INFECTION CONTROL COLLECTION

LONG-TERM CARE SURVEY MANUAL
PREPARED BY MU NHA CONSULTANT

SECTION 8 - INFECTION CONTROL COLLECTION

Infection Control - *We at QIPMO have put together several resources to help you in your efforts to manage the infection control challenges at your homes as well as guide you through the Infection Control Focused Surveys. In this section, you will find a number of documents and resources that can be a guide and help in this process.*

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Dear long-term care leader:

In this current COVID-19 world it is becoming more obvious that infection control is the number one challenge for nursing homes and probably will be for some time. We at QIPMO have put together several resources to help you in your efforts to manage the infection control challenges at your homes as well as guide you through the Infection Control Focused Surveys. You will find a number of documents and resources that can be a guide and help in this process.

The first two documents, ***Coronavirus Disease 2019 (COVID-19) Preparedness Checklist for Nursing Homes and other Long-Term Care Settings*** and ***Infection Prevention and Control Assessment Tool for Nursing Homes Preparing for COVID-19*** are the starting point for an overview and assessment for where your facility is and where you might still have work to do. While both documents cover similar material, the first is an overview that focuses on policies and systems for your facility. The second looks at the specifics of daily practices to manage infection control.

COVID-19 Focused Survey Protocol gives an overview of the whole survey process: before, during and after surveyors enter a facility.

Information Needed from the Facility Immediately Upon Entrance is the list given the facility administrator as soon as the surveyors enter a building.

The next two documents, ***Infection Prevention, Control & Immunizations*** and ***COVID-19 Focused Survey for Nursing Homes*** are the guides used by surveyors as they conduct surveys.

COVID-19 Personal Protective Equipment for Healthcare Personnel and ***Using Personal Protective Equipment*** are resources to use when educating and informing your staff about PPE.

Also enclosed is a list of ***Resources from Nursing Home Help*** (the QIPMO website) with a number of different resources and related links. This document also includes a link (on page three) to access the *Policy & Memos to States and Regions from the Center for Clinical Standards and Quality/Quality, Safety & Oversight Group (QSOs)* that provide the latest guidance for nursing homes.

It is our hope that this collection of information will be useful to you and provide a guide in the process of making and keeping your homes as free from infection as possible. As always, feel free to reach out to any of us on the QIPMO team.

Best regards from your Long-Term Care Leadership Coaches,

~Nicky Martin, Libby Youse, and Mark Francis

Coronavirus Disease 2019 (COVID-19) Preparedness Checklist for Nursing Homes and other Long-Term Care Settings

Nursing homes and other long-term care facilities can take steps to assess and improve their preparedness for responding to coronavirus disease 2019 (COVID-19). Each facility will need to adapt this checklist to meet its needs and circumstances based on differences among facilities (e.g., patient/resident characteristics, facility size, scope of services, hospital affiliation). This checklist should be used as one tool in developing a comprehensive COVID-19 response plan. Additional information can be found at www.cdc.gov/COVID-19. Information from state, local, tribal, and territorial health departments, emergency management agencies/authorities, and trade organizations should be incorporated into the facility's COVID-19 plan. Comprehensive COVID-19 planning can also help facilities plan for other emergency situations.

This checklist identifies key areas that long-term care facilities should consider in their COVID-19 planning. Long-term care facilities can use this tool to self-assess the strengths and weaknesses of current preparedness efforts. Additional information is provided via links to websites throughout this document. However, it will be necessary to actively obtain information from state, local, tribal, and territorial resources to ensure that the facility's plan complements other community and regional planning efforts. This checklist does not describe mandatory requirements or standards; rather, it highlights important areas to review to prepare for the possibility of residents with COVID-19.

A preparedness checklist for hospitals, including long-term acute care hospitals is available.
https://www.cdc.gov/coronavirus/2019-ncov/downloads/hospital-preparedness-checklist.pdf

Interim Infection Prevention and Control Recommendations for Patients with Confirmed Coronavirus Disease 2019 (COVID-19) or Persons Under Investigation for COVID-19 in Healthcare Settings:
https://www.cdc.gov/coronavirus/2019-ncov/infection-control/control-recommendations.html

Strategies to Prevent the Spread of COVID-19 in Long-Term Care Facilities (LTCF):
https://www.cdc.gov/coronavirus/2019-ncov/healthcare-facilities/prevent-spread-in-long-term-care-facilities.html

1. Structure for planning and decision making

	Completed	In Progress	Not Started
▪ COVID-19 has been incorporated into emergency management planning for the facility.	☐	☐	☐
▪ A multidisciplinary planning committee or team* has been created to specifically address COVID-19 preparedness planning.	☐	☐	☐

List committee's or team's name:

**An existing emergency or disaster preparedness team may be assigned this responsibility.*

continue on next page

	Completed	In Progress	Not Started
cont.			
▪ People assigned responsibility for coordinating preparedness planning, hereafter referred to as the COVID-19 response coordinator. **Insert name(s), title(s), and contact information:**	☐	☐	☐
▪ Members of the planning committee include the following: (Develop a list of committee members with the name, title, and contact information for each personnel category checked below and attach to this checklist.) ▪ Facility administration ▪ Medical director ▪ Director of Nursing ▪ Infection control ▪ Occupational health ▪ Staff training and orientation ▪ Engineering/maintenance services ▪ Environmental (housekeeping) services ▪ Dietary (food) services ▪ Pharmacy services ▪ Occupational/rehabilitation/physical therapy services ▪ Transportation services ▪ Purchasing agent ▪ Facility staff representative ▪ Other member(s) as appropriate (e.g., clergy, community representatives, department heads, resident and family representatives, risk managers, quality improvement, direct care staff including consultant services, union representatives)	☐	☐	☐
▪ The facility's COVID-19 response coordinator has contacted local or regional planning groups to obtain information on coordinating the facility's plan with other COVID-19 plans. **Insert groups and contact information:**	☐	☐	☐

2. Development of a written COVID-19 plan.

	Completed	In Progress	Not Started
▪ A copy of the COVID-19 preparedness plan is available at the facility and accessible by staff.	☐	☐	☐
▪ Relevant sections of federal, state, regional, or local plans for COVID-19 or pandemic influenza are reviewed for incorporation into the facility's plan.	☐	☐	☐
▪ The facility plan includes the Elements listed in #3 below.	☐	☐	☐
▪ The plan identifies the person(s) authorized to implement the plan and the organizational structure that will be used.	☐	☐	☐

3. Elements of a COVID-19 plan.

	Completed	In Progress	Not Started
General:			
▪ A plan is in place for protecting residents, healthcare personnel, and visitors from respiratory infections, including COVID-19, that addresses the elements that follow.	☐	☐	☐
▪ A person has been assigned responsibility for monitoring public health advisories (federal and state) and updating the COVID-19 response coordinator and members of the COVID-19 planning committee when COVID-19 is in the geographic area. For more information, see https://www.cdc.gov/coronavirus/2019-ncov/index.html.	☐	☐	☐
Insert name, title, and contact information of person responsible.			
▪ The facility has a process for inter-facility transfers that includes notifying transport personnel and receiving facilities about a resident's suspected or confirmed diagnosis (e.g., presence of respiratory symptoms or known COVID-19) prior to transfer.	☐	☐	☐
▪ The facility has a system to monitor for, and internally review, development of COVID-19 among residents and healthcare personnel (HCP) in the facility. Information from this monitoring system is used to implement prevention interventions (e.g., isolation, cohorting), see CDC guidance on respiratory surveillance: https://www.cdc.gov/longtermcare/pdfs/LTC-Resp-OutbreakResources-P.pdf.	☐	☐	☐
▪ The facility has infection control policies that outline the recommended Transmission-Based Precautions that should be used when caring for residents with respiratory infection. (In general, for undiagnosed respiratory infection, Standard, Contact, and Droplet Precautions with eye protection are recommended unless the suspected diagnosis requires Airborne Precautions; see: https://www.cdc.gov/infectioncontrol/guidelines/isolation/appendix/type-duration-precautions.html.) For recommended Transmission-Based Precautions for residents with suspected or confirmed COVID-19, the policies refer to CDC guidance; see: https://www.cdc.gov/coronavirus/2019-ncov/infection-control/control-recommendations.html.	☐	☐	☐
▪ The facility periodically reviews specific IPC guidance for healthcare facilities caring for residents with suspected or confirmed COVID-19 (available here: https://www.cdc.gov/coronavirus/2019-ncov/infection-control/control-recommendations.html) and additional long-term care guidance (available here: https://www.cdc.gov/coronavirus/2019-ncov/healthcare-facilities/prevent-spread-in-long-term-care-facilities.html).	☐	☐	☐
Facility Communications:			
▪ Key public health points of contact during a COVID-19 outbreak have been identified. (Insert name, title, and contact information for each.)	☐	☐	☐
Local health department contact:			
State health department contact:			
State long-term care professional/trade association:			

continue on next page

cont.	Completed	In Progress	Not Started
▪ A person has been assigned responsibility for communications with public health authorities during a COVID-19 outbreak. **Insert name and contact information:**	☐	☐	☐
▪ Key preparedness (e.g., Healthcare coalition) points of contact during a COVID-19 outbreak have been identified. **Insert name, title, and contact information for each:**	☐	☐	☐
▪ A person has been assigned responsibility for communications with staff, residents, and their families regarding the status and impact of COVID-19 in the facility. (Having one voice that speaks for the facility during an outbreak will help ensure the delivery of timely and accurate information.)	☐	☐	☐
▪ Contact information for family members or guardians of facility residents is up to date.	☐	☐	☐
▪ Communication plans include how signs, phone trees, and other methods of communication will be used to inform staff, family members, visitors, and other persons coming into the facility (e.g., consultants, sales and delivery people) about the status of COVID-19 in the facility.	☐	☐	☐
▪ A list has been created of other healthcare entities and their points of contact (e.g., other long-term care and residential facilities, local hospitals and hospital emergency medical services, relevant community organizations—including those involved with disaster preparedness) with whom it will be necessary to maintain communication during an outbreak. Attach a copy of contact list.	☐	☐	☐
▪ A facility representative(s) has been involved in the discussion of local plans for inter-facility communication during an outbreak.	☐	☐	☐
Supplies and resources:			
The facility provides supplies necessary to adhere to recommended IPC practices including:			
▪ Alcohol-based hand sanitizer for hand hygiene is available in every resident room (ideally both inside and outside of the room) and other resident care and common areas (e.g., outside dining hall, in therapy gym).	☐	☐	☐
▪ Sinks are well-stocked with soap and paper towels for hand washing.	☐	☐	☐
▪ Signs are posted immediately outside of resident rooms indicating appropriate IPC precautions and required personal protective equipment (PPE).	☐	☐	☐
▪ Facility provides tissues and facemasks for coughing people near entrances and in common areas with no-touch receptacles for disposal.	☐	☐	☐
▪ Necessary PPE is available immediately outside of the resident room and in other areas where resident care is provided. **continue on next page**	☐	☐	☐

cont.

	Completed	In Progress	Not Started
▪ Facilities should have supplies of facemasks, respirators (if available *and* the facility has a respiratory protection program with trained, medically cleared, and fit-tested HCP), gowns, gloves, and eye protection (i.e., face shield or goggles).	☐	☐	☐
▪ Trash disposal bins should be positioned near the exit inside of the resident room to make it easy for staff to discard PPE after removal, prior to exiting the room, or before providing care for another resident in the same room.	☐	☐	☐
▪ Facility ensures HCP have access to EPA-registered hospital-grade disinfectants to allow for frequent cleaning of high-touch surfaces and shared resident care equipment. ▫ *Products with EPA-approved emerging viral pathogens claims are recommended for use against COVID-19. If there are no available EPA-registered products that have an approved emerging viral pathogen claim for COVID-19, products with label claims against human coronaviruses should be used according to label instructions.*	☐	☐	☐
▪ The facility has a process to monitor supply levels.	☐	☐	☐
▪ The facility has a contingency plan, that includes engaging their health department and healthcare coalition when they experience (or anticipate experiencing) supply shortages. Contact information for healthcare coalitions is available here: https://www.phe.gov/Preparedness/planning/hpp/Pages/find-hc-coalition.aspx	☐	☐	☐
Identification and Management of Ill Residents:			
▪ The facility has a process to identify and manage residents with symptoms of respiratory infection (e.g., cough, fever, sore throat) upon admission and daily during their stay in the facility, which include implementation of appropriate Transmission-Based Precautions.	☐	☐	☐
▪ The facility has criteria and a protocol for initiating active surveillance for respiratory infection among residents and healthcare personnel. CDC has resources for performing respiratory surveillance in long-term care facilities during an outbreak, see: https://www.cdc.gov/longtermcare/pdfs/LTC-Resp-OutbreakResources-P.pdf	☐	☐	☐
▪ Plans developed on how to immediately notify the health department for clusters of respiratory infections, severe respiratory infections, or suspected COVID-19.	☐	☐	☐
▪ The facility has criteria and a protocol for: limiting symptomatic and exposed residents to their room, halting group activities and communal dining, and closing units or the entire facility to new admissions.	☐	☐	☐
▪ The facility has criteria and a process for cohorting residents with symptoms of respiratory infection, including dedicating HCP to work only on affected units.	☐	☐	☐
Considerations about Visitors:			
▪ The facility has plans and material developed to post signs at the entrances to the facility instructing visitors not to visit if they have fever or symptoms of a respiratory infection.	☐	☐	☐
▪ The facility has criteria and protocol for when visitors will be limited or restricted from the facility.	☐	☐	☐

continue on next page

cont.	Completed	In Progress	Not Started
▪ Should visitor restrictions be implemented, the facility has a process to allow for remote communication between the resident and visitor (e.g., video-call applications on cell phones or tablets) and has policies addressing when visitor restrictions will be lifted (e.g., end of life situation).	☐	☐	☐
For more information about managing visitor access and movement in the facility see: https://www.cdc.gov/coronavirus/2019-ncov/infection-control/control-recommendations.html			
Occupational Health:			
▪ The facility has sick leave policies that are non-punitive, flexible, and consistent with public health policies that allow ill healthcare personnel (HCP) to stay home.	☐	☐	☐
▪ The facility instructs HCP (including consultant personnel) to regularly monitor themselves for fever and symptoms of respiratory infection, as a part of routine practice.	☐	☐	☐
▪ The facility has a process to actively screen HCP for fever and symptoms when they report to work.	☐	☐	☐
▪ The facility has a process to identify and manage HCP with fever and symptoms of respiratory infection.	☐	☐	☐
▪ The facility has a plan for monitoring and assigning work restrictions for ill and exposed HCP. (See: https://www.cdc.gov/coronavirus/2019-ncov/hcp/guidance-risk-assesment-hcp.html)	☐	☐	☐
▪ The facility has a respiratory protection plan that includes medical evaluation, training, and fit testing of employees.	☐	☐	☐
Education and Training:			
▪ The facility has plans to provide education and training to HCP, residents, and family members of residents to help them understand the implications of, and basic prevention and control measures for, COVID-19. Consultant HCP should be included in education and training activities.	☐	☐	☐
▪ A person has been designated with responsibility for coordinating education and training on COVID-19 (e.g., identifies and facilitates access to available programs, maintains a record of personnel attendance).	☐	☐	☐
Insert name, title, and contact information:			
▪ Language and reading-level appropriate materials have been identified to supplement and support education and training programs to HCP, residents, and family members of residents (e.g., available through state and federal public health agencies such and through professional organizations), and a plan is in place for obtaining these materials.	☐	☐	☐

continue on next page

cont.

	Completed	In Progress	Not Started
▪ Plans and material developed for education and job-specific training of HCP which includes information on recommended infection control measures to prevent the spread of COVID-19, including: ▪ Signs and symptoms of respiratory illness, including COVID-19. ▪ How to monitor residents for signs and symptoms of respiratory illness. ▪ How to keep residents, visitors, and HCP safe by using correct infection control practices including proper hand hygiene and selection and use of PPE. Training should include return demonstrations to document competency. ▪ Staying home when ill. ▪ HCP sick leave policies and recommended actions for unprotected exposures (e.g., not using recommended PPE, an unrecognized infectious patient contact).	☐	☐	☐
▪ See: "Strategies to prevent the spread of COVID-19 in long-term care facilities," available at: https://www.cdc.gov/coronavirus/2019-ncov/healthcare-facilities/prevent-spread-in-long-term-care-facilities.html	☐	☐	☐
▪ The facility has a plan for expediting the credentialing and training of non-facility HCP brought in from other locations to provide resident care when the facility reaches a staffing crisis.	☐	☐	☐
▪ Informational materials (e.g., brochures, posters) on COVID-19 and relevant policies (e.g., suspension of visitation, where to obtain facility or family member information) have been developed or identified for residents and their families. These materials are language and reading-level appropriate, and a plan is in place to disseminate these materials in advance of the actual pandemic.	☐	☐	☐
Surge Capacity:			
Staffing			
▪ A contingency staffing plan has been developed that identifies the minimum staffing needs and prioritizes critical and non-essential services based on residents' health status, functional limitations, disabilities, and essential facility operations.	☐	☐	☐
▪ A person has been assigned responsibility for conducting a daily assessment of staffing status and needs during a COVID-19 outbreak.	☐	☐	☐
Insert name, title, and contact information: ☐			
▪ Legal counsel and state health department contacts have been consulted to determine the applicability of declaring a facility "staffing crisis" and appropriate emergency staffing alternatives, consistent with state law.	☐	☐	☐
▪ The staffing plan includes strategies for collaborating with local and regional planning and response groups to address widespread healthcare staffing shortages during a crisis.	☐	☐	☐

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cont.	Completed	In Progress	Not Started
Consumables and durable medical equipment and supplies			
▪ Estimates have been made of the quantities of essential resident care materials and equipment (e.g., intravenous pumps and ventilators, pharmaceuticals) and personal protective equipment (e.g., masks, respirators, gowns, gloves, and hand hygiene products), that would be needed during an eight-week outbreak.	☐	☐	☐
▪ Estimates have been shared with local, regional, and tribal planning groups to better plan stockpiling agreements.	☐	☐	☐
▪ A plan has been developed to address likely supply shortages (e.g., personal protective equipment), including strategies for using normal and alternative channels for procuring needed resources.	☐	☐	☐
▪ A strategy has been developed for how priorities would be made in the event there is a need to allocate limited resident care equipment, pharmaceuticals, and other resources.	☐	☐	☐
▪ A process is in place to track and report available quantities of consumable medical supplies including PPE.	☐	☐	☐
Postmortem care:			
▪ A contingency plan has been developed for managing an increased need for postmortem care and disposition of deceased residents.	☐	☐	☐
▪ An area in the facility that could be used as a temporary morgue has been identified.	☐	☐	☐
▪ Local plans for expanding morgue capacity have been discussed with local and regional planning contacts.	☐	☐	☐

NURSING HOME COVID-19 INFECTION CONTROL ASSESSMENT AND RESPONSE (ICAR) TOOL

| VERSION 3.0 |

Date of the assessment: _____

Name of ICAR facilitator: _____

U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

Section 1. Facility Demographics and Critical Infrastructure

This section should be completed by the facility prior to the ICAR (provided as separate PDF to send to facility: https://www.cdc.gov/coronavirus/2019-ncov/downloads/hcp/nursing-home-icar-section1-demographics.pdf).

