompromised-travelers)*in assessing the general level of immune competence in a patient include disease severity, duration, clinical stability, complications, comorbidities, and any potentially immune-suppressing treatment. Age or place of residence alone (e.g., residence in a*[*long-term care setting external icon*](https://acl.gov/covid19/covid-19-vaccine-access-long-term-care-settings)*), independent of a patient’s medical condition, should not be used to determine the level of immune competence, as the balance of benefits and risks of an additional primary dose for people who are not moderately or severely immunocompromised is currently unknown.*

Additionally, this new (2/2) guidance states “Ultimately, the degree of immunocompromise for the patient is determined by the treating provider, and preventive actions are tailored to each individual and situation.”

What scrutiny is to be expected of a decision as to who can take care of which residents based on immunocompromised state? **ANSWER:** The decision should be based on the facility policy, the treating provider, and the individual resident’s needs.

**Additional Provider Questions:**

1. Will the provider need to provide an automatic 4-week lookback for the survey team, or will they want a 1-week lookback, or will it vary depending on the 10% discrepancy of onsite vs NHSN and how that is addressed during the survey?
* If a 4-week lookback is what the survey team wants upon entrance of a facility survey, should the data match NHSN week ending dates or the date the surveyor requests the information? **ANSWER:** The only 4-week data that will be requested is the COVID-19 positive residents and staff, indicating whether any residents were hospitalized or expired.
* Same question as above if the surveyors want a 1-week look back. **ANSWER:** The surveyors ask for current staff status.
1. Facilities report for the week prior each week (on 2/3/22 a facility reported for the week of 1/14/2022-1/31/2022 – Will the facility need to match their reporting periods for any requested surveyor reports that are requested during a survey? **ANSWER:** No
2. The surveyor guidance asks for a “percent of current staff” – Does this mean leave off any terminated staff? **ANSWER:** Yes

Matrix Grid for Vaccination:

1. Will this be automatically given, or will there be prior steps required to determine compliance prior to the matrix grid needing to be completed? **ANSWER:** Yes, it will be provided as well as the instructions.
	* Will an electronic version be acceptable? **ANSWER:** Yes
2. What will the sample pool look like if everyone is either vaccinated or has an approved exemption filed? **ANSWER:** Would only look at those according to the sample selection. Sample will not be expanded if the facility does not have anyone in the category.
3. When will the comparison of NHSN% to the onsite survey % occur? Immediately upon entrance, later in the day on day one, or day two, or end of the survey? **ANSWER:** On the first day of the survey after the completed Matrix is received.
	* Will the surveyors consider the # of religious exemptions documented prior to investigating further? i.e., they have the matrix grid that will show 100% compliance, however there is a greater than 10% variance between it and NHSN. The discrepancy is the consideration of the religious exemptions. Will the investigation stop there, or will there be additional investigative steps? – if yes, then what are the steps? **ANSWER:** Discrepancies will be reviewed taking all categories into consideration.

Testing CDC Recommendations vs CMS QSO testing memorandum:

1. Do the current CDC recommendations on testing for staff supersede the CMS QSO for testing? No, they do not. **ANSWER:** The SNF/NF facilities should continue to follow the CMS QSO memo for testing.

 Will there be an update to the CMS QSO to mirror what CDC recommends? **ANSWER:** Unknown

* + If the QSO is not updated, what are the expectations, as CDC, in general, gives recommendations?
	+ Please review what Indiana expects with testing – CMS or CDC? – they do not match. **ANSWER:** SNF/NF facilities should follow CMS.
	+ The updates to testing of Residents is confusing: Here is what a member understands and wants support if this is correct:

Despite vaccination status, all residents who are new admissions and/or had exposure, must test 24 hours of exposure and at days 5-7. **ANSWER:** Correct

However, those who are up to date with vaccines do not need to quarantine and those who are not up to date must quarantine for 10 days, or 7 days if no symptoms and a negative test within 48 hours of removal from TBP. – correct? **ANSWER:** Yes, correct.