1. Facility name: _____

2. County in which the facility is located: _____

3. Type of care provided by the facility (please select all that apply):

- ☐ Skilled nursing
- ☐ Subacute rehabilitation
- ☐ Long-term care
- ☐ Ventilator care
- ☐ Tracheostomy care
- ☐ Dementia/memory care
- ☐ Psychiatric care
- ☐ In-facility dialysis
- ☐ Other, please specify: _____

4. Total number of licensed beds in the facility: _____

5. Total number of residents currently in the facility: _____

6. Total number of units in the facility: _____

7. Total number of each resident room type in the facility:

- Singles/Privates: _____
- Doubles/Semi-Privates: _____
- Triples: _____
- Quads: _____
- Other, please specify: _____

8. Current number of healthcare personnel (HCP) working in the facility:

8a. Total number of HCP: _____

8b. Number of nurses (RNs, LVNs, etc.): _____

8c. Number of nursing aides: _____

8d. Number of environmental service staff (i.e., housekeeping): _____

8e. Number of ancillary personnel (physical therapy, nutrition services, etc.): _____

> "HCP refers to all paid and unpaid persons serving in healthcare settings who have the potential for direct or indirect exposure to residents or infectious materials, including body substances (e.g., blood, tissue, and specific body fluids); contaminated medical supplies, devices, and equipment; contaminated environmental surfaces; or contaminated air." HCP include, but are not limited to, emergency medical service personnel, nurses, nursing assistants, physicians, technicians, therapists, and persons not directly involved in resident care, but who could be exposed to infectious agents that can be transmitted in the healthcare setting (e.g., clerical, dietary, environmental services, laundry, security, engineering and facilities management, administrative, billing, and volunteer personnel).
>
> **Source:** https://www.cdc.gov/infectioncontrol/guidelines/healthcare-personnel/appendix/terminology.html

9. In the last 6 months, has the facility had **any** infection prevention and control (IPC) assistance (e.g., consultation, assessment, survey) from groups outside the facility?

- ◯ Yes
- ◯ No
- ◯ Unknown

If YES,

9a. From whom (please select all that apply):

☐ Public health ☐ Survey agency ☐ Corporate entity ☐ Other, please specify: _____

9b. Please summarize any changes made in IPC policies or practices as a result of the assistance (account for all on-site visits if more than one has occurred).

_____

10. Which of the following describes the current level of SARS-CoV-2 transmission in the county where your facility is located?

○ Low ○ Moderate ○ Substantial ○ High ○ Unknown

11. Has your facility had any residents with SARS-CoV-2 infection (asymptomatic or symptomatic) *in the previous 90 days*?

○ Yes ○ No ○ Unknown

If YES,

11a. Total number of residents with SARS-CoV-2 infection currently in the facility who have not met criteria for discontinuation of Transmission-Based Precautions (i.e., isolation): _____

11b. Date *most recent* resident(s) with SARS-CoV-2 infection had a positive viral test (asymptomatic or symptomatic): _____

11c. Total number of residents with at least one positive viral test for SARS-CoV-2 in the previous 90 days (include those diagnosed both at the facility and at other locations): _____

12. What proportion of your residents are fully vaccinated against SARS-CoV-2?

○ Greater than 90% ○ Between 50-90% ○ Less than 50% ○ None ○ Unknown

13. Has your facility had any HCP with SARS-CoV-2 infection (asymptomatic or symptomatic) *in the previous 90 days*?

○ Yes ○ No ○ Unknown

If YES,

13a. Total number of HCP with SARS-CoV-2 infection that have not met criteria to return to work: _____

13b. Date *most recent* HCP with SARS-CoV-2 infection had a positive viral test (asymptomatic or symptomatic): _____

13c. Total number of HCP with at least one positive viral test for SARS-CoV-2 in the previous 90 days: _____

14. What proportion of your HCP are fully vaccinated against SARS-CoV-2?

○ Greater than 90%
○ Between 50-90%
○ Less than 50%
○ None
○ Unknown

15. If facility PPE supply and demand remains in its current state, with conventional use of PPE, do you have greater than 2 weeks supply of the following?

Eye protection (face shields or goggles)

○ Yes ○ No ○ Unknown

Facemasks

○ Yes ○ No ○ Unknown

Disposable, single-use respirators (such as N95 filtering facepiece respirators)

○ Yes ○ No ○ Unknown

Elastomeric respirators

○ Yes ○ No ○ Unknown ○ N/A

Powered air purifying respirators (PAPR)

○ Yes ○ No ○ Unknown ○ N/A

Gowns

○ Yes ○ No ○ Unknown

Gloves

○ Yes ○ No ○ Unknown

16. List the EPA registration numbers for cleaning and disinfection products used in the facility (if one product is used to clean and another to disinfect, list both products):

16a. For high touch surfaces in resident rooms: _____

16b. For high touch surfaces in common areas: _____

16c. For shared, non-disposable resident equipment: _____

NOTES

Sections 2-9 are intended for a discussion about IPC policies and practices with the facility either remotely or in-person prior to touring the facility.

17. Currently, what is the facility's greatest challenge with SARS-CoV-2 infection prevention and control?

18. Are there any successes or lessons learned that you would like to share?

Section 2. Routine Infection Prevention Practices During the COVID-19 Pandemic

2.A. Source Control, Physical Distancing, and Universal Use of Personal Protective Equipment

19. Can the facility describe what is meant by source control?

○ Yes ○ No ○ Not assessed

20. What options for source control are used by HCP while at the facility (please select all that apply)?

- ☐ NIOSH-approved N95 respirator
- ☐ A respirator approved under standards used in other countries (e.g., KN95)
- ☐ A well-fitting facemask
- ☐ Other, please specify: _____
- ☐ Unknown
- ☐ Not assessed

21. When do HCP discard their source control (please select all that apply)?

- ☐ Whenever it is removed during the shift (e.g., for breaks)
- ☐ Whenever soiled, damaged, or hard to breathe through
- ☐ At the end of a shift
- ☐ Source control is discarded, and PPE is donned when indicated by patient factors (e.g., caring for a patient with COVID-19)
- ☐ Other, please specify: _____
- ☐ Unknown
- ☐ Not assessed

22. Do HCP always wear source control when they are in areas of the facility in which they could encounter residents?

○ Yes ○ No ○ Unknown ○ Not assessed

23. Are there any circumstances in which HCP might choose to NOT use source control?

○ Yes ○ No ○ Unknown ○ Not assessed

If YES,

23a. With which of the following criteria in place (please select all that apply)?

- ☐ Community transmission is low or moderate
- ☐ HCP are fully vaccinated
- ☐ Source control is removed only in well-defined areas not accessed by residents (e.g., break rooms)
- ☐ Other, please specify: _____
- ☐ Unknown
- ☐ Not assessed

24. When transmission in the community is **substantial or high**, do HCP always wear eye protection during resident care activities?

- ○ Yes
- ○ No
- ○ Unknown
- ○ Not assessed

25. When transmission in the community is **substantial or high**, do HCP wear a NIOSH-approved N95 or equivalent or higher respirator when aerosol generating procedures are being performed?

- ○ Yes
- ○ No
- ○ No aerosol generating procedures performed
- ○ Unknown
- ○ Not assessed

26. How is physical distancing of HCP being encouraged (please select all that apply)?

- ☐ Breaks are scheduled
- ☐ Seating in breakrooms or meeting rooms is limited to allow for physical distancing
- ☐ Audits of breakrooms to ensure compliance
- ☐ Other, please specify: _____
- ☐ Physical distancing of HCP is not being encouraged
- ☐ Unknown
- ☐ Not assessed

27. Do residents use source control?

- ○ Yes
- ○ No
- ○ Unknown
- ○ Not assessed

If YES,

27a. Are there certain times or certain residents that might NOT be required to use source control?

- ○ Yes
- ○ No
- ○ Unknown
- ○ Not assessed

If YES,

27b. How does the facility determine which residents are NOT required to wear source control (please select all that apply)?

- ☐ Fully vaccinated residents
- ☐ Residents not suspected or confirmed to have SARS-CoV-2
- ☐ Residents that have not had close contact with someone with SARS-CoV-2 infection in the previous 14 days
- ☐ Residents that are not moderately or severely immunocompromised
- ☐ Residents that are NOT at increased risk for severe disease
- ☐ Other, please specify: _____
- ☐ Unknown
- ☐ Not assessed

27c. When might residents NOT be required to use source control (please select all that apply)?

- ☐ When community transmission is low to moderate
- ☐ When in their room
- ☐ In communal areas with other fully vaccinated residents
- ☐ During indoor visitation with fully vaccinated visitors
- ☐ During outdoor visitation with fully vaccinated visitors
- ☐ Other, please specify: _____
- ☐ Unknown
- ☐ Not assessed

28. Does the facility have a process for identifying residents at risk for severe disease?

- ○ Yes
- ○ No
- ○ Unknown
- ○ Not assessed

If YES,

28a. Please describe this process:

29. Do **visitors, vendors, and contractors** (i.e., all those entering the facility) always wear source control?

○ Yes ○ No ○ Unknown ○ Not assessed

If YES,

29a. Are there any circumstances in which **visitors** are **NOT** required to use source control?

○ Yes ○ No ○ Unknown ○ Not assessed

If YES,

29b. With which of the following criteria in place (please select all that apply)?

- ☐ Community transmission is low or moderate
- ☐ Visitors are fully vaccinated
- ☐ Resident is fully vaccinated
- ☐ Resident is not suspected or confirmed to have SARS-CoV-2
- ☐ Resident has not had close contact with someone with SARS-CoV-2 infection in the previous 14 days
- ☐ Visitors have not had close contact with someone with SARS-CoV-2 infection in the previous 14 days
- ☐ Resident is not moderately or severely immunocompromised
- ☐ Other, please specify: _____
- ☐ Unknown
- ☐ Not assessed

NOTES

2.B. Visitation Policies and Procedures

30. Has the facility provided updated information about visitation to families of residents?

○ Yes ○ No ○ Unknown ○ Not assessed

30a. When was the visitation plan/information last updated?

_____

31. How does the facility encourage visitor adherence to SARS-CoV-2 IPC measures (please select all that apply)?

- ☐ Visitor movement in the facility is limited (i.e., visitors go directly to visit the resident)
- ☐ Visits are scheduled so that the facility can maintain physical distancing
- ☐ Visits occur in a designated area
- ☐ If in-room visits occur, the facility attempts to maintain requirements for physical distancing
- ☐ Visitors are not monitored
- ☐ Other, please specify: _____
- ☐ Unknown
- ☐ Not assessed

NOTES

Section 3. Infection Prevention and Control Program

3.A. The Infection Prevention Program

32. Does the facility have at least one individual with training in infection control who provides on-site management of the IPC program?

◯ Yes ◯ No ◯ Unknown ◯ Not assessed

If YES,

32a. What type of IPC training has the individual received (please select all that apply)?

☐ CDC Nursing Home Infection Preventionist Training Course
☐ Corporate training program
☐ State or local health department led trainings
☐ Certification in Infection Control (CIC)
☐ Other, please specify: _____
☐ Unknown
☐ Not assessed

32b. Does the Infection Preventionist have other ongoing job duties?

◯ Yes ◯ No ◯ Unknown ◯ Not assessed

If YES,

32c. Please specify:

_____

NOTES

3.B. Hand Hygiene

33. Does the facility encourage the use of alcohol-based hand sanitizer with 60-95% alcohol in most clinical situations unless the hands are visibly soiled?

○ Yes ○ No ○ Unknown ○ Not assessed

34. Does the facility have alcohol-based hand sanitizer inside of each resident room?

○ Yes ○ No ○ Unknown ○ Not assessed

If NO,

34a. Why doesn't the facility have alcohol-based hand sanitizer in each room (please select all that apply)?

- ☐ They have been told they can't have it in resident rooms
- ☐ They didn't know they should put it in resident rooms
- ☐ They can't afford it
- ☐ They can't acquire it due to current shortage
- ☐ Other, please specify: _____
- ☐ Unknown
- ☐ Not assessed

35. Does the facility have alcohol-based hand sanitizer in hallways containing resident rooms?

- ○ Yes, outside each resident room
- ○ Yes, in multiple locations in the hallway but not outside each room
- ○ No
- ○ Other
- ○ Unknown
- ○ Not assessed

35a. If *OTHER*, please specify:

36. Where are sinks located for HCP handwashing before and after resident care (please select all that apply)?

- ☐ In the hallways with resident rooms
- ☐ At nurses' stations
- ☐ In resident bathrooms
- ☐ In resident rooms, not in the bathroom
- ☐ Other, please specify: _____
- ☐ Unknown
- ☐ Not assessed

NOTES

3.C. Environmental Cleaning and Disinfection

37. Can a facility representative explain the meaning of a disinfectant contact time?

○ Yes ○ No ○ Not assessed

38. Does the facility representative know the contact time of the facility's disinfectant product(s)?

○ Yes ○ No ○ Not assessed

39. Does the facility use disinfecting agents such as liquid bleach that require a pre-cleaning step?

○ Yes ○ No ○ Unknown ○ Not assessed

40. Do any of the facility's cleaning or disinfecting agents require additional preparation prior to use (i.e., mixing with other chemicals, diluting with water)?

◯ Yes ◯ No ◯ Unknown ◯ Not assessed

If YES,

40a. Which agents require preparation prior to use?

40b. Who is preparing these agents (please select all that apply)?

☐ Environmental services (EVS) supervisor
☐ Individual EVS staff
☐ Other, please specify: _____
☐ Unknown
☐ Not assessed

40c. Does the EVS staff wear the recommended PPE for agent preparation?

◯ Yes ◯ No ◯ Unknown ◯ Not assessed

40d. Are each of the agents prepared according to the product label?

◯ Yes ◯ No ◯ Unknown ◯ Not assessed

40e. How long does the facility store agents that require preparation?

◯ Stored for 24 hours
◯ Less than 24 hours
◯ More than 24 hours
◯ Unknown
◯ Not assessed

NOTES

Section 4. Evaluating and Managing Healthcare Personnel (HCP) and Visitors

4.A. Evaluating and Managing Healthcare Personnel (HCP)

41. What is the facility process for screening **HCP** when they arrive for their shift?

- ☐ Individual screening on arrival
- ☐ Electronic monitoring system
- ☐ Self-monitoring with attestation
- ☐ Other, please specify: _____
- ☐ The facility does not screen HCP
- ☐ Unknown
- ☐ Not assessed

42. Are all HCP, even those that are fully vaccinated, assessed for the presence of any of the following elements before each work shift (please select all that apply)?

- ☐ A positive viral test for SARS-CoV-2 within the previous 10 days
- ☐ Symptoms of COVID-19
- ☐ High risk exposures for which quarantine or exclusion from work are recommended
- ☐ Other, please specify: _____
- ☐ HCP not assessed before each work shift
- ☐ Unknown
- ☐ Not assessed

43. What symptoms of SARS-CoV-2 infection are included in screening of HCP (please select all that apply)?

- ☐ Fever or Chills
- ☐ New or worsening cough
- ☐ Shortness of breath
- ☐ Muscle aches
- ☐ New onset loss of taste or smell
- ☐ Fatigue
- ☐ Headache
- ☐ Sore throat
- ☐ Runny nose
- ☐ GI symptoms such as nausea, vomiting, diarrhea
- ☐ Other, please specify: _____
- ☐ Unknown
- ☐ Not assessed

NOTES

4.B. Healthcare Personnel Return to Work

44. When would the facility allow HCP with SARS-CoV-2 infection that remained **asymptomatic AND** who are **not** moderately to severely immuno-compromised to return to work (please select all that apply)?

- ☐ 10 days have passed since the date of their first positive viral diagnostic test (if not moderately to severely immunocompromised)
- ☐ Using a test-based strategy
- ☐ Other, please specify: _____
- ☐ Unknown
- ☐ Not assessed

45. When would the facility allow HCP with SARS-CoV-2 infection with **mild to moderate illness AND** who are ***not*** *moderately to severely immunocompromised* to return to work (please select all that apply)?

- ☐ At least 10 days have passed *since symptoms first appeared*
- ☐ At least 24 hours have passed *since last* fever without the use of fever-reducing medications
- ☐ Symptoms (e.g., cough, shortness of breath) have improved
- ☐ A test-based strategy
- ☐ Other, please specify: _____
- ☐ Unknown
- ☐ Not assessed

46. When would the facility allow HCP with SARS-CoV-2 infection that had **severe to critical illness OR** who **are** moderately to severely immunocompromised return to work (please select all that apply)?

- ☐ At least 10 days and up to 20 days have passed *since symptoms first appeared*
- ☐ At least 24 hours have passed *since last* fever without the use of fever-reducing medications
- ☐ Symptoms (e.g., cough, shortness of breath) have improved
- ☐ Using a test-based strategy
- ☐ After consulting with an infectious disease physician
- ☐ Other, please specify: _____
- ☐ Unknown
- ☐ Not assessed

NOTES

4.C. Evaluating and Managing Visitors, Vendors, or Contractors

47. Does the process for evaluating visitors, vendors, or contractors include assessment for the presence of any of the following elements (please select all that apply)?

- ☐ A positive viral test for SARS-CoV-2 in the previous 10 days
- ☐ Symptoms of COVID-19
- ☐ High risk exposures for which quarantine or exclusion from work are recommended
- ☐ Visitors, vendors, or contractors not assessed before entering facility
- ☐ Other, please specify: _____
- ☐ Unknown
- ☐ Not assessed

48. Does symptom screening for visitors, vendors, or contractors include the same symptoms as for HCP?

○ Yes ○ No ○ Unknown ○ Not assessed

NOTES

Section 5. Evaluating and Managing Residents

5.A. New Admissions, Readmissions, Residents that Leave the Facility

49. How does the facility determine where new admissions can be placed (please select all that apply)?

- ☐ New admissions with **confirmed SARS-CoV-2** who have **not met** criteria to discontinue Transmission-Based Precautions are placed in the COVID-19 care unit
- ☐ Unvaccinated new admissions and readmissions are placed in a 14-day quarantine, even if they test negative on admission
- ☐ New admissions that are fully vaccinated or within 90 days of a SARS-CoV-2 infection **are not** placed in quarantine
- ☐ All new admissions are quarantined with no exceptions
- ☐ Other, please specify: _____
- ☐ Unknown
- ☐ Not assessed

50. Are residents that leave the facility for more than 24 hours managed in the same way as new admissions and readmissions?

○ Yes ○ No ○ Unknown ○ Not assessed

51. What actions are taken when residents leave the facility (please select all that apply)?

- ☐ Residents are reminded to follow recommendations for source control, physical distancing and hand hygiene
- ☐ Those accompanying residents are educated about IPC practices
- ☐ Regular communication occurs with clinics that provide ongoing care to residents about potential exposures (either at the clinic or the nursing home)
- ☐ Other, please specify: _____
- ☐ No actions taken
- ☐ Unknown
- ☐ Not assessed

NOTES

5.B Resident Monitoring

52. Ask the facility to describe how **asymptomatic residents** are monitored for signs and symptoms of COVID-19:

52a. Monitored at least daily?

○ Yes ○ No ○ Unknown ○ Not assessed

53. Are resident temperatures measured?

○ Yes ○ No ○ Unknown ○ Not assessed

54. How does the facility define fever (please select all that apply)?

☐ Oral temperature of 100.0 degrees F or higher

☐ Repeated oral temperature of greater than 99.0 degrees F

☐ Single temperature greater than 2 degrees F over baseline from any site

☐ Other, please specify: _____

☐ Unknown

☐ Not Assessed

55. Does the facility use pulse oximetry to measure oxygen saturation daily?

○ Yes ○ No ○ Unknown ○ Not assessed

If YES,

55a. Are all personnel that measure oxygen saturation levels educated on when to alert nursing personnel to abnormal values?

○ Yes ○ No ○ Unknown ○ Not assessed

56. Are residents assessed for the same symptoms of SARS-CoV-2 as HCP and visitors?

○ Yes ○ No ○ Unknown ○ Not assessed

NOTES

Section 6. Care of Residents Suspected or Confirmed to Have SARS-CoV-2 Infection

6.A. The COVID-19 Care Area

57. Does the facility **currently have** or **plan to have** a designated COVID-19 care unit for residents with confirmed SARS-CoV-2 infections?

○ Yes ○ No ○ Unknown ○ Not assessed

If YES,

57a. Area is physically separated from rooms with residents not known to be infected.

○ Yes ○ No ○ Unknown ○ Not assessed

57b. Are HCP providing care for SARS-CoV-2 residents dedicated to the COVID-19 care area?

○ Yes ○ No ○ Unknown ○ Not assessed

If YES,

57c. Are EVS staff (i.e., housekeepers) included among HCP dedicated to the COVID-19 care area?

○ Yes ○ No ○ Unknown ○ Not assessed

NOTES

6.B. Residents with Confirmed SARS-CoV-2 Infection

58. Describe **where** a resident with confirmed SARS-CoV-2 infection would be roomed (please select all that apply):

☐ In a designated area for residents with confirmed SARS-CoV-2 infections

☐ Not in a designated area for residents with confirmed SARS-CoV-2 infections, please specify where:

_____

☐ Other, please specify: _____

☐ Unknown

☐ Not assessed

59. Describe **with whom** a resident with confirmed SARS-CoV-2 infection would be roomed (please select all that apply):

☐ Without roommates

☐ With roommate(s) with confirmed SARS-CoV-2 infection

☐ With roommate(s) without confirmed SARS-CoV-2 infection

☐ Other, please specify: _____

☐ Unknown

☐ Not assessed

60. How often are residents with **suspected or confirmed** SARS-CoV-2 infection monitored for signs and symptoms of severe illness?

- ◯ Fewer than three times a day
- ◯ At least three times a day
- ◯ Unknown
- ◯ Not assessed

NOTES

6.C. PPE Use

61. What PPE do HCP wear when caring for a resident with suspected or confirmed SARS-CoV-2 infection (please select all that apply)?

- ☐ Gown
- ☐ Gloves
- ☐ Eye Protection
- ☐ NIOSH approved N95 or equivalent or higher respirator
- ☐ Other, please specify: _____
- ☐ Unknown
- ☐ Not assessed

62. Is all PPE readily available outside of the room of each resident on SARS-CoV-2 transmission-based precautions?

- ◯ Yes
- ◯ No
- ◯ Unknown
- ◯ Not assessed

63. Where do HCP put on (don) PPE (please select all that apply)?

- ☐ Immediately prior to entering the room of a resident on transmission-based precautions for SARS-CoV-2
- ☐ Immediately prior to entering the COVID-19 care area
- ☐ Other, please specify: _____
- ☐ Unknown
- ☐ Not assessed

64. Is alcohol-based hand sanitizer with 60-95% alcohol immediately available for HCP to use when donning or doffing PPE?

- ◯ Yes
- ◯ No
- ◯ Unknown
- ◯ Not assessed

65. When do HCP remove (doff) PPE (please select all that apply)?

- ☐ Gloves and gown are removed and discarded (or placed in soiled linen if gown is launderable) immediately prior to exiting the resident room
- ☐ Eye protection (if use is not extended) is removed immediately outside the resident room
- ☐ Respirators (if use is not extended) are removed and discarded immediately outside the resident room
- ☐ Other, please specify: _____
- ☐ Unknown
- ☐ Not assessed

66. Is PPE immediately discarded following use?

○ Yes ○ No ○ Unknown ○ Not assessed

67. Following removal of PPE, do HCP put on new source control?

○ Yes ○ No ○ Unknown ○ Not assessed

68. Can the respondent describe what extending the use of PPE means?

○ Yes ○ No ○ Not assessed

NOTES

6.D. Respirators

69. Are all respirators that are used as PPE in the facility NIOSH approved?

○ Yes ○ No ○ Unknown ○ Not assessed

70. Are all HCP currently fit-tested for the type of respirator they are using?

○ Yes ○ No ○ Unknown ○ Not assessed

If YES,

70a. Are HCP medically cleared prior to fit-testing?

○ Yes ○ No ○ Unknown ○ Not assessed

71. Are HCP trained on the use of their respirators?

○ Yes ○ No ○ Unknown ○ Not assessed

72. Is the facility currently practicing extended use of disposable respirators?

○ Yes ○ No ○ Unknown ○ Not assessed

73. Is the facility currently reusing disposable respirators?

○ Yes ○ No ○ Unknown ○ Not assessed

NOTES

6.E. Eye Protection

74. What type of eye protection is the facility using (please select all that apply)?

- ☐ Single use, disposable face shields/goggles
- ☐ Reusable face shields/goggles
- ☐ Other, please specify: _____
- ☐ Unknown
- ☐ Not assessed

75. Is the facility currently practicing extended use of eye protection?

○ Yes ○ No ○ Unknown ○ Not assessed

76. Is the facility currently reusing eye protection?

○ Yes ○ No ○ Unknown ○ Not assessed

If YES,

76a. What type of eye protection is the facility currently reusing (please select all that apply)?

- ☐ Reusable face shields/goggles
- ☐ Single use, disposable face shields/goggles
- ☐ Unknown
- ☐ Not assessed

76b. Do HCP clean and disinfect eye protection immediately after removal?

○ Yes ○ No ○ Unknown ○ Not assessed

76c. Do HCP clean and disinfect eye protection if soiled?

○ Yes ○ No ○ Unknown ○ Not assessed

76d. Where do HCP store reusable eye protection (please select all that apply)?

- ☐ In a designated storage area within the facility
- ☐ Somewhere in the facility but not in a designated storage area
- ☐ HCP store them outside the building (e.g., in their cars)
- ☐ Other, please specify: _____
- ☐ Unknown
- ☐ Not assessed

76e. Are disposable face shields/goggles dedicated to one HCP?

- ○ Yes
- ○ No
- ○ Unknown
- ○ Not assessed
- ○ Disposable face shields/goggles not used in the facility

NOTES

6.F. Gowns

77. What types of gowns are being used (please select all that apply)?

☐ Disposable isolation ☐ Other, please specify: _____ ☐ Not assessed
☐ Launderable ☐ Unknown

78. Are gowns worn by HCP outside of resident rooms?

○ Yes ◎ No ◎ Unknown ◎ Not assessed

If YES,

78a. Under what circumstance are they worn by HCP outside of resident rooms?

_____

78b. Do HCP wear the same gown to care for more than one resident?

○ Yes ◎ No ◎ Unknown ◎ Not assessed

NOTES

6.G. Gloves

79. Are gloves changed between the care of different residents?

○ Yes ◎ No ◎ Unknown ◎ Not assessed

80. Are gloves being worn by HCP outside of resident rooms?

○ Yes ◎ No ◎ Unknown ◎ Not assessed

If YES,

80a. Under what circumstances are they being worn by HCP outside of resident rooms?

_____

NOTES

6.H. Duration of Transmission-Based Precautions for SARS-CoV-2 Infection

81. When would the facility discontinue Transmission-Based Precautions for residents with SARS-CoV-2 infection who remained **asymptomatic AND** who **are not** moderately or severely immunocompromised (i.e., end isolation) (please select all that apply)?

- ☐ At least 10 days have passed since the date of their first positive viral diagnostic test
- ☐ Using a test-based strategy
- ☐ Other, please specify: _____
- ☐ Unknown
- ☐ Not assessed

82. When would the facility discontinue Transmission-Based Precautions for SARS-CoV-2 infected residents with **mild to moderate illness AND** who **are not** moderately or severely immunocompromised (i.e., end isolation) (please select all that apply)?

- ☐ At least 10 days have passed *since symptoms first appeared*
- ☐ At least 24 hours have passed *since last* fever without the use of fever-reducing medications
- ☐ Symptoms (e.g., cough, shortness of breath) have improved
- ☐ Other, please specify: _____
- ☐ Unknown
- ☐ Not assessed

83. When would the facility discontinue Transmission-Based Precautions for SARS-CoV-2 infected residents with **severe to critical** illness **OR** who **are** moderately or severely immunocompromised (i.e., end isolation) (please select all that apply)?

- ☐ At least 10 days and up to 20 days have passed *since symptoms first appeared*
- ☐ At least 24 hours have passed *since last* fever without the use of fever-reducing medications
- ☐ Symptoms (e.g., cough, shortness of breath) have improved
- ☐ After consulting with an infectious disease physician
- ☐ Using a test-based strategy
- ☐ Other, please specify: _____
- ☐ Unknown
- ☐ Not assessed

NOTES

Section 7. SARS-CoV-2 Testing

84. Where is viral laboratory testing for SARS-CoV-2 conducted (please select all that apply)?

- ☐ At the facility
- ☐ At a contracted laboratory
- ☐ Other, please specify: _____
- ☐ Unknown
- ☐ Not assessed

85. What type of testing for SARS-CoV-2 is conducted (please select all that apply)?

- ☐ Point of care antigen testing
- ☐ Rapid molecular point of care testing (e.g., Abbott BinaxNow)
- ☐ Nucleic Acid Amplification Tests (NAAT) (e.g., Reverse-transcriptase polymerase chain reaction [RT-PCR])
- ☐ Other, please specify: _____
- ☐ Unknown
- ☐ Not assessed

86. How long does it typically take for viral testing results to return?

◯ Less than 48 hours ◯ Greater than 48 hours ◯ Unknown ◯ Not assessed

87. If antigen testing is utilized, does the facility confirm negative antigen test results from symptomatic residents and HCP with a Nucleic Acid Amplification Test (NAAT) (e.g., reverse-transcriptase polymerase chain reaction (RT-PCR)) within 48 hours?

◯ Yes ◯ Facility not using rapid antigen testing
◯ No ◯ Not assessed
◯ Unknown

88. Do all residents and HCP with **even mild symptoms** of COVID-19, receive a viral test as soon as possible regardless of vaccination status?

◯ Yes ◯ No ◯ Unknown ◯ Not assessed

89. Is the facility able to perform routine testing of HCP based on the level of community transmission in the county where they are located as per CMS guidance?

◯ Yes ◯ No ◯ Unknown ◯ Not assessed

90. Where in the facility are specimens collected for residents (please select all that apply)?

☐ In the resident's room with the door closed ☐ Unknown
☐ Other, please specify: ☐ Not assessed

_____

91. Where in the facility are specimens collected for HCP (please select all that apply)?

☐ An outdoor location
☐ A designated room inside the facility with the door closed with one HCP at a time
☐ A large room (e.g., gymnasium) where sufficient space can be maintained between swabbing stations (e.g., greater than 6 feet apart)
☐ Other, please specify:_____
☐ Unknown
☐ Not assessed

NOTES

Section 8. New SARS-CoV-2 Infection among HCP or Residents

92. When a new case of SARS-CoV-2 is identified, does the facility increase the frequency of monitoring all residents to every shift?

○ Yes ○ No ○ Unknown ○ Not assessed

93. Are symptomatic residents restricted to their rooms?

○ Yes ○ No ○ Unknown ○ Not assessed

94. Are Transmission-Based Precautions used when caring for symptomatic residents, while test results are pending?

○ Yes ○ No ○ Unknown ○ Not assessed

95. If symptomatic residents have negative viral tests, when are Transmission-Based Precautions stopped (please select all that apply)?

☐ After one negative respiratory specimen tested using an FDA-authorized molecular viral assay to detect SARS-CoV-2 RNA

☐ If a higher level of clinical suspicion for SARS-CoV-2 infection exists despite one negative SARS-CoV-2 RNA test, Transmission-Based Precautions would be continued until a second SARS-CoV-2 RNA test is performed and results as negative

☐ Other, please specify: _____

☐ Unknown

☐ Not assessed

96. In response to new cases of SARS-CoV-2, who does the facility test (please select all that apply)?

☐ All staff with symptoms are tested

☐ All residents with symptoms are tested

☐ Close contacts are tested

☐ HCP with higher risk exposures are tested

☐ All staff and residents on affected units

☐ All staff and residents are tested if contact and exposures cannot be clearly identified

☐ Other, please specify: _____

☐ Unknown

☐ Not assessed

97. How does the respondent define a higher-risk HCP exposure (please select all that apply)?

☐ Close contact of 15 minutes or more duration

☐ HCP not wearing a respirator or facemask

☐ HCP not wearing eye protection if the person with SARS-CoV-2 infection was not wearing a cloth mask or facemask

☐ HCP not wearing all recommended PPE (i.e., gown, gloves, eye protection, respirator) while performing an aerosol-generating procedure

☐ Other, please specify: _____

☐ Unknown

☐ Not assessed

98. Are HCP higher-risk exposures and residents with close contact tested regardless of vaccination status?

○ Yes ○ No ○ Unknown ○ Not assessed

If YES,

98a. When are HCP with higher-risk exposures and residents with close contact tested (please select all that apply)?

- ☐ Not earlier than 2 days after exposure
- ☐ Again 5-7 days after exposure
- ☐ Other, please specify: _____
- ☐ Unknown
- ☐ Not assessed

98b. Which residents and HCP are included among those tested (please select all that apply)?

- ☐ All residents with close contact, regardless of vaccination status
- ☐ All HCP with higher-risk exposures, regardless of vaccination status
- ☐ Residents that have recovered from SARS-CoV-2 infection in the previous 90 days are **NOT** tested
- ☐ HCP that returned to work following SARS-CoV-2 infection in the previous 90 days are **NOT** tested
- ☐ Other, please specify: _____
- ☐ Unknown
- ☐ Not assessed

99. If testing of close contacts reveals additional HCP or residents with SARS-CoV-2 infection, what approach does the facility take to identify additional cases/contacts (please select all that apply)?

- ☐ Targeted testing if contacts are limited in number and clearly identifiable
- ☐ Facility or group-wide approach if unable to identify contacts
- ☐ Facility or group-wide approach if contacts are too numerous to manage
- ☐ Other, please specify: _____
- ☐ Unknown
- ☐ Not assessed

100. When performing an outbreak response to a known case, how would the facility manage unvaccinated residents and HCP (please select all that apply)?

- ☐ Unvaccinated residents are restricted to their rooms, even if testing is negative
- ☐ HCP caring for unvaccinated residents use an N95 or higher-level respirator, eye protection, gloves and gown when providing care
- ☐ Unvaccinated residents do not participate in group activities
- ☐ Other, please specify: _____
- ☐ Unknown
- ☐ Not assessed

101. When performing an outbreak response to a known case, how would the facility manage fully vaccinated residents and HCP (please select all that apply)?

- ☐ Fully vaccinated residents are NOT restricted to their rooms
- ☐ HCP do NOT use full PPE when caring for fully vaccinated residents
- ☐ Other, please specify: _____
- ☐ Unknown
- ☐ Not assessed

NOTES

Section 9. Continuous Quality Improvement

102. Have all HCP recently **demonstrated competency** in:

102a. Hand hygiene with alcohol-based hand sanitizer

○ Yes ○ No ○ Unknown ○ Not assessed

102b. Hand hygiene with soap and water

○ Yes ○ No ○ Unknown ○ Not assessed

102c. Selecting the correct PPE for the anticipated task (e.g., using all recommended PPE for the care of residents with SARS-CoV-2 infection)

○ Yes ○ No ○ Unknown ○ Not assessed

102d. Donning and doffing PPE

○ Yes ○ No ○ Unknown ○ Not assessed

102e. Use of cleaning and disinfection products for resident rooms for all HCP with cleaning responsibility such as EVS, nursing aides, etc.

○ Yes ○ No ○ Unknown ○ Not assessed

102f. Use of cleaning and disinfection products for resident equipment for all HCP with cleaning responsibility such as EVS, nursing aides, etc. (e.g., vital signs equipment)

○ Yes ○ No ○ Unknown ○ Not assessed

103. Does the facility **audit** (i.e., monitor and document) HCP compliance with the following IPC practices?

103a. Hand Hygiene

○ Yes ○ No ○ Unknown ○ Not assessed

103b. Selection of the correct PPE for the anticipated task (e.g., using all recommended PPE for the care of residents with SARS-CoV-2 infection)

○ Yes ○ No ○ Unknown ○ Not assessed

103c. PPE donning and doffing

○ Yes ○ No ○ Unknown ○ Not assessed

103d. Cleaning and disinfection of resident rooms

○ Yes ○ No ○ Unknown ○ Not assessed

103e. Cleaning and disinfection of resident equipment (e.g., vital signs equipment)

○ Yes ○ No ○ Unknown ○ Not assessed

NOTES

End remote TeleICAR assessment if video tour is not planned. Continue to the next sections if video or in-person tour are planned.

Sections 10a-10f: The following sections should be completed during a video tour as part of a remote assessment or as part of an in-person tour of the facility. These sections are intended to visualize how facilities are implementing some of the previously discussed policies and practices. If the tool is used during an in-person tour, check "not applicable" under the "video assessment attempted" element for each section but proceed to record responses for the rest of the section. If the ICAR facilitator is unable to visualize any of listed elements during a video or in-person tour, answer "not assessed" for that element.

In the notes sections, be sure to note when there are discrepancies between what was discussed during the policy and procedures discussion and what was visualized as part of the tour.

Considerations when using video during remote assessments:

It is important to acknowledge that video tours of facilities during remote assessments have their own limitations and challenges to include technical issues, limited internet service in some facilities, and the general inability to visualize the facility in the same way one could during an on-site visit. However, video can increase the quality of the remote assessment by allowing a facilitator to visualize how facilities are implementing some essential IPC practices when compared to conducting an assessment via phone alone.

Some factors to consider:

- To ensure resident privacy, recordings and pictures during the assessment are generally discouraged.
- During the ICAR scheduling process, the facilitator should emphasize their desire to conduct a video tour as part of the assessment process and determine the facility's ability to utilize a video conferencing platform to conduct the tour. The tour will require movement to different parts of the facility and thus will require the video conferencing platform to be located on a moveable device such as a laptop or cell phone.
- If the facility is unable to complete both the policies and practices discussion and video tour on the same day, the video tour could be delayed to another day.
- In general, the average video tour will take 20-30 minutes to complete.

Begin tour: If HCP, visitors, or vendors are being actively screened, ask to see the screening areas.

Section 10. Facility Tour

10.A. Screening Stations

104. Video assessment attempted

- ◯ Yes
- ◯ No **(SKIP TO 112)**
- ◯ Not applicable, assessment part of an on-site visit

105. Who is being screened at this location (please select all that apply)?

- ☐ HCP
- ☐ Visitors
- ☐ Other, please specify: _____
- ☐ Not assessed

106. The facility entry is monitored.

◯ Yes ◯ No ◯ Not assessed

107. What PPE is worn by HCP performing the screening (please select all that apply)?

- ☐ Respirators
- ☐ Facemasks
- ☐ Eye Protection
- ☐ Gowns
- ☐ Gloves
- ☐ Other, please specify: _____
- ☐ Not assessed

108. If temperatures are actively taken, what type of thermometer is being used (please select all that apply)?

- ☐ No touch
- ☐ Oral
- ☐ Ear/Tympanic
- ☐ Temperatures are not actively measured
- ☐ Other, please specify: _____
- ☐ Unknown
- ☐ Not assessed

109. Screening questions assess the following (please select all that apply):

- ☐ Temperature of 100.0F (37.8C) or higher
- ☐ Subjective fever
- ☐ Chills
- ☐ New or worsening cough
- ☐ Shortness of breath
- ☐ Muscle aches
- ☐ New onset loss of taste or smell
- ☐ Fatigue
- ☐ Headache
- ☐ Sore throat
- ☐ Runny nose
- ☐ GI symptoms such as nausea, vomiting, diarrhea
- ☐ If they have been told they should quarantine after close contact with someone who has COVID-19
- ☐ Other, please specify: _____
- ☐ Unknown
- ☐ Not assessed

110. Alcohol-based hand sanitizer with 60-95% alcohol is available at the entry to the facility.

○ Yes ○ No ○ Not assessed

111. All persons entering the facility wear source control.

○ Yes ○ No ○ Not assessed

NOTES (especially note areas where discrepancies may have existed between the discussion and facility tour)

Ask to be brought onto a resident floor not currently housing residents with SARS-CoV-2 infections to assess Sections 10B – 10E.

10.B. Hand Hygiene

112. Video assessment attempted

- ◯ Yes
- ◯ No **(SKIP TO 117)**
- ◯ Not applicable, assessment part of an on-site visit

Ask facility to activate/push several alcohol-based hand sanitizer dispensers.

113. All demonstrated dispensers are functional.

- ◯ Yes
- ◯ No
- ◯ Not assessed

114. Alcohol-based hand sanitizer is located **outside** resident rooms.

- ◯ Yes
- ◯ No
- ◯ Not assessed

115. Alcohol-based hand sanitizer is located **inside** resident rooms.

- ◯ Yes
- ◯ No
- ◯ Not assessed

116. List other locations where alcohol-based hand sanitizer can be found (e.g., medicine carts, nursing stations) on the resident floor:

_____

NOTES **(especially note areas where discrepancies may have existed between the discussion and facility tour)**

Ask the facility to show you several examples of HCP wearing PPE on the resident floor.

10.C. PPE Use

117. Video assessment attempted

- ◯ Yes
- ◯ No **(SKIP TO 123)**
- ◯ Not applicable, assessment part of an on-site visit

118. All visualized HCP are correctly wearing facemasks or respirators in the facility.

- ◯ Yes
- ◯ No
- ◯ Not assessed

119. HCP are wearing eye protection for all resident care encounters if there is **substantial to high community transmission.**

- ○ Yes
- ○ No
- ○ Not applicable
- ○ Not assessed

120. Describe where personnel get new PPE (please select all that apply):

- ☐ In carts outside of resident rooms
- ☐ From a donning area on the COVID-19 care unit
- ☐ From the nurse's stations
- ☐ Other, please specify: _____
- ☐ Not assessed

121. A dedicated area is used to clean and disinfect eye protection.

- ○ Yes
- ○ No
- ○ Not applicable
- ○ Not assessed

122. Eye protection is stored in a clean area that avoids contamination.

- ○ Yes
- ○ No
- ○ Not applicable
- ○ Not assessed

NOTES (especially note areas where discrepancies may have existed between the discussion and facility tour)

Ask to interview a frontline HCP on the floor such as a nurse or nurse's aide.

10.D. Frontline HCP Interview

123. Interviewed frontline HCP

- ○ Yes
- ○ No **(SKIP TO 128)**

124. HCP describe when they perform hand hygiene (please select all that apply):

- ☐ Before touching a resident
- ☐ After touching a resident
- ☐ Before clean/aseptic procedures
- ☐ After body fluid exposure
- ☐ After touching resident surroundings
- ☐ Other, please specify: _____
- ☐ Not assessed

125. HCP describe when they use alcohol-based hand sanitizer (ABHS):

- ○ In most clinical situations
- ○ Not in most clinical situations.
- ○ Not assessed

125a. If *NOT* in most clinical situations, please describe why ABHS is not used:

126. HCP can describe when they would perform hand hygiene using soap and water (please select all that apply):

- ☐ When hands are visibly soiled
- ☐ Before eating and drinking
- ☐ After using the restroom
- ☐ During an outbreak of *Clostridioides difficile* or norovirus
- ☐ If they work in the kitchen
- ☐ Other, please specify: _____
- ☐ Unknown
- ☐ Not assessed

127. Watch or ask a frontline HCP to describe how they would doff PPE.

127a. Select one:

- ○ The facilitator observed HCP doff PPE
- ○ The facilitator listened to HCP describe the doffing process
- ○ Not assessed

127b. Was this done in a manner that limited self-contamination?

○ Yes ○ No ○ Not assessed

127c. Did the HCP perform hand hygiene after doffing PPE?

○ Yes ○ No ○ Not assessed

NOTES (especially note areas where discrepancies may have existed between the discussion and facility tour)

Ask to interview an EVS staff member (i.e., housekeeper).

10.E. Environmental Services (i.e., housekeeping)

128. Interviewed EVS staff member

- ○ Yes
- ○ No **(SKIP TO 132)**

129. EVS staff member can name several high touch surfaces in a room.

○ Yes ○ No ○ Not assessed

130. EVS staff member can state the contact time of disinfection products.

○ Yes ○ No ○ Not assessed

131. EVS staff member can describe the order in which they clean a resident room.

○ Yes ○ No ○ Not assessed

NOTES **(especially note areas where discrepancies may have existed between the discussion and facility tour)**

Ask to view the facility's designated COVID-19 area. If there are no current residents with SARS-CoV-2 infection, ask to see the location where the care area would be created.

10.F. Designated COVID-19 Care Area

132. Video assessment attempted

- ○ Yes
- ○ No **(END VIDEO)**
- ○ Not applicable, facility does not plan on creating a designated COVID-19 area **(END VIDEO)**
- ○ Not applicable, assessment part of an on-site visit

133. The designated COVID-19 care area is physically separated from other rooms or units housing residents without confirmed SARS-CoV-2 infections.

○ Yes ○ No ○ Not assessed

134. Alcohol-based hand sanitizer is available **inside** each room.

○ Yes ○ No ○ Not assessed

135. Alcohol-based hand sanitizer is available **outside** of each room.

○ Yes ○ No ○ Not assessed

136. Dedicated medical equipment is used for this care area.

○ Yes ○ No ○ Not assessed ○ Not applicable, no residents currently on this unit

137. Dedicated medical equipment is stored in the resident room.

○ Yes ○ No ○ Not assessed ○ Not applicable, no residents currently on this unit

138. Entrance to COVID-19 care area is controlled.

○ Yes ○ No ○ Not assessed ○ Not applicable, no residents currently on this unit

138a. Signage indicating only designated HCP should enter is present.

○ Yes ○ No ○ Not assessed ○ Not applicable, no residents currently on this unit

139. Room doors are kept closed (unless resident safety concerns require opening).

○ Yes ○ No ○ Not assessed ○ Not applicable, no residents currently on this unit

140. PPE is available for donning at entrance to each room for COVID-19 residents.

○ Yes ○ No ○ Not assessed ○ Not applicable, no residents currently on this unit

141. HCP doff gowns and gloves prior to exiting the room.

○ Yes ○ No ○ Not assessed ○ Not applicable, no residents currently on this unit

NOTES **(especially note areas where discrepancies may have existed between the discussion and facility tour)**

cdc.gov/coronavirus

U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

CS 327800-A | 01/05/2022

COVID-19 Focused Infection Control (FIC) Survey Protocol with Staff Vaccination Mandate

Prior to Survey *(Note: Surveyors in a state that is subject to QSO-22-07-ALL should start using this protocol on 1/27/2022. Surveyors in a state that is subject to QSO-22-09-ALL should start using this protocol on 2/14/2022. Surveyors in a state that is subject to* **QSO-22-11-All** *should start using this protocol on 2/22/2022.)*

- Surveyors should have access to this protocol, COVID-19 FIC survey entrance conference worksheet, infection control pathway, *Staff Formula excel spreadsheet, and the COVID-19 Staff Vaccination Matrix with instructions for facilities and surveyors* in the event infection control concerns are identified while in the facility. This survey protocol should be used in the following ways:
  - COVID-19 FIC Survey for Nursing Homes: Surveyors must evaluate the facility's compliance at all critical elements (CE) with the exception of CE#8 and CE#9 per CMS 20054, Infection Prevention, Control & Immunizations pathway. The surveyor must also examine the facility's compliance at §483.475(b)(6) or E0024 (at Appendix Z) if the full Emergency Preparedness survey is not being conducted.
  - This survey protocol provides surveyors with guidance to conduct a focused review of the critical elements associated with the transmission of COVID-19. Surveyors should be mindful to ensure their activities do not interfere with the active treatment or prevention of transmission of COVID-19.

- As surveyors will enter a facility with confirmed or suspected COVID-19 cases, or a facility requiring certain personal protective equipment (PPE) to enter, SSAs should ensure surveyors have needed PPE that could be required onsite. Surveyors should not expect a facility to provide PPE and supplies.
- Ensure surveyors are medically cleared and fit tested if using respirators with tight-fitting face-pieces (e.g., a NIOSH-certified disposable N95) and trained in the proper use of respirators, safe removal and disposal, and medical contraindications to respirator use. Refer to latest CDC guidance on use of PPE at: *https://www.cdc.gov/coronavirus/2019-ncov/hcp/ppe-strategy/index.html*
- Create a survey shell. Under Survey Properties:
  - When conducting a complaint investigation, the SA will code the Type of Survey in ACO as A=complaint and U=COVID-19 (M=Other will automatically be marked). The extent (if needed) should be marked as E=abbreviated survey. When conducting a COVID-19 Focused Survey, the SA will code the Type of Survey as U=COVID-19 (M=Other will automatically be marked). The extent (if needed) should be marked as E=abbreviated survey
  - **There should be no offsite surveys coded in ACO.**
- Conduct offsite planning based on the following:
  - Facility reported information provided to the CDC National Healthcare Safety Network (NHSN) and state or local health department information (if available); and
  - Complaint allegations.
  - *Review NHSN data which can be accessed directly from this link*

- *Find the nursing home in the Excel spreadsheet by using CTRL+F;*
- *On the infection control screen in the notes field (or on the pathway), document the "reported for week ending on" date listed in the report header*
- *Document the 'Recent Percentage of Staff who are Fully Vaccinated' (do not round);*
- Prioritize observations to key areas and activities related to infection control;
- Identify the records that need to be reviewed;
- Medical record reviews, including resident test results and vaccinations;
- Staff vaccination *status* and test results (Reports of COVID-19 community transmission levels are available on the following website *(select Data Tracker Home and county view)*: *https://covid.cdc.gov/covid-data-tracker/#county-view);*
- Comprehensive Review of Facility Policies/Procedures (e.g., Infection Prevention and Control Program, Emergency Preparedness Plan, residents and staff who refuse testing or are unable to be tested, resident immunizations, *and COVID-19 Health Care Staff Vaccinations*); and
- Review communication(s) to residents, representatives and families (e.g., listserv, newsletter, etc.).

o Surveyors should add the COVID-19 FIC Survey subfolder to their desktop.

o *From the Survey Resource folder, print the COVID-19 Staff Vaccination Matrix with instructions (1 copy of instructions, multiple copies of the blank matrix). Note: Facilities may complete the COVID-19 Staff Vaccination Matrix or provide a list containing the same information as required in the staff matrix.*

o *Surveyors may add the following links to their desktop:*

- *COVID-19 Vaccination Effectiveness Research: https://www.cdc.gov/vaccines/covid-19/effectiveness-research/protocols.html*
- *FAQs on Reporting COVID-19 Vaccination Data: https://www.cdc.gov/nhsn/hps/weekly-covid-vac/faqs.html*
- *Healthcare Workers: Information on COVID-19: https://www.cdc.gov/coronavirus/2019-nCoV/hcp/index.html*
- Interim Infection Prevention and Control Recommendations to Prevent SARS-CoV-2 Spread in Nursing Homes: https://www.cdc.gov/coronavirus/2019-ncov/hcp/long-term-care.html
- Interim Infection Prevention and Control Recommendations for Healthcare Personnel During the Coronavirus Disease 2019 (COVID-19) Pandemic: https://www.cdc.gov/coronavirus/2019-ncov/hcp/infection-control-recommendations.html
- SARS-CoV-2 Antigen Testing in Long Term Care Facilities: https://www.cdc.gov/coronavirus/2019-ncov/hcp/nursing-homes-antigen-testing.html
- Optimizing Personal Protective Equipment (PPE) Supplies: https://www.cdc.gov/coronavirus/2019-ncov/hcp/ppe-strategy/index.html
- Interim Guidance for Managing Healthcare Personnel with SARS-CoV-2 Infection or Exposure to SARS-CoV-2: https://www.cdc.gov/coronavirus/2019-

ncov/hcp/guidance-risk-assesment-hcp.html

NOTE: Offsite activities are no longer necessary for FIC surveys. Once the team enters the facility, all survey-related activities will be conducted onsite.

Entrance Conference

- If the survey team identifies an active COVID-19 case after entering a facility, the survey team should contact their State Survey Agency (SSA) and verify that the facility has notified the state or local health department.
- Notify the Facility administrator of the limited nature of the COVID-19 focused survey:
  - Prioritize observations on day one; and
  - Complete remaining *facility record reviews, medical record reviews*, observations and interviews on day two.
- Follow the COVID-19 FIC Survey Entrance Conference Worksheet to request information.

Survey Activities

- In situations where there is only one surveyor conducting the survey (e.g., complaint or EP), to the extent possible, the surveyor should begin the survey activity in an area with COVID-19 negative residents and not return to that area once positive residents have been encountered.
- Adhere to Standard and Transmission-Based Precautions and refer to CDC's "Interim Infection Prevention and Control Recommendations to Prevent SARS-CoV-2 Spread in Nursing Homes" and "Interim Infection Prevention and Control Recommendations for Healthcare Personnel During the Coronavirus Disease 2019 (COVID-19) Pandemic."
- Refer to CMS-20054, Infection Prevention, Control and Immunizations pathway *(January 2022),* to guide your investigation and make compliance determinations. Document your investigation on the electronic version of the pathway and/or electronic or paper-based surveyor notes worksheets. Scan and attach these documents, *including the COVID-19 Staff Vaccination Matrix and Staff Formula spreadsheet,* to the survey kit for upload to ACO/ARO.
- While the primary focus is COVID-19, you should investigate any other areas of potential noncompliance where there is a likelihood of immediate jeopardy (IJ). Follow the interpretive guidance and CE pathways relevant to the area of concern.
- Be alert to situations that may create a likelihood for serious injury, harm, impairment, or death, use guidance in Appendix Q and complete an IJ Template.

NOTE: Surveyors should limit photocopies to only those records necessary for confirming noncompliance or to support findings of deficient practice.

Concluding the Survey

- Conduct a survey exit discussion with the facility.
- Draft the statement of deficiencies (CMS-2567). If citing for noncompliance related to COVID-19, the surveyor(s) must include the following language at

the beginning of the Deficient Practice Statement or other place determined appropriate on the Form CMS-2567: "Based on [observations/interviews/record review], the facility failed to [properly prevent and/or contain – or other appropriate statement] COVID-19."

- *When determining the **severity and scope for F888**, surveyors must refer to Attachment A* in the *QSO-22-07-ALL (starting on 1/27/22), QSO-22-09-ALL (starting on 2/14/22) and* QSO-22-11-All *(starting on 2/22/2022), for detailed instructions.*

COVID-19 Focused Infection Control (FIC) Survey with Staff Vaccination Mandate Entrance Conference Worksheet

(Note: Surveyors in a state that is subject to QSO-22-07-ALL should start using this protocol on 1/27/2022. Surveyors in a state that is subject to QSO-22-09-ALL should start using this protocol on 2/14/2022. Surveyors in a state that is subject to QSO-22-11-ALL should start using this protocol on 2/22/2022).

INFORMATION NEEDED FROM THE FACILITY IMMEDIATELY UPON ENTRANCE*
❑ 1. Census number
❑ 2. An alphabetical list of all residents and room numbers (note any resident out of the facility).
❑ 3. A list of residents who are confirmed or suspected cases of COVID-19
❑ 4. Name of facility staff responsible for Infection Prevention and Control Program.
❑ 5. Name of facility staff responsible for overseeing the COVID-19 vaccination effort.
ENTRANCE CONFERENCE
❑ 6. Conduct a brief Entrance Conference with the Administrator.
❑ 7. Signs announcing the survey that are posted in high-visibility areas.
❑ 8. A copy of an updated facility floor plan, if changes have been made, including observation and COVID-19 units.
❑ *9.Complete the COVID-19 Staff Vaccination Matrix or provide a list containing the same information as soon as possible.*
INFORMATION NEEDED FROM FACILITY WITHIN ONE HOUR OF ENTRANCE*
❑ 10. The actual working schedules for all staff, separated by departments, for the survey time period.
❑ 11. List of key personnel location, and phone numbers. Note contract staff (e.g., rehab services). Also include the staff responsible for notifying all residents, representatives, and families of confirmed or suspected COVID-19 cases in the facility.
❑ 12. Provide each surveyor with access to all resident electronic health records (EHRs) – do not exclude any information that should be a part of the resident's medical record. Provide instructions on how surveyors can access the EHRs outside of the conference room. Please complete the attached form on page 3 which is titled "Electronic Health Record Information."
❑ 13. Facility Policies and Procedures: • Infection Prevention and Control Program Policies and Procedures, to include the Surveillance Plan • Procedures to address residents and staff who refuse testing or are unable to be tested • Emergency Preparedness Policy and Procedure to include Emergency Staffing Strategies • Influenza, Pneumococcal, and COVID-19 Vaccination Policy & Procedures • *COVID-19 Healthcare Staff Vaccination Policies and Procedures*
❑ 14. The facility's mechanism(s) used to inform residents, their representatives, and families of confirmed or suspected COVID-19 cases in the facility and mitigating actions taken by the facility to prevent or reduce the risk of transmission, including if normal operations in the nursing home will be altered (e.g., supply the newsletter, email, website, etc.). If the system is dependent on the resident or representative to obtain the information themselves (e.g., website), provide the notification/information given to residents, their representatives, and families informing them of how to obtain COVID-19 updates.

COVID-19 Focused Infection Control (FIC) Survey with Staff Vaccination Mandate Entrance Conference Worksheet

❑	15. Documentation related to COVID-19 testing, which may include the facility's testing plan, logs of county level positivity rates (before 09-10-2021) and the level of community transmission (after 09-10-2021), testing schedules, list of staff who have confirmed or suspected cases of COVID-19 over the last 4 weeks, and, if there were testing issues, contact with state and local health departments.
❑	16. A list of residents and their COVID-19 vaccination status.
❑	*17. Numbered list of resident cases of confirmed COVID-19 over the last 4 weeks. Indicate whether any resident cases resulted in hospitalization or death.*

*The timelines for requested information in the table are based on normal circumstances. Surveyors should be flexible on the time to receive information based on the conditions in the facility. For example, do not require paperwork within an hour if it interrupts critical activities that are occurring to prevent the transmission of COVID-19.

COVID-19 Focused Infection Control (FIC) Survey with Staff Vaccination Mandate Entrance Conference Worksheet
ELECTRONIC HEALTH RECORD (EHR) INFORMATION

Please provide the following information to the survey team within one hour of Entrance.

Provide specific instructions on where and how surveyors can access the following information in the EHR (or -	
1. Infections	
2. Hospitalization	
3. Change of condition	
4. Medications	
5. Diagnoses	
6. COVID-19 test results	
7. Immunization data	

Please provide name and contact information for IT and back-up IT for questions:

IT Name and Contact Info: _____

Back-up IT Name and Contact Info: _____

Infection Prevention, Control & Immunizations (January 2022)

Infection Control: This facility task must be used to investigate compliance at F880, F881, F882, F883, F885, F886, F887, and F888. For the purpose of this task, "staff" includes facility employees (regardless of clinical responsibilities or resident contact), licensed practitioners, adult students, trainees, and volunteers; and individuals who provide care, treatment or other services for the facility and/or its residents, under contract or by other arrangement. The infection prevention and control program (IPCP) must be facility-wide and include all departments and contracted services. If a specific care area concern is identified, it should be evaluated under the specific care area, such as for pressure ulcers, respiratory care, catheter care, and medication pass observations which include central lines, peripheral IVs, and oral/IM/respiratory medications.

Entry and screening procedures as well as resident care guidance have varied over the progression of COVID-19 transmission in facilities. Facilities are expected to be in compliance with CMS requirements and surveyors will use guidance that is in effect at the time of the survey. Refer to QSO memos released at: https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Policy-and-Memos-to- States-and-Regions.

If citing for noncompliance related to COVID-19, the surveyor(s) must include the following language at the beginning of the Deficient Practice Statement or other place determined appropriate on the Form CMS-2567: "Based on [observations/interviews/record review], the facility failed to [properly prevent and/or contain – or other appropriate statement] COVID-19."

Please Note:
Surveyors conducting a COVID-19 Focused Infection Control (FIC) Survey for Nursing Homes (not associated with a recertification survey), must evaluate the facility's compliance at all critical elements (CE) with the exception of CE #8 and CE #9. The surveyor must also examine the facility's compliance at §483.73(b)(6) or E0024 (at Appendix Z) if the full Emergency Preparedness survey is not being conducted.

Surveyors conducting a complaint survey, regardless of the nature of the complaints, must evaluate the facility's compliance at CE #13, #14, and #15 related to F888.

Infection Prevention, Control & Immunizations (January 2022)

Coordination:

☐ Each surveyor is responsible for assessing the facility for breaks in infection control throughout the survey and is to answer CEs of concern (e.g., standard and transmission-based precautions, source control).

☐ One surveyor performs or coordinates (e.g., immunization review) the facility task to review for:

- Standard and transmission-based precautions
- Resident care for COVID-19
- Infection Prevention and Control Program (IPCP) standards, policies, and procedures
- Infection surveillance
- Visitor entry
- Staff and resident COVID-19 testing
- Suspected or confirmed COVID-19 reporting to residents, representatives, and families
- Laundry services
- Antibiotic stewardship program
- Infection Preventionist
- Influenza, pneumococcal, and COVID-19 immunizations

☐ Sample residents/staff as follows:

- Sample three staff, include at least one staff member who was confirmed COVID-19 positive or had signs or symptoms consistent with COVID-19 (if this has occurred in the facility), for purposes of determining compliance with infection prevention and control national standards such as exclusion from work, testing, and reporting.
- Sample three residents for purposes of determining compliance with infection prevention and control national standards such as transmission-based precautions, as well as resident care, screening, testing, and reporting.
    - Include at least one resident who was confirmed COVID-19 positive or had signs or symptoms consistent with COVID-19 (if any).
    - Include at least one resident on transmission-based precautions (if any), for any reason other than COVID-19.
- Sample five residents for influenza, pneumococcal, and COVID-19 immunizations (select COVID-19 unvaccinated residents).
  Note: If there are less than five COVID-19 unvaccinated residents, review all unvaccinated COVID-19 residents first. Then, select residents who are fully vaccinated to complete the sample.
- Sample eight staff for COVID-19 immunization review.

Standard and Transmission-Based Precautions (TBPs)

State and Federal surveyors should not cite facilities for not having certain supplies (e.g., Personal Protective Equipment (PPE) such as gowns, N95 respirators, surgical masks) if they are having difficulty obtaining these supplies for reasons outside of their control (e.g., national or regional shortage). However, we do expect facilities to take actions to mitigate any resource shortages and show they are taking all appropriate steps to obtain the necessary supplies as soon as possible. Current CDC guidance for healthcare professionals is located at:

Infection Prevention, Control & Immunizations (January 2022)

https://www.cdc.gov/coronavirus/2019-nCoV/hcp/index.html and healthcare facilities is located at: https://www.cdc.gov/coronavirus/2019-ncov/hcp/us-healthcare-facilities.html. Guidance on strategies for optimizing PPE supply is located at: https://www.cdc.gov/coronavirus/2019-ncov/hcp/ppe-strategy/index.html. If a surveyor believes a facility should be cited for not having or providing the necessary supplies, the State Agency should contact the CMS Regional Location.

General Standard Precautions:

☐ Staff are performing the following appropriately:

- Respiratory hygiene/cough etiquette,
- Environmental cleaning and disinfection, and
- Reprocessing of reusable resident medical equipment (e.g., cleaning and disinfection of glucometers per device and disinfectant manufacturer's instructions for use).

Hand Hygiene:

☐ Appropriate hand hygiene practices (i.e., alcohol-based hand rub (ABHR) or soap and water) are followed.

☐ Staff wash hands with soap and water when their hands are visibly soiled (e.g., blood, body fluids), or after caring for a resident with known or suspected C. difficile infection (CDI) or norovirus during an outbreak, or if endemic rates of CDI are high. ABHR is not appropriate to use under these circumstances.

☐ Staff perform hand hygiene (even if gloves are used) in the following situations:

- Before and after contact with the resident;
- After contact with blood, body fluids, or visibly contaminated surfaces;
- After contact with objects and surfaces in the resident's environment;
- After removing personal protective equipment (e.g., gloves, gown, eye protection, facemask); and
- Before performing a procedure such as an aseptic task (e.g., insertion of an invasive device such as a urinary catheter, manipulation of a central venous catheter, and/or dressing care).

☐ When being assisted by staff, resident hand hygiene is performed after toileting and before meals. How are residents reminded to perform hand hygiene?

☐ Interview appropriate staff to determine if hand hygiene supplies (e.g., ABHR, soap, paper towels) are readily available and who they contact for replacement supplies.

Personal Protective Equipment (PPE) Use For Standard Precautions:

☐ Determine if staff appropriately use and discard PPE including, but not limited to, the following:

- Gloves are worn if potential contact with blood or body fluid, mucous membranes, or non-intact skin;

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- Gloves are removed after contact with blood or body fluids, mucous membranes, or non-intact skin (and hand hygiene performed);
- Gloves are changed and hand hygiene is performed before moving from a contaminated body site to a clean body site during resident care;
- An isolation gown is worn for direct resident contact if the resident has uncontained secretions or excretions (e.g., changing a resident and their linens when excretions would contaminate staff clothing);
- Appropriate mouth, nose, and eye protection (e.g., facemasks, goggles, face shield) along with isolation gowns are worn for resident care activities or procedures that are likely to contaminate mucous membranes, or generate splashes or sprays of blood, body fluids, secretions or excretions;
- All staff are following appropriate source control (i.e., facemasks or respirators) in accordance with national standards;
- 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;
- PPE is appropriately discarded after resident care, prior to leaving room (except in the case of extended use of PPE per national and/or local recommendations), followed by hand hygiene;
- During the COVID-19 public health emergency, if facilities are experiencing PPE shortages outside of their control, they are using PPE optimization strategies in accordance with national standards; and
- Supplies necessary for adherence to proper PPE use (e.g., gloves, gowns, masks) are readily accessible in resident care areas (e.g., nursing units, therapy rooms).

☐ Interview appropriate staff to determine if PPE supplies are readily available, accessible, and used by staff, and who they contact for replacement supplies.

- Are there sufficient PPE supplies available to follow infection prevention and control guidelines? In the event of PPE shortages, what procedures is the facility taking to address this issue?
- How do you obtain PPE supplies before providing care?
- Who do you contact for replacement supplies?

Source Control for COVID-19:

☐ Ensure residents (when receiving visitors or while outside of their room), visitors, and others at the facility are wearing appropriate source control, in accordance with national standards, while in the facility or while around others outside.

Transmission-Based Precautions (TBP):

☐ Determine if appropriate transmission-based precautions are implemented, including but not limited to:

- For a resident on contact precautions: staff don gloves and isolation gown before contact with the resident and/or his/her environment;
- 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 resident room entry;
- For a resident on airborne precautions: staff don a fit-tested N95 or higher-level respirator prior to room entry of a resident;

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- For a resident with an undiagnosed respiratory infection (and tested negative for COVID-19): staff follow standard, contact, and droplet precautions (i.e., facemask, gloves, isolation gown) with eye protection when caring for a resident unless the suspected diagnosis requires airborne precautions (e.g., tuberculosis);
- For a resident with known or suspected COVID-19: staff wear gloves, isolation gown, eye protection and an N95 or higher-level respirator if available. A facemask is an acceptable alternative if a respirator is not available.
    - Some procedures performed on residents with known or suspected COVID-19 could generate infectious aerosols (i.e., aerosol-generating procedures (AGPs)). In particular, procedures that are likely to induce coughing (e.g., sputum induction, open suctioning of airways) should be performed cautiously. If performed, the following should occur:
        - Staff in the room should wear an N95 or higher-level respirator, eye protection, gloves, and an isolation gown;
        - The number of staff present during the procedure should be limited to only those essential for resident care and procedure support;
        - AGPs should ideally take place in an airborne infection isolation room (AIIR). If an AIIR is not available and the procedure is medically necessary, then it should take place in a private room with the door closed; and
        - Clean and disinfect the room surfaces with an appropriate disinfectant. Use disinfectants on EPA's List N: Disinfectants for Coronavirus (COVID-19) or other national recommendations.
- Dedicated or disposable noncritical resident-care equipment (e.g., blood pressure cuffs, blood glucose monitor equipment) is used, or if not available, then reusable resident medical equipment is cleaned and disinfected according to manufacturers' instructions using an EPA-registered disinfectant for healthcare settings and effective against the identified organism (if known) prior to use on another resident.
- Objects and environmental surfaces that are touched frequently and in close proximity to the resident (e.g., bed rails, over-bed table, bedside commode, lavatory surfaces in resident bathrooms) are cleaned and disinfected with an EPA-registered disinfectant for healthcare settings and effective against the organism identified (if known) at least daily and when visibly soiled.
- Signage on the use of specific PPE (for staff) is posted in appropriate locations in the facility (e.g., outside of a resident's room, wing, or facility-wide).

☐ Observe staff to determine if they use appropriate infection control precautions when moving between resident rooms, units and other areas of the facility.

☐ Interview appropriate staff to determine if they are aware of processes/protocols for transmission-based precautions and how staff is monitored for compliance.

☐ If concerns are identified, expand the sample to include more residents on transmission-based precautions.

1. Did the staff implement appropriate standard (e.g., hand hygiene, appropriate use of PPE, environmental cleaning and disinfection, and reprocessing of reusable resident medical equipment) and transmission-based precautions (if applicable)? ☐ Yes ☐ **No F880**

Resident Care for COVID-19

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☐ Residents on transmission-based precautions are restricted to their rooms except for medically necessary purposes. If these residents have to leave their room, they are wearing source control, performing hand hygiene, limiting their movement in the facility, and performing social distancing (efforts are made to keep them at least 6 feet away from others).

☐ The facility ensures only COVID-19 negative, and those not on TBP or under quarantine for COVID-19, participate in group outings, group activities, and communal dining. The facility is ensuring that residents are maintaining social distancing (e.g., limited number of people in areas and spaced by at least 6 feet), performing hand hygiene, and wearing source control, in accordance with national standards.

☐ The facility has a plan (including appropriate placement and PPE use) to manage residents that are new/readmissions, those exposed to COVID-19, and those suspected of COVID-19. These actions are based on national (e.g., CDC), state and/or local public health authority recommendations.

☐ The facility has a plan to prevent transmission, including a dedicated space in the facility for cohorting and managing care for residents with COVID-19. These actions are based on national (e.g., CDC), state and/or local public health authority recommendations.

☐ For residents who develop severe symptoms of illness and require transfer to a hospital for a higher level of care, the facility alerts emergency medical services and the receiving facility of the resident's diagnosis (suspected, observation/quarantine, or confirmed COVID-19) and precautions to be taken by transferring and receiving staff as well as placing source control on the resident during transfer (as tolerated).

☐ For residents who need to leave the facility for care (e.g., dialysis, etc.), the facility ensures that residents physically distance and wear source control in accordance with national standards.

☐ In response to an outbreak, interview staff to determine how the facility ensures that residents physically distance and wear source control in accordance with national standards.

2. Did staff provide appropriate resident care for COVID-19 related concerns? ☐ Yes ☐ **No F880**

IPCP Standards, Policies, Procedures and Education:

☐ The facility established a facility-wide IPCP including written IPCP standards, policies, and procedures that are current and based on the facility assessment [according to 483.70(e)] and national standards (e.g., for undiagnosed respiratory illness and COVID-19).

☐ The facility's policies or procedures include which communicable diseases are reportable to local and/or state public health authorities and contain when to notify if there are clusters of respiratory illness or cases of COVID-19 that are identified or suspected. The facility has a current list of reportable communicable diseases.

☐ Staff (e.g., nursing and unit managers) can identify and describe the communication protocol with local/state public health officials (e.g., to whom and when communicable diseases, healthcare-associated infections (as appropriate), and potential outbreaks must be reported).

☐ There is evidence the facility has provided education to staff on COVID-19 (e.g., symptoms, how it is transmitted, self-monitoring for symptoms, work exclusions). How does the facility convey updates on COVID-19 to all staff?

☐ The policies and procedures are reviewed at least annually.

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☐ Concerns must be corroborated as applicable including the review of pertinent policies/procedures as necessary.

3. Does the facility have a facility-wide IPCP including standards, policies, procedures and education that are current, based on national standards, and reviewed at least annually? ☐ Yes ☐ **No F880**

Infection Surveillance:

☐ The facility has a system in place for staff to report a communicable illness, including symptoms of COVID-19; a positive test for COVID-19; and if he/she meets criteria for quarantine/work exclusion. The facility has a policy for monitoring and evaluating clusters or outbreaks of illness among staff. The facility is documenting staff with signs/symptoms (e.g., fever) of COVID-19 according to their surveillance plan.

☐ Interview staff to determine what actions the facility took if they have had signs/symptoms of COVID-19 (e.g., work exclusion, COVID-19 testing).

☐ If staff develop symptoms at work (as stated above), the facility:

- Informs the facility's infection preventionist and includes information on individuals, equipment, and locations the person came in contact with; and
- Follows current guidance about returning to work (e.g., local health department, CDC: https://www.cdc.gov/coronavirus/2019-ncov/hcp/guidance-risk-assesment-hcp.html).

☐ The facility identifies the number of residents and staff in the facility, if any, that have fever, respiratory signs/symptoms, or other signs/symptoms related to COVID-19.

☐ The facility identifies the number of residents and staff, if any, that have been diagnosed with COVID-19 and when the first case was confirmed.

☐ The facility prohibits employees with a communicable disease or infected skin lesions from direct contact with residents or their food, if direct contact will transmit disease. Staff are excluded from work according to national standards.

☐ The facility has established/implemented a surveillance plan, based on a facility assessment, for identifying, tracking, monitoring and/or reporting of infections and outbreaks. For COVID-19 that includes resident surveillance of fever, respiratory illness, or other signs/symptoms of COVID-19 at least daily, and immediately isolate anyone who is symptomatic.

☐ The plan includes early detection, management of a potentially infectious, symptomatic resident that requires laboratory testing and/or the implementation of appropriate transmission-based precautions/PPE (the plan may include tracking this information in an infectious disease log).

☐ The plan uses evidence-based surveillance criteria (e.g., CDC NHSN Long-Term Care or revised McGeer Criteria) to define infections and the use of a data collection tool.

☐ The plan includes ongoing analysis of surveillance data and review of data and documentation of follow-up activity in response.

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☐ The facility has a process for communicating at time of transfer to an acute care hospital or other healthcare provider the diagnosis to include infection or multidrug-resistant organism colonization status, special instructions or precautions for ongoing care such as transmission-based precautions, medications [e.g., antibiotic(s)], laboratory and/or radiology test results, treatment, and discharge summary (if discharged).

☐ The facility has a process for obtaining pertinent notes such as discharge summary, lab results, current diagnoses, treatment, and infection or multidrug-resistant organism colonization status when residents are transferred back from acute care hospitals.

☐ Interview appropriate staff to determine if infection control concerns are identified, reported, and acted upon.

4. Did the facility provide appropriate infection surveillance? ☐ Yes ☐ **No F880**

Visitor Entry

☐ Determine if:

- Visitation is conducted according to residents' rights for visitation and in a manner that does not lead to transmission of COVID-19; and
- Signage posted at facility entrances alerting visitors when they should not enter the facility (e.g., symptoms of illness, under quarantine, tested positive for COVID-19).

☐ The facility informs those who enter to frequently perform hand hygiene; limit their interactions with others in the facility and surfaces touched; restrict their visit to the resident's room or other location designated by the facility; and follow other current infection prevention and control standards (e.g., social distancing or source control). What is the facility's process for communicating this information?

☐ The facility informs those who enter to monitor for signs and symptoms of COVID-19 and appropriate actions to take if signs and/or symptoms occur.

5. Did the facility inform visitors when they should not enter the facility and inform the visitor of appropriate infection prevention and control actions to take while in the facility? ☐ Yes ☐ **No F880**

Suspected or Confirmed COVID-19 Reporting to Residents, Representatives, and Families

This CE is relevant to facilities that have had confirmed cases or clusters of suspected COVID-19 infection.

Identify the mechanism(s) the facility is using to inform residents, their representatives, and families (e.g., newsletter, email, website, recorded voice message):

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☐ The facility informed all residents, their representatives, and families by 5 PM the next calendar day following the occurrence of a single confirmed COVID-19 infection or of three or more residents or staff with new onset of respiratory symptoms that occurred within 72 hours of each other.

☐ The information included mitigating actions taken by the facility to prevent or reduce the risk of transmission, including if normal operations in the nursing home will be altered (e.g., visitation or group activities).

☐ The information did not include personally identifiable information.

☐ The facility provides cumulative updates to residents, their representatives, and families at least weekly or by 5 PM the next calendar day following the subsequent occurrence of either: each time a confirmed COVID-19 infection is identified, or whenever three or more residents or staff with new onset of respiratory symptoms occurs within 72 hours of each other.

☐ Interview a resident and a resident representative or family member to determine whether they are receiving timely notifications.

6. Did the facility inform residents, their representatives, and families of suspected or confirmed COVID-19 cases in the facility along with mitigating actions in a timely manner? ☐ Yes ☐ **No F885** ☐ N/A

Staff and Resident COVID-19 Testing

Review the facility's testing documentation (e.g., logs of community transmission levels, testing schedules, staff and resident records, other documentation). If possible, observe how the facility conducts testing, including the use of PPE and specimen collection. If such observation is not possible, interview an individual responsible for testing and inquire how testing is conducted (e.g., "what are the steps taken to conduct each test?").

☐ The facility conducts testing of unvaccinated staff based on the level of community transmission according to the recommended frequency.

☐ Based on observation or interview, the facility conducts testing and specimen collection in a manner that is consistent with current standards of practice for conducting COVID-19 tests.

☐ The facility's documentation demonstrates the facility conducts testing of residents or staff with signs or symptoms of COVID-19 in a manner that is consistent with current standards of practice for conducting COVID-19 tests.

☐ The facility's documentation demonstrates the facility conducts testing of residents and staff based on the identification of an individual diagnosed with COVID-19 in the facility in a manner that is consistent with current standards of practice for conducting COVID-19 tests.

☐ The facility takes actions to prevent the transmission of COVID-19 upon the identification of an individual with symptoms consistent with or who tests positive for COVID-19.

☐ The facility has procedures for addressing residents and staff that refuse testing or are unable to be tested.

☐ If there was an issue related to testing supplies or processing tests, ensure the facility made adequate attempts to obtain supplies by contacting the state and/or local health departments, local laboratories for assistance. If the facility conducts their own tests, they should also contact the supplier.

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Laundry Services:

☐ Determine whether staff handle, store, and transport linens appropriately including, but not limited to:

- Using standard precautions (e.g., gloves, gowns when sorting and rinsing) and minimal agitation for contaminated linen;
- Holding contaminated linen and laundry bags away from his/her clothing/body during transport;
- Bagging/containing contaminated linen where collected, and sorted/rinsed only in the contaminated laundry area (double bagging of linen is only recommended if outside of the bag is visibly contaminated or is observed to be wet on the outside of the bag);
- Transporting contaminated and clean linens in separate carts; if this is not possible, the contaminated linen cart should be thoroughly cleaned and disinfected per facility protocol before being used to move clean linens. Clean linens are transported by methods that ensure cleanliness, e.g., protect from dust and soil;
- Ensuring mattresses, pillows, bedding, and linens are maintained in good condition and are clean (Refer to F584); and
- If a laundry chute is in use, laundry bags are closed with no loose items.

☐ Laundry Rooms – Determine whether staff:

- Maintain/use washing machines/dryers according to the manufacturer's instructions for use;
- If concerns, request evidence of maintenance log/record; and
- Use detergents, rinse aids/additives, and follow laundering directions according to the manufacturer's instructions for use.

8. Did the facility store, handle, transport, and process linens properly? ☐ Yes ☐ **No F880** ☐ **N/A, not a recertification survey**

Antibiotic Stewardship Program:

☐ Determine whether the facility has an antibiotic stewardship program that includes:

- Written antibiotic use protocols on antibiotic prescribing, including the documentation of the indication, dosage, and duration of use of antibiotics;
- Protocols to review clinical signs and symptoms and laboratory reports to determine if the antibiotic is indicated or if adjustments to therapy should be made and identify what infection assessment tools or management algorithms are used for one or more infections (e.g., SBAR tool for urinary tract infection (UTI) assessment, Loeb minimum criteria for initiation of antibiotics);
- A process for a periodic review of antibiotic use by prescribing practitioners: for example, review of laboratory and medication orders, progress notes and medication administration records to determine whether or not an infection or communicable disease has been documented and whether an appropriate antibiotic has been prescribed for the recommended length of time. Determine whether the antibiotic use monitoring system is reviewed when the resident is new to the facility, when a prior resident returns or is transferred from a

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hospital or other facility, during each monthly drug regimen review when the resident has been prescribed or is taking an antibiotic, or any antibiotic drug regimen review as requested by the QAA committee;

- Protocols to optimize the treatment of infections by ensuring that residents who require antibiotics are prescribed the appropriate antibiotic; and
- A system for the provision of feedback reports on antibiotic use, antibiotic resistance patterns based on laboratory data, and prescribing practices for the prescribing practitioner.

9. Did the facility conduct ongoing review for antibiotic stewardship? ☐ Yes ☐ No F881 ☐ N/A, not a recertification survey

Infection Preventionist (IP):

During interview with facility administration and Infection Preventionist(s), determine the following:

☐ The facility designated one or more individual(s) as the infection preventionist(s) who are responsible for the facility's IPCP.

☐ The Infection Preventionist(s) works at least part-time at the facility.

☐ The Infection Preventionist(s) completed specialized training in infection prevention and control.

10. Did the facility designate at least one qualified IP, who is responsible for the facility's IPCP? ☐ Yes ☐ No F882

Influenza, Pneumococcal, and COVID-19 Immunizations for Residents:

☐ Select five residents in the sample to review for the provision of influenza, pneumococcal, and COVID-19 immunizations.

Note: Include COVID-19 unvaccinated residents as indicated on the vaccination status list.☐ Document the names of residents selected for review.

☐ Review the records of the five residents (influenza, pneumococcal, and COVID-19) for documentation of:

- Screening and eligibility to receive the vaccine(s);
- The provision of education related to the influenza, pneumococcal, and COVID-19 vaccines (such as the benefits and potential side effects);
- The administration of vaccines in accordance with national recommendations, which includes doses administered.
- Facilities must follow the CDC and Advisory Committee on Immunization Practices **(**ACIP) recommendations for vaccines; and
- Allowing a resident or representative to accept or refuse the influenza, pneumococcal, and COVID-19 vaccines. If not provided, documentation as to why the vaccine(s) was not provided.

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☐ For surveys occurring during influenza season, unavailability of the influenza vaccine can be a valid reason why a facility has not implemented the influenza vaccine program, especially during the early weeks of the influenza season. Similarly, COVID-19 vaccine supplies may be limited. Ask the facility to demonstrate that:

- The vaccine has been ordered and the facility received a confirmation of the order indicating that the vaccine has been shipped or that the product is not available but will be shipped when the supply is available;
- It made efforts to obtain the COVID-19 vaccine and provided information to residents on obtaining the vaccine if it is not available; and
- Plans are developed on how and when the vaccines are to be administered when they are available.

☐ As necessary, determine if the facility developed influenza, pneumococcal and COVID-19 vaccine policies and procedures for all facility residents. Review policies and procedures and interview facility staff, residents and/or resident representatives to determine:

- How residents and/or resident representatives, and staff receive education on the benefits and potential side effects before being offered a vaccine. If multiple doses are required, how residents and/or resident representatives, will again receive education on the benefits and potential side effects before being offered the vaccine;
- How residents' vaccination status is tracked; and
- How screening is conducted for eligibility (e.g., medical contraindications, previous vaccination), the vaccines are offered, and consent or refusal is obtained.

11. Did the facility provide influenza and/or pneumococcal immunizations as required or appropriate for residents?
☐ Yes ☐ **No F883**

12. Did the facility provide COVID-19 immunization as required or appropriate for residents? ☐ Yes ☐ **No F887**

COVID-19 Vaccination for Facility Staff:

Policy and Procedure for Staff COVID-19 Vaccinations:

☐ Determine whether the facility's COVID-19 vaccination policies and procedures for staff include the following:

- All staff (except pending or granted requests for exemptions/temporarily delayed) have received, at a minimum, one dose of COVID-19 vaccine prior to providing care/treatment/services for the facility and/or its residents;
- A process to ensure that all staff (except those who have been granted an exemption or have a temporary delay) are fully vaccinated for COVID-19;
- Additional <u>precautions</u> 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.,

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telework), or to duties which 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 located in a county with low to moderate community transmission.
    - 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) for 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.
- Track and securely document the COVID-19 vaccination status for all staff, including booster doses;
- Process by which staff may request an exemption from the COVID-19 Health Care Staff vaccination requirements;
- Track and securely document staff who have requested or have been granted an exemption by the facility for COVID-19 vaccination;
- Documentation for each staff who requests medical exemption must include:
    - The authorized COVID-19 vaccines that are contraindicated and the clinical reasons; and
    - A practitioner statement that the staff member be exempted from the facility's COVID-19 vaccination requirements; and
    - Must be signed and dated by a licensed practitioner, who is not the individual requesting the exemption.
- Track/secure documentation of delayed staff vaccination for clinical precautions/considerations; and
- Contingency plans for staff that are not fully vaccinated for COVID-19:
    - 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?

13. Did the facility develop policies and procedures that address the above components? ☐ Yes ☐ **No F888**

Verification of National Healthcare Safety Network (NHSN) data: Please fill in the blanks with data directly from this link.

NHSN as reported for week ending on (report header): _____

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Recent Percentage of Staff who are Fully Vaccinated: ☐

Note: if there is no data present in NHSN, please ask the facility staff the rationale while onsite.

☐ Review the COVID-19 Staff Vaccination Matrix or the facility's list of all staff and their vaccination status, which is obtained on the first day of the survey. Calculate the percentage of the current staff who received completed vaccinations using the formula listed in Figure 1 on the Surveyor Instructions on the COVID-19 Staff Vaccination Matrix (do not round). Compare the facility's data with the above NHSN data.

- If there is a 10% or less difference between the facility documentation and the NHSN data, no further investigation is required.
- If there is a greater than 10% difference, ask the facility to verify and explain why there is a significant variation.
  - If the information presented to the surveyor is incorrect (and NHSN is correct), or if both sources are incorrect, this likely demonstrates the facility's failure to have a process for tracking and securely documenting the COVID-19 vaccination status for all staff [per §483.80(i)(3)(iv)], consider citing F888.
  - If the information reported to NHSN is incorrect (and the information reviewed onsite is correct) or there is no data present in NHSN, inform the facility to immediately correct the information in the NHSN system.

14. Did the facility implement their policy and have a process to track and securely document the COVID-19 vaccination status for all staff (per 483.80(i)(3)(iv))? ☐ Yes ☐ **No F888**

Determine the percentage of staff vaccinated and when to cite F888 in ASE-Q or LTCSP: (Refer to the surveyor instructions section III on the COVID-19 Staff Vaccination Matrix)

☐ Surveys conducted per QSO Memo 22-07-ALL (effective 01/27/2022–2/27/2022) / QSO-22-09-ALL (effective 02/14/2022-03/14/2022)/QSO-22-11-ALL (effective 02/22/2022-03/20/2022)

- 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.

☐ Surveys conducted per QSO-22-07-ALL (effective on 02/28/2022 and thereafter) / QSO-22-09-ALL (effective 03/15/2022 and thereafter) / QSO-22-11-ALL (effective 03/21/2022 and thereafter)

- If the percent vaccinated is less than 100% of all staff have received at least **one dose of a single-dose vaccine**, or **all doses of a multiple vaccine series**, or have been **granted** a qualifying exemption, or identified as having a temporary delay recommended by the CDC, cite F888.

Record Review, Staff Interviews, and Observations:

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☐ Randomly select 8 staff from the completed COVID-19 Staff Vaccination Matrix, as described below, unless concerns exist for specific staff (e.g., complaints, infection control practice observations)

- 2 vaccinated staff
  - One certified nurse aide (CNA).
  - One individual who provides care, treatment, or other services for the facility and/or its residents under contract or by other arrangements (e.g., hospice and dialysis staff, physical therapists, occupational therapists, mental health professionals, licensed practitioners).
- 6 unvaccinated staff (if available)
  - Three unvaccinated staff (two of whom are CNAs, if available) without exemption or reason for being temporarily delayed.
  - One unvaccinated staff with a non-medical exemption such as religious exemption.
  - One unvaccinated staff with a medical exemption. (Note: If there are 2 or more staff with medical exemptions listed on the COVID-19 Staff Vaccination Matrix, select 50% of the facility staff from this category for review).
  - One unvaccinated staff whose primary vaccine series has been delayed.

Note: If there are no staff who meet one of the above unvaccinated criteria, you do not need to increase the sample size for another category. If the surveyor identifies any staff that were not vaccinated and were not granted a qualifying exemption or have a temporary delay (and weren't marked as such on the staff matrix), that individual(s) should be added to the sample.

☐ Observe and interview sampled staff who are not vaccinated to ensure additional precautions are in place to help prevent the spread of COVID-19.

- If reassigned: When were you reassigned duties?
- Are you being tested for COVID-19? If so, how often?
- 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) and maintaining physical distance including areas that are restricted from resident access (e.g., staff meeting rooms, kitchen).
- Determine whether other additional precautions are in place to mitigate the transmission of COVID-19.

☐ For all sampled staff, determine whether the COVID-19 vaccination documentation includes the following:

- Screening and eligibility to receive the vaccine(s); and
- The provision of education related to the COVID-19 vaccines such as the benefits and potential side effects; and offering of the COVID-19 vaccines to staff by the facility per requirements at 42 CFR 483.80(d)(3), F887.

Note: These provisions do not apply to sampled staff that received their vaccination outside of the facility.

☐ For sampled **vaccinated staff**, determine whether the facility documented the vaccination status for:

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- a single-dose COVID-19 vaccine, or
- all required doses for a multi-dose COVID-19 vaccine, and
- a booster dose.

☐ For the sampled **unvaccinated staff**:

- For staff who **do not have an exemption or reason for temporary delay,** ask the following:
  - Are you scheduled to receive a COVID-19 vaccine? If so, confirm the staff is scheduled.
  - If the staff isn't scheduled to receive a vaccine: Do you have a request for exemption pending?
  - When did the facility become aware staff did not have an exemption or reason for temporary delay?
  - What actions did the facility take to educate and offer COVID-19 vaccines to staff?
  - What actions did the facility take when staff indicated that they will not get vaccinated and do not qualify for an exemption?
- For staff who have requested and/or are granted **non-medical exemption**, verify facility records are tracked and secure, and interview staff to determine the following:
  - What is the process to request a non-medical exemption, such as a religious exemption?
  - How are staff informed about the process to request a non-medical exemption?
  - Ensure the facility has an effective process for staff to request a non-medical exemption. Surveyors will not focus on the details of the request, approval, or denial of non-medical exemptions.
- For staff who have requested and/or are granted **medical exemption,** verify facility records are tracked, secure, and include the following:
  - Which COVID-19 vaccine is clinically contraindicated;
  - The recognized clinical reasons for the contraindication;
  - A statement by the practitioner recommending the staff member be exempted from the COVID-19 vaccination requirement; and
  - A signature and date by a licensed practitioner who is not the individual requesting the exemption.
- For staff whose primary vaccine series is **temporarily delayed,** verify facility records are tracked, secure, and include the following:
  - An explanation for delay as per CDC clinical precautions and considerations;
  - How long the delay is planned; and
  - A plan for vaccination when the temporary delay is over (date when vaccination can resume).
- Review facility records and interview staff to confirm the facility has instituted the contingency plan, if needed:
  - Verify the actions taken by the facility for any staff who indicated they would not get vaccinated and were not qualified for an exemption?
  - When was staff given a deadline to receive the first dose of a vaccine? Confirm the date.
  - If the deadline has passed: What actions were taken?

15. Did the facility implement their policy and procedures to ensure:

a) all staff are vaccinated for COVID-19;

Infection Prevention, Control & Immunizations (January 2022)

b) there is a process to request an exemption;

c) vaccination status is tracked, and documentation is secure for staff with an exemption or temporary delay; and

d) contingency plans are developed and followed?

☐ Yes ☐ **No F888**

Educate and Offer COVID-19 Immunizations for Staff at Requirement 483.80(d)(3)

☐ Use the same staff sample used for CE #15 to determine compliance with CE #16.

☐ Review the facility's policies and procedures related to COVID-19 vaccination and ask the facility:

- What efforts has the facility made to obtain the COVID-19 vaccine? How was information provided to staff on obtaining the vaccine if it was not available?
- How are staff educated on the benefits and potential side effects before being offered a vaccine including any additional dose?
- How are staff vaccination status tracked or documented?
- How are staff screened for eligibility (e.g., medical contraindications, previous vaccination), that the vaccines are offered, and consent or refusal is obtained?

16. Did the facility maintain staff documentation of screening, education, offering, and current COVID-19 vaccination status?

☐ Yes ☐ **No F887**

COVID-19 STAFF VACCINATION MATRIX INSTRUCTIONS FOR PROVIDERS

The Matrix is used to identify the vaccination status for all staff. The facility completes this form, including section I, staff name, and columns 1–11, which are described in detail below, or provide a list containing the same information required in the matrix.

Unless stated otherwise, for each staff mark an X for all columns that are pertinent.

1. **Direct facility hire (DH), Contracted hire (C), or Other (O):** Direct facility hires (DH) are employees who are directly hired by the facility. Contracted hires (C) provide care, treatment, or other services for the facility and/or its residents under contract or by other arrangements. Other (O) includes adult students, trainees, and volunteers.
2. **Title:** Identify the staff's title (e.g., RN, LPN, CNA, PA, RD).
3. **Position:** Identify the staff's position (e.g., staff nurse, charge nurse, infection preventionist, restorative aide).
4. **Assigned work area:** The physical location in the facility (e.g., laundry room, kitchen, unit, ward, wing). If the staff is PRN/floater/agency, indicate their assigned work area on the first day of the survey.
5. **Partially vaccinated:** Staff who have received one dose of a multi-dose vaccine.
6. **Completely vaccinated:** Staff who have received one dose of a single dose vaccine or all doses of a multi-dose vaccine. (For the purpose of this document, fully vaccinated and completely vaccinated are the same)
7. **Booster dose:** A dose of vaccine administered when the initial sufficient immune response to the primary vaccination series is likely to have waned over time.
8. **Pending (P) or Granted (G) medical exemption:** Per CDC certain allergies or recognized medical conditions, which may provide grounds for a medical exemption (Please refer to the CDC).
9. **Pending (PN) or Granted (GN) non-medical exemption:** May be a religious exemption in accordance with Title VII.
10. **Temporary delay per CDC/new hire:** Vaccination that must be temporarily postponed, as recommended by the CDC, due to clinical precautions and considerations. Newly hired staff, who are not completely vaccinated due to timing requirements between doses.
11. **Not vaccinated without exemption or delay:** Any staff who have not received any doses of a vaccine and do not qualify for any of the exemptions or delays.

Section I

Total number of staff: All staff that work in the facility. Staff includes facility employees (regardless of clinical responsibilities or resident contact), licensed practitioners, adult students, trainees, and volunteers; and individuals who provide care, treatment, or other services for the facility and/or its residents, under contract or by other arrangement.

Number partially vaccinated staff (column 5): Number of current staff who received partial vaccination at any time as defined as, current staff who have received at a minimum, the first dose of the primary vaccination series for a multi-dose COVID-19 vaccine.

Number completely vaccinated staff (column 6): Number of current staff who completed vaccination at any time is defined as, current staff with administration of a single-dose vaccine, or the administration of all required doses of a multi-dose vaccine

Number of staff with pending exemption (columns 8 and 9): Number of current staff with a request (pending) a medical or non-medical exemption.

Number of staff with granted exemption (columns 8 and 9): Number of current staff who was granted a qualifying medical or non-medical exemption.

Number of staff with temporary delay (column 11): Number of current staff whose COVID-19 vaccination must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations.

Number of staff not vaccinated without exemption or delay: Number of current staff who have not received any doses of a vaccine and do not qualify for an exemption or temporary delay.

COVID-19 Staff Vaccination Status for Providers

Complete this form or provide a list containing the same information required in this form.

Section I: *Complete based on the Day 1 of the survey:*

Total # of staff:

partially vaccinated staff (5):

completely vaccinated staff (6):

pending exemption (8 and 9):

granted exemption (8 and 9):

temporary delay/new hire (10):

not vaccinated without exemption/delay (11):

Note: The sum of the #'s for columns 5, 6, 8 through 11 should equal the total # of staff.

					Vaccinated			Not Vaccinated			
Staff Name	**Direct facility hire (DH), Contracted hire (C), Other (O)**	**Title**	**Position**	**Assigned work area**	**Partially vaccinated**	**Completely vaccinated**	**Booster dose**	**Pending (P) or Granted (G) medical exemption**	**Pending (PN) or Granted (GN) non-medical exemption**	**Temporary delay per CDC/ new hire**	**Not vaccinated without exemption/delay**
	1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**

Instructions for Surveyors to Determine Compliance at §483.80(i) COVID-19 Vaccination of Facility Staff

Note: A Staff Formula spreadsheet is available in the Survey Resources folder that can be used to calculate the formulas listed below. **Please attach the completed spreadsheet to the LTCSP software or the survey shell.**

Section II – Verification of National Health Care Safety Network (NHSN) data

- Please fill in the blanks with data directly from this link.
- NHSN as reported for week ending on (report header): _____
- Recent Percentage of Staff who are Fully Vaccinated: _____ If there is no data present in NHSN, please ask the facility staff the rationale while onsite. (For the purpose of this document, fully vaccinated and completely vaccinated are the same)
- Review the staff matrix or the facility's list of all staff and their vaccination status, which is obtained on the first day of the survey. Calculate the percentage of the current staff who have completed vaccinations using the formula listed in Figure 1 (do not round). Compare the facility's data with the above NHSN data.

Figure 1: Formula to calculate percentage of current vaccinated staff to compare with NHSN data

$$\textbf{\% current staff received completed vaccination} = \frac{\text{\# Completely vaccinated (6)}}{\text{\# of total staff}} \times 100$$

- If there is a 10% or less difference between the facility documentation and the NHSN data, no further investigation is required.
- If there is a greater than 10% difference, ask the facility to verify and explain why there is a significant variation.
- If the information presented to the surveyor is incorrect (and NHSN is correct), or if both sources are incorrect, this likely demonstrates the facility's failure to have a process for tracking and securely documenting the COVID-19 vaccination status for all staff [per §483.80(i)(3)(iv)], consider citing F888.
- If the information reported to NHSN is incorrect (and the information reviewed onsite is correct) or data is not present, inform the facility to immediately correct the information in the NHSN system.

Section III – Determine when to cite F888

Determine the percentage of staff vaccinated: (Follow the data in Section I provided on the facility matrix)

- **When surveying between 30 - 59 days following issuance of the QSO-22-07-ALL (effective 1/27/2022–2/27/2022) / QSO-22-09-ALL (effective 2/14/2022-3/14/2022)/ QSO-22-11-ALL (effective 02/22/2022-03/20/2022) :** Use the formula below (or in the Staff Formula spreadsheet) to calculate the percentage (round to the whole number) of staff that received a COVID-19 vaccination using the information the facility completed in Section I above.

Formula for surveys conducted between 30 - 59 days following issuance of the QSO memo

$$\%\text{Vaccinated} = \frac{\text{\# Partially vaccinated (5)} + \text{\# Completely vaccinated (6)} + \text{\# Pending exemption (8 and 9)} + \text{\# Granted exemption (8 and 9)} + \text{\# Temporarily delayed (10)}}{\text{\# of total staff}} \times 100$$

- If the percent vaccinated is less than 100%, cite F888.

- **When surveying 60 days following issuance of the QSO-22-07-ALL (effective 2/28/22 and thereafter) / QSO-22-09-ALL (effective 3-15-2022 and thereafter) / QSO-22-11-ALL (effective 03/21/2022 and thereafter):** Use the formula below (or in the Staff Formula spreadsheet) to calculate the percentage (round to the whole number) of staff that received a completed COVID-19 vaccination series.

Formula for surveys conducted 60 following issuance of the QSO memo

$$\%\text{Vaccinated} = \frac{\text{\# Completely vaccinated (6)} + \text{\# Granted exemption (8 and 9)} + \text{\# Temporarily delayed (10)}}{\text{\# of total staff}} \times 100$$

- If the percent vaccinated is less than 100%, cite F888.
- Note: If the facility's staff vaccination rate is below 100% because of newly hired staff, who are not yet eligible to receive the second dose in a two-dose series, the facility will be considered compliant with the 100% staff vaccination requirement. The facility would need to be incompliance with §483.80(i)(3)(iii), including adhering to additional precautions that are intended to mitigate the spread of COVID-19.

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop C2-21-16
Baltimore, Maryland 21244-1850

Center for Clinical Standards and Quality/Quality, Safety & Oversight Group

Ref: QSO-22-11-ALL

DATE: **January 20, 2022**

TO: State Survey Agency Directors

FROM: Directors
Quality, Safety & Oversight Group (QSOG) and Survey & Operations Group (SOG)

SUBJECT: Guidance for the Interim Final Rule - Medicare and Medicaid Programs; Omnibus COVID-19 Health Care Staff Vaccination

Memorandum Summary

- CMS is committed to ensuring America's healthcare facilities respond effectively in an evidence-based way to the Coronavirus Disease 2019 (COVID-19) Public Health Emergency (PHE).
- On November 05, 2021, CMS published an interim final rule with comment period (IFC). This rule establishes requirements regarding COVID-19 vaccine immunization of staff among Medicare- and Medicaid-certified providers and suppliers.
- CMS is providing guidance and survey procedures for assessing and maintaining compliance with these regulatory requirements.
- The guidance in this memorandum specifically applies to the following state: **Texas**.
- States that are not identified above are expected to continue under the timeframes and parameters identified in either the December 28, 2021 or January 14, 2022 memoranda (QSO-22-07-ALL and QSO 22-09-ALL**).**

Background

Since the beginning of the Public Health Emergency, CMS and the Centers for Disease Control and Prevention (CDC) data show as of mid-October, over 44 million COVID-19 cases, 3 million COVID-19 related hospitalization, and 720,000 COVID-19 deaths have been reported. The CDC has reported that COVID-19 vaccines are safe and effective at preventing severe illness from COVID-19 and limiting the spread of the virus that causes it. On December 11, 2020, the Advisory Committee in Immunization Practices (ACIP) recommended, as interim guidance, that both 1) health care personnel, and 2) residents of long-term care (LTC) facilities be offered COVID-19 vaccine in the initial phase of the vaccination program. To support this recommendation, on May 13, 2021, CMS published an interim final rule with comment period (IFC), entitled "Medicare and Medicaid Programs; COVID-19 Vaccine Requirements for Long-Term Care (LTC) Facilities and Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICFs-IID) Residents, Clients, and Staff" (86 FR 26306). Also, CMS released

guidance for surveyors and LTC facilities in the CMS memo, QSO-21-19-NH, Interim Final Rule - COVID-19 Vaccine Immunization Requirements for Residents and Staff. This rule required all certified LTC facilities (i.e., nursing homes) to educate all residents and staff on the benefits and potential side effects associated with the COVID-19 vaccine, and offer the vaccine.

The regulation was intended to help increase vaccination rates among nursing home residents and staff to reduce the risk of infection and disease associated with COVID-19. Approximately two months after the publication of the rule, about 80 percent of nursing home residents were vaccinated. However, during that same time, roughly 60% of nursing home staff were vaccinated.[1] Therefore, more actions are warranted to increase vaccination rates among staff.

On August 18, 2021, CMS announced that it would be issuing a regulation that all nursing home staff would have to be vaccinated against COVID-19 as a requirement for LTC facilities participating with the Medicare and Medicaid programs. Subsequently, on September 9, 2021, CMS announced that this requirement would be extended to nearly all Medicare and Medicaid-certified providers and suppliers. These actions aim to support increasing vaccination rates among staff working in all facilities, providers, and certified suppliers that participate in Medicare and Medicaid.

Discussion

On November 5, 2021, CMS published an IFC with comment period (86 FR 61555), entitled "Medicare and Medicaid Programs; Omnibus COVID-19 Health Care Staff Vaccination," revising the infection control requirements that most Medicare- and Medicaid-certified providers and suppliers must meet to participate in the Medicare and Medicaid programs. These changes are necessary to protect the health and safety of patients and staff during the COVID-19 public health emergency. The COVID-19 vaccination requirements and policies and procedures required by this IFC must comply with applicable federal non-discrimination and civil rights laws and protections, including providing reasonable accommodations to individuals who are legally entitled to them because they have a disability or sincerely held religious beliefs, practices, or observations that conflict with the vaccination requirement. More information on federal non-discrimination and civil rights laws is available here: https://www.eeoc.gov/wysk/what-you-should-know-about-covid-19-and-ada-rehabilitation-act-and-other-eeo-laws.

Vaccination Enforcement– Surveying for Compliance

Medicare and Medicaid-certified facilities are expected to comply with all regulatory requirements, and CMS has a variety of established enforcement remedies. For nursing homes, home health agencies, and hospice (beginning in 2022), this includes civil monetary penalties, denial of payments, and—as a final measure—termination of participation from the Medicare and Medicaid programs. The sole enforcement remedy for non-compliance for hospitals and certain other acute and continuing care providers is termination; however, CMS's primary goal is to bring health care facilities into compliance. Termination would generally occur only after providing a facility with an opportunity to make corrections and come into compliance.

[1] COVID-19 Nursing Home Data - Centers for Medicare & Medicaid Services Data (cms.gov)

CMS expects all providers' and suppliers' staff to have received the appropriate number of doses by the timeframes specified in the QSO-22-07 unless exempted as required by law, or delayed as recommended by CDC. **Facility staff vaccination rates under 100% constitute non-compliance under the rule.** Non-compliance does not necessarily lead to termination, and facilities will generally be given opportunities to return to compliance. Consistent with CMS's existing enforcement processes, this guidance will help surveyors determine the severity of a noncompliance deficiency finding at a facility when assigning a citation level. These enforcement action thresholds are as follows:

Within 30 days after issuance of this memorandum[2], if a facility demonstrates that:

- Policies and procedures are developed and implemented for ensuring all facility staff, regardless of clinical responsibility or patient or resident contact are vaccinated for COVID-19; **and**
- 100% of staff have received at least one dose of COVID-19 vaccine, or have a pending request for, or have been granted qualifying exemption, or identified as having a temporary delay as recommended by the CDC, the **facility is compliant under the rule; or**
- 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, the **facility is non-compliant under the rule.** The facility will receive notice[3] of their non-compliance with the 100% standard. A facility that is above 80% **and** has a plan to achieve a 100% staff vaccination rate within 60 days would not be subject to additional enforcement action. States should work with their CMS location for cases that exceed these thresholds, yet pose a threat to patient health and safety. Facilities that do not meet these parameters could be subject to additional enforcement actions depending on the severity of the deficiency and the type of facility (e.g., plans of correction, civil monetary penalties, denial of payment, termination, etc.).

Within 60 days after the issuance of this memorandum[4], if the facility demonstrates that:

- Policies and procedures are developed and implemented for ensuring all facility staff, regardless of clinical responsibility or patient or resident contact are vaccinated for COVID-19; **and**
- 100% of staff have received the necessary doses to complete the vaccine series (i.e., one dose of a single-dose vaccine or all doses of a multiple-dose vaccine series), or have been granted a qualifying exemption, or identified as having a temporary delay as recommended by the CDC, the **facility is compliant under the rule; or**
- Less than 100% of all staff have received at least one dose of a single-dose vaccine, or all doses of a multiple-dose vaccine series, or have been granted a qualifying exemption, or identified as having a temporary delay as recommended by the CDC, the **facility is non-**

[2] If 30 days falls on a weekend or designated federal holiday, CMS will use enforcement discretion to initiate compliance assessments the next business day.
[3] This information will be communicated through the CMS Form-2567, using the applicable Automated Survey Process Environment (ASPEN) federal tag.
[4] If 60 days falls on a weekend or designated federal holiday, CMS will use enforcement discretion to initiate compliance assessments the next business day.

compliant under the rule. The facility will receive notice[5] of their non-compliance with the 100% standard. A facility that is above 90% **and** has a plan to achieve a 100% staff vaccination rate within 30 days would not be subject to additional enforcement action. States should work with their CMS location for cases that exceed these thresholds, yet pose a threat to patient health and safety. Facilities that do not meet these parameters could be subject to additional enforcement actions depending on the severity of the deficiency and the type of facility (e.g., plans of correction, civil monetary penalties, denial of payment, termination, etc.).

Within 90 days and thereafter following issuance of this memorandum, facilities failing to maintain compliance with the 100% standard may be subject to enforcement action.

Federal, state, Accreditation Organization, and CMS-contracted surveyors will begin surveying for compliance with these requirements as part of initial certification, standard recertification or reaccreditation, and complaint surveys 30 days following the issuance of this memorandum. Additional information and expectations for compliance can be found at the provider-specific guidance attached to this memorandum.

Provider-Specific Guidance:

Guidance specific to provider types and certified suppliers is provided in the following attachments. The provider-specific guidance should be used in conjunction with the information in this memo.

- Attachment A: LTC Facilities (nursing homes)
- Attachment B: ASC
- Attachment C: Hospice
- Attachment D: Hospitals
- Attachment E: PRTF
- Attachment F: ICF/IID
- Attachment G: Home Health Agencies
- Attachment H: CORF
- Attachment I: CAH
- Attachment J: OPT
- Attachment K: CMHC
- Attachment L: HIT
- Attachment M: RHC/FQHC
- Attachment N: ESRD Facilities

Enforcement Actions

CMS will follow current enforcement procedures based on the level of deficiency cited during a survey.

Contact:
DNH_TriageTeam@cms.hhs.gov for questions related to nursing homes;

[5] This information will be communicated through the CMS Form-2567, using the applicable Automated Survey Process Environment (ASPEN) tag.

QSOG_Emergencyprep@cms.hhs.gov for question related to acute and continuing care providers.

Effective Date: This policy should be communicated with all survey and certification staff, their managers, and the State/CMS Location training coordinators immediately. The effective dates of the specific actions are specified above.

/s/

Karen L. Tritz
Director, Survey & Operations Group

David R. Wright
Director, Quality, Safety & Oversight Group

cc: Survey and Operations Group Management
Attachments: A through N

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop C2-21-16
Baltimore, Maryland 21244-1850

Center for Clinical Standards and Quality/Survey & Certification Group

Ref: QSO-20-39-NH

DATE: **September 17, 2020** ***REVISED 11/12/2021***

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Nursing Home Visitation - COVID-19 *(REVISED)*

Memorandum Summary

- CMS is committed to continuing to take critical steps to ensure America's healthcare facilities are prepared to respond to the Coronavirus Disease 2019 (COVID-19) Public Health Emergency (PHE).
- **Visitation Guidance:** CMS is issuing new guidance for visitation in nursing homes during the COVID-19 PHE, including the impact of COVID-19 vaccination.
- ***Visitation is now allowed for all residents at all times.***

Background

Nursing homes have been severely impacted by COVID-19, with outbreaks causing high rates of infection, morbidity, and mortality.[1] The vulnerable nature of the nursing home population combined with the inherent risks of congregate living in a healthcare setting have required aggressive efforts to limit COVID-19 exposure and to prevent the spread of COVID-19 within nursing homes.

In March 2020, CMS issued memorandum QSO-20-14-NH providing guidance to facilities on restricting visitation of all visitors and non-essential healthcare personnel, except for certain compassionate care situations, such as an end-of-life situation. In May 2020, CMS released Nursing Home Reopening Recommendations, which provided additional guidance on visitation for nursing homes as their states and local communities progress through the phases of reopening.

While CMS guidance has focused on protecting nursing home residents from COVID-19, we recognize that physical separation from family and other loved ones has taken a physical and emotional toll on residents and their loved ones. Residents may feel socially isolated, leading to increased risk for depression, anxiety, and expressions of distress. Residents living with cognitive impairment or other disabilities may find visitor restrictions and other ongoing changes related to

[1] Information on outbreaks and deaths in nursing homes may be found at https://data.cms.gov/stories/s/COVID-19-Nursing-Home-Data/bkwz-xpvg.

COVID-19 confusing or upsetting. CMS understands that nursing home residents derive value from the physical, emotional, and spiritual support they receive through visitation from family and friends. In light of this, CMS is revising the guidance regarding visitation in nursing homes during the COVID-19 PHE. The information contained in this memorandum supersedes and replaces previously issued guidance and recommendations regarding visitation.

Since the release of QSO memorandum 20-39-NH on September 17, 2020, COVID-19 vaccines have received *full approval and* Emergency Use Authorization from the Food and Drug Administration. Millions of vaccinations have since been administered to nursing home residents and staff, and these vaccines have been shown to help prevent symptomatic SARS-CoV-2 infection (i.e., COVID-19). *In addition, CMS requires nursing homes to educate residents and staff on the risks and benefits of the vaccines, offer to administer the vaccine, and report resident and staff vaccination data to CDC's National Healthcare Safety Network. CMS now posts this information on the CMS COVID-19 Nursing Home Data website along with other COVID-19 data, such as the weekly number of COVID-19 cases and deaths.* **Therefore, CMS, in conjunction with the Centers for Disease Control and Prevention (CDC), is updating its visitation guidance accordingly, but emphasizing the importance of maintaining infection prevention practices.**

We note that the reason for visitation restrictions during the COVID-19 PHE were to mitigate the opportunity for visitors to introduce COVID-19 into the nursing home. Per 42 CFR § 483.10(f)(4), a resident has the right to receive visitors of his or her choosing at the time of his or her choosing, and in a manner that does not impose on the rights of another resident, such as a clinical or safety restriction (see 42 CFR § 483.10(f)(4)(v)). In other words, while all residents have a right to visitation, fully open and unrestricted visitation posed a clinical health and safety risk to other residents during this PHE, and therefore, it was reasonable to place limits on visitation. However, current nursing home COVID-19 data shows approximately 86% of residents and 74% of staff are fully vaccinated, and the number of new COVID-19 cases each week has been dramatically reduced. For example, the average number of national resident COVID-19 weekly cases in January 2021 was approximately 20,000 per week, whereas the average number in September 2021 was approximately 5100 per week (approximately an 80% reduction), demonstrating the effectiveness of the vaccines.

We note that staff vaccination rates remain significantly lower than resident vaccination rates. Therefore, we remain concerned about the transmission of the virus from unvaccinated staff to residents and are taking additional measures, such as establishing a staff vaccination requirement, to mitigate the spread of COVID-19 and protect residents. On November 4, 2021, CMS issued a regulation *requiring that all nursing home staff be vaccinated against COVID-19 as a requirement for participating in the Medicare and Medicaid programs. This requirement also applies to nearly all Medicare and Medicaid-certified providers and suppliers. CMS will continue to monitor vaccination and infection rates, including the effects of COVID-19 variants on nursing home residents, which have recently caused the number of cases to slightly increase. However, at this time, continued restrictions on this vital resident's right are no longer necessary.*

We acknowledge that there are still concerns associated with visitation, such as visitation with an unvaccinated resident while the nursing home's county COVID-19 level of community transmission[2]

[2] *Level of Community Transmission: This metric ** uses two indicators for categorization (1. Total number of new cases per 100,000 persons within the last 7 days and 2. Percentage of positive diagnostic and screening nucleic acid*

is substantial or high. However, adherence to the core principles of COVID-19 infection prevention mitigates these concerns. Furthermore, we remind stakeholders that, per 42 CFR § 483.10(f)(2), the resident has the right to make choices about aspects of his or her life in the facility that are significant to the resident. We further note that residents may deny or withdraw consent for a visit at any time, per 42 CFR § 483.10(f)(4)(ii) and (iii). Therefore, if a visitor, resident, or their representative is aware of the risks associated with visitation, and the visit occurs in a manner that does not place other residents at risk (e.g., in the resident's room), the resident must be allowed to receive visitors as he/she chooses.

Guidance

Visitation can be conducted through different means based on a facility's structure and residents' needs, such as in resident rooms, dedicated visitation spaces, *and* outdoors. Regardless of how visits are conducted, certain core principles and best practices reduce the risk of COVID-19 transmission:

Core Principles of COVID-19 Infection Prevention

- *Visitors who have a positive viral test for COVID-19, symptoms of COVID-19, or currently meet the criteria for quarantine, should not enter the facility. Facilities should screen all who enter for these visitation exclusions.*
- Hand hygiene (use of alcohol-based hand rub is preferred)
- Face covering or mask (covering mouth and nose) and *physical* distancing at least six feet between people, in accordance with CDC guidance
- Instructional signage throughout the facility and proper visitor education on COVID-19 signs and symptoms, infection control precautions, other applicable facility practices (e.g., use of face covering or mask, specified entries, exits and routes to designated areas, hand hygiene)
- Cleaning and disinfecting high-frequency touched surfaces in the facility often, and designated visitation areas after each visit
- Appropriate staff use of Personal Protective Equipment (PPE)
- Effective cohorting of residents (e.g., separate areas dedicated to COVID-19 care)
- Resident and staff testing conducted as required at 42 CFR § 483.80(h) (see QSO-20- 38-NH)

These core principles are consistent with the Centers for Disease Control and Prevention (CDC) guidance for nursing homes, and should be **adhered to at all times**. Additionally, visitation should be person-centered, consider the residents' physical, mental, and psychosocial well-being, and support their quality of life. The risk of transmission can be further reduced through the use of physical barriers (e.g., clear Plexiglass dividers, curtains). Also, nursing homes should enable visits to be conducted with an adequate degree of privacy. Visitors who are unable to adhere to the core principles of COVID-19 infection prevention should not be permitted to visit or should be asked to leave. By following a person-centered approach and adhering to these core principles, visitation can occur safely based on the below guidance.

Outdoor Visitation

amplification tests (NAAT) during the last 7 days), which can be found on the CDC COVID-19 Integrated County View site at https://covid.cdc.gov/covid-data-tracker/#county-view.

While taking a person-centered approach and adhering to the core principles of COVID-19 infection prevention, outdoor visitation is preferred when the resident and*/or* visitor are *not* fully vaccinated[3] against COVID-19. Outdoor visits generally pose a lower risk of transmission due to increased space and airflow. For outdoor visits, facilities should create accessible and safe outdoor spaces for visitation, such as in courtyards, patios, or parking lots, including the use of tents, if available. However, weather considerations (e.g., inclement weather, excessively hot or cold temperatures, poor air quality) or an individual resident's health status (e.g., medical condition(s), COVID-19 status, quarantine status) may hinder outdoor visits. When conducting outdoor visitation, all appropriate infection control and prevention practices should be followed.

Indoor Visitation

Facilities must allow indoor visitation at all times and for all residents as permitted under the regulations. While previously acceptable during the PHE, facilities can no longer limit the frequency and length of visits for residents, the number of visitors, or require advance scheduling of visits.

Although there is no limit on the number of visitors that a resident can have at one time, visits should be conducted in a manner that adheres to the core principles of COVID-19 infection prevention and does not increase risk to other residents. Facilities should ensure that physical distancing can still be maintained during peak times of visitation (e.g., lunch time, after business hours, etc.). Also, facilities should avoid large gatherings (e.g., parties, events) where large numbers of visitors are in the same space at the same time and physical distancing cannot be maintained. During indoor visitation, facilities should limit visitor movement in the facility. For example, visitors should not walk around different halls of the facility. Rather, they should go directly to the resident's room or designated visitation area. *Facilities may contact their local health authorities for guidance or direction on how to structure their visitation to reduce the risk of COVID-19 transmission.*

If a resident's roommate is unvaccinated or immunocompromised (regardless of vaccination status), visits should not be conducted in the resident's room, if possible. For situations where there is a roommate and the health status of the resident prevents leaving the room, facilities should attempt to enable in-room visitation while adhering to the core principles of infection prevention.

If the nursing home's county COVID-19 community level of transmission is substantial to high, all residents and visitors, regardless of vaccination status, should wear face coverings or masks and physically distance, at all times. In areas of low to moderate transmission, the safest practice is for residents and visitors to wear face coverings or masks and physically distance, particularly if either of them is at increased risk for severe disease or are unvaccinated. If the resident and all their visitor(s) are fully vaccinated and the resident is not moderately or severely immunocompromised, they may choose not to wear face coverings or masks and to have physical contact. Visitors should wear face coverings or masks when around other residents or healthcare personnel, regardless of vaccination status. Additional information on levels of community transmission is available on the CDC's COVID-19 Integrated County View webpage.

While not recommended, residents who are on transmission-based precautions (TBP) or quarantine can still receive visitors. In these cases, visits should occur in the resident's room and the resident

[3] Fully vaccinated *refers to the CDC definition. The current definition can be found on CDC's website: "Interim Public Health Recommendations for Fully Vaccinated People."*

should wear a well-fitting facemask (if tolerated). Before visiting residents, who are on TBP or quarantine, visitors should be made aware of the potential risk of visiting and precautions necessary in order to visit the resident. Visitors should adhere to the core principles of infection prevention. Facilities may offer well-fitting facemasks or other appropriate PPE, if available; however, facilities are not required to provide PPE for visitors.

NOTE: CMS and CDC continue to recommend facilities, residents, and families adhere to the core principles of COVID-19 infection. This continues to be the safest way to prevent the spread of COVID-19, particularly if either party has not been fully vaccinated. However, we acknowledge the toll that separation and isolation has taken. We also acknowledge that there is no substitute for physical contact, such as the warm embrace between a resident and their loved one. Therefore, if the resident is fully vaccinated, they can choose to have close contact (including touch) with their visitor in accordance with the CDC's *"Interim Infection Prevention and Control Recommendations for Healthcare Personnel During the Coronavirus Disease 2019 (COVID-19) Pandemic." Unvaccinated residents may also choose to have physical touch based on their preferences and needs, such as with support persons for individuals with disabilities and visitors participating in certain religious practices, including in end-of-life situations. In these situations, unvaccinated residents (or their representative) and their visitors should be advised of the risks of physical contact prior to the visit.* Visitors should *also* physically distance from other residents and staff in the facility.

Indoor Visitation during an Outbreak *Investigation*

An outbreak *investigation is initiated* when a new nursing home onset of COVID-19 occurs (i.e., a new COVID-19 case among residents or staff). To swiftly detect cases, we remind facilities to adhere to CMS regulations and guidance for COVID-19 testing, including routine *unvaccinated* staff testing, testing of individuals with symptoms, and outbreak testing.

When a new case of COVID-19 among residents or staff is identified, a facility should immediately begin outbreak testing *in accordance with CMS QSO 20-38-NH REVISED and CDC guidelines.*

While it is safer for visitors not to enter the facility during an outbreak investigation, visitors must still be allowed in the facility. Visitors should be made aware of the potential risk of visiting during an outbreak investigation and adhere to the core principles of infection prevention. If residents or their representative would like to have a visit during an outbreak investigation, they should wear face coverings or masks during visits, regardless of vaccination status, and visits should ideally occur in the resident's room. Facilities may contact their local health authorities for guidance or direction on how to structure their visitation to reduce the risk of COVID-19 transmission during an outbreak investigation.

Visitor Testing and Vaccination

While not required, we encourage facilities in *counties with substantial* or high *levels of community transmission* to offer testing to visitors, if feasible. *If facilities do not offer testing, they should* encourage visitors to be tested on their own *before* coming to the facility (e.g., within 2–3 days).

CMS strongly encourages all visitors to become vaccinated and facilities should educate and also encourage visitors to become vaccinated. Visitor testing and vaccination can help prevent the spread of COVID-19 and facilities *may ask about a visitors' vaccination status, however, **visitors***

are **not required to be tested or vaccinated** (or show proof of such) as a condition of visitation. *If the visitor declines to disclose their vaccination status, the visitor should wear a face covering or mask at all times.* This also applies to representatives of the Office of the State Long-Term Care Ombudsman and protection and advocacy systems, as described below.

Compassionate Care Visits

Compassionate care visits are allowed at all times. Previously during the PHE, there were some scenarios where residents should only have compassionate care visits. However, visitation is now allowed at all times for all residents, in accordance with CMS regulations. Therefore, we believe there are few scenarios when visitation should be limited only to compassionate care visits. In the event a scenario arises that would limit visitation for a resident (e.g., a resident is severely immunocompromised and the number of visitors the resident is exposed to needs to be kept to a minimum), compassionate care visits would still be allowed at all times. CMS expects these scenarios to be rare events.

Required Visitation

Facilities shall not restrict visitation without a reasonable clinical or safety cause, consistent with 42 CFR § 483.10(f)(4)(v). *In previous nursing home visitation guidance during the PHE, CMS outlined some scenarios related to COVID-19 that would constitute a clinical or safety reason for limited visitation. However, there are no longer scenarios related to COVID-19 where visitation should be limited, except for certain situations when the visit is limited to being conducted in the resident's room or the rare event that visitation is limited to compassionate care. Therefore, a* nursing home **must** facilitate in-person visitation consistent with the applicable CMS regulations, which can be done by applying the guidance stated above. Failure to facilitate visitation, per 42 CFR § 483.10(f)(4), *which states "The resident has a right to receive visitors of his or her choosing at the time of his or her choosing, subject to the resident's right to deny visitation when applicable, and in a manner that does not impose on the rights of another resident," would constitute a potential violation* and the facility would be subject to citation and enforcement actions.

As stated above, we acknowledge that there are still risks associated with visitation and COVID-19. However, the risks are reduced by adhering to the core principles of COVID-19 infection prevention. Furthermore, we remind facilities and all stakeholders that, per 42 CFR §483.10(f)(2), residents have the right to make choices about aspects of his or her life in the facility that are significant to the resident. Visitors, residents, or their representative should be made aware of the potential risk of visiting and necessary precautions related to COVID-19 in order to visit the resident. However, if a visitor, resident, or their representative is aware of the risks associated with visitation, and the visit occurs in a manner that does not place other residents at risk (e.g., in the resident's room), the resident must be allowed to receive visitors as he/she chooses.

Access to the Long-Term Care Ombudsman

As stated in previous CMS guidance QSO-20-28-NH (revised), regulations at 42 CFR § 483.10(f)(4)(i)(C) require that a Medicare and Medicaid-certified nursing home provide representatives of the Office of the State Long-Term Care Ombudsman with immediate access to any resident. *If an ombudsman is planning to visit a resident who is in TBP or quarantine, or an unvaccinated resident in a nursing home in a county where the level of community transmission is*

substantial or high in the past 7 days, the resident and ombudsman should be made aware of the potential risk of visiting, and the visit should take place in the resident's room. We note that representatives of the Office of the Ombudsman should adhere to the core principles of COVID-19 infection prevention as described above. *If the resident or the Ombudsman program requests alternative communication in lieu of an in-person visit,* facilities must, at a minimum, facilitate alternative resident communication with the Ombudsman *program*, such as by phone or through use of other technology. Nursing homes are also required under 42 CFR § 483.10(h)(3)(ii) to allow the Ombudsman to examine the resident's medical, social, and administrative records as otherwise authorized by State law.

Federal Disability Rights Laws and Protection & Advocacy (P&A) Programs

42 CFR § 483.10(f)(4)(i)(E) and (F) requires the facility to allow immediate access to a resident by any representative of the protection and advocacy systems, as designated by the state, and as established under the Developmental Disabilities Assistance and Bill of Rights Act of 2000 (DD Act), and of the agency responsible for the protection and advocacy system for individuals with a mental disorder (established under the Protection and Advocacy for Mentally Ill Individuals Act of 2000). P&A programs authorized under the DD Act protect the rights of individuals with developmental and other disabilities and are authorized to "investigate incidents of abuse and neglect of individuals with developmental disabilities if the incidents are reported to the system or if there is probable cause to believe the incidents occurred." 42 U.S.C. § 15043(a)(2)(B). Under its federal authorities, representatives of P&A programs are permitted access to all facility residents, which includes "the opportunity to meet and communicate privately with such individuals regularly, both formally and informally, by telephone, mail and in person." 42 CFR § 51.42(c); 45 CFR § 1326.27.

If the P&A is planning to visit a resident who is in TBP or quarantine, or an unvaccinated resident in a county where the level of community transmission is substantial or high in the past 7 days, the resident and P&A representative should be made aware of the potential risk of visiting and the visit should take place in the resident's room.

Additionally, each facility must comply with federal disability rights laws such as Section 504 of the Rehabilitation Act *of 1973, 29 U.S.C. § 794 (Section 504)* and the Americans with Disabilities Act *of 1990, 42 U.S.C. §§ 12101 et seq.* (ADA).

For example, *if communicating with individuals who are deaf or hard of hearing, it is recommended to use a clear mask or mask with a clear panel. Face coverings should not be placed on anyone who has trouble breathing or is unable to wear a mask due to a disability, or anyone who is unconscious, incapacitated, or otherwise unable to remove the mask without assistance.*

In addition, if a resident requires assistance to ensure effective communication (e.g., a qualified interpreter or someone to facilitate communication) and the assistance is not available by onsite staff or effective communication cannot be provided without such entry (e.g., video remote interpreting), the facility must allow the individual entry into the nursing home to interpret or facilitate, with some exceptions. This would not preclude nursing homes from imposing legitimate safety measures that are necessary for safe operations, such as requiring such individuals to adhere to the core principles of COVID-19 infection prevention. Any questions about or issues related to enforcement or oversight of the non-CMS requirements and citations referenced above under this section subject heading should be referred to the HHS Office for Civil Rights *(Toll-free: 800-368-*

1019) (TDD toll-free: 800-537-7697), the Administration for Community Living *(202-401-4634)*, or other appropriate oversight agency.

Entry of Healthcare Workers and Other Providers of Services

All healthcare workers must be permitted to come into the facility as long as they are not subject to a *work exclusion* or showing signs or symptoms of COVID-19. *In addition to health care workers, personnel educating and assisting in resident transitions to the community should be permitted entry consistent with this guidance.* We note that EMS personnel do not need to be screened, so they can attend to an emergency without delay. We remind facilities that all staff, including individuals providing services under arrangement as well as volunteers, should adhere to the core principles of COVID-19 infection prevention and must comply with COVID-19 testing requirements.

Communal Activities, Dining *and Resident Outings*

While adhering to the core principles of COVID-19 infection prevention, communal activities and dining may occur. Book clubs, crafts, movies, exercise, and bingo are all activities that can be facilitated with alterations to adhere to the guidelines for preventing transmission. *The safest approach is for everyone, regardless of vaccination status, to wear a face covering or mask while in communal areas of the facility. For more information, see the Implement Source Control section of the CDC guidance "Interim Infection Prevention and Control Recommendations for Healthcare Personnel During the Coronavirus Disease 2019 (COVID-19) Pandemic."*

Facilities must permit residents to leave the facility as they choose. Should a resident choose to leave, the facility should remind the resident and any individual accompanying the resident to follow all recommended infection prevention practices including wearing a face covering or mask, physical distancing, and hand hygiene and to encourage those around them to do the same.

Upon the resident's return, nursing homes should take the following actions:

- *Screen residents upon return for signs or symptoms of COVID-19.*
  - *If the resident or family member reports possible close contact to an individual with COVID-19 while outside of the nursing home, test the resident for COVID-19, regardless of vaccination status. Place the resident on quarantine if the resident has not been fully vaccinated.*
  - *If the resident develops signs or symptoms of COVID-19 after the outing, test the resident for COVID-19 and place the resident on Transmission-Based Precautions, regardless of vaccination status.*
- *A nursing home may also opt to test unvaccinated residents without signs or symptoms if they leave the nursing home frequently or for a prolonged length of time, such as over 24 hours.*
- *Facilities might consider quarantining unvaccinated residents who leave the facility if, based on an assessment of risk, uncertainty exists about their adherence or the adherence of those around them to recommended infection prevention measures.*
- *Monitor residents for signs and symptoms of COVID-19 daily.*

Residents who leave the facility for 24 hours or longer should generally be managed as a new admission or readmission, as recommended by the CDC's "Interim Infection Prevention and Control Recommendations to Prevent SARS-CoV-2 Spread in Nursing Homes." Please note that there are exceptions to quarantine, including for fully vaccinated residents.

Survey Considerations

State survey agencies and CMS are ultimately responsible for ensuring surveyors are compliant with the applicable expectations. Therefore, LTC facilities are not permitted to restrict access to surveyors based on vaccination status, nor ask a surveyor for proof of his or her vaccination status as a condition of entry. If facilities have questions about the process a state is using to ensure surveyors can enter a facility safely, those questions should be addressed to the State Survey Agency. Surveyors should not enter a facility if they *have a positive viral test for COVID-19,* signs or symptoms of COVID-19, *or currently meet the criteria for quarantine*. Surveyors should also adhere to the core principles of COVID-19 infection prevention and adhere to any COVID-19 infection prevention requirements set by *federal and* state *agencies (including Executive Orders).*

- For concerns related to resident communication with and access to persons and services inside and outside the facility, surveyors should investigate for non-compliance at 42 CFR § 483.10(b), F550.
- For concerns related to a facility limiting visitors, surveyors should investigate for non-compliance at 42 CFR § 483.10(f)(4), F563.
- For concerns related to ombudsman access to the resident and the resident's medical record, surveyors should investigate for non-compliance at 42 CFR §§ 483.10(f)(4)(i)(C), F562 and 483.10(h)(3)(ii), F583.
- For concerns related to lack of adherence to infection control practices, including practices for residents and staff based on COVID-19 vaccination status, surveyors should investigate for non-compliance at 42 CFR § 483.80(a), F880.

Contact: Questions related to this memorandum may be submitted to: DNH_TriageTeam@cms.hhs.gov.

Effective Date: Immediately. This policy should be communicated with all survey and certification staff, their managers, and the State/CMS Locations within 30 days of this memorandum.

/s/
David R. Wright

cc: Survey Operations Group

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop C2-21-16
Baltimore, Maryland 21244-1850

Center for Clinical Standards and Quality/Survey & Certification Group

Ref: QSO-20-38-NH
REVISED 09/10/2021

DATE: **August 26, 2020**

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: **Interim Final Rule (IFC), CMS-3401-IFC, Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency related to Long-Term Care (LTC) Facility Testing Requirements**

Memorandum Summary

- CMS is committed to taking critical steps to ensure America's healthcare facilities continue to respond effectively to the Coronavirus Disease 2019 (COVID-19) Public Health Emergency (PHE).
- On August 25, 2020, CMS published an interim final rule with comment period (IFC). This rule establishes **Long-Term Care (LTC) Facility Testing Requirements for Staff and Residents.** Specifically, facilities are required to test residents and staff, including individuals providing services under arrangement and volunteers, for COVID-19 based on parameters set forth by the HHS Secretary. This memorandum provides guidance for facilities to meet the new requirements.
- *Revised COVID-19 staff testing is based on the facility's county level of community transmission instead of county test positivity rate. The frequency of testing has also been updated.*
- *Facilities now have two options to conduct outbreak testing, through either a contact tracing or broad-based testing approach.*

On August 25, 2020, CMS published an interim final rule with comment period (IFC), CMS-3401-IFC, entitled "Medicare and Medicaid Programs, Clinical Laboratory Improvement Amendments of 1988 (CLIA), and Patient Protection and Affordable Care Act; Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency". CMS's recommendation below to test with authorized nucleic acid or antigen detection assays is an important addition to other infection prevention and control (IPC) recommendations aimed at preventing COVID-19 from entering nursing homes, detecting cases quickly, and stopping transmission. Swift identification of confirmed COVID-19 cases allows the facility to take immediate action to remove exposure risks to nursing home residents and staff. CMS has added 42 CFR § 483.80(h) which requires that the facility test all residents and staff for COVID-19.

Guidance related to the requirements is located below. Noncompliance related to this new requirement will be cited at new tag F886.

§ 483.80 Infection control

* * * * *

§ 483.80(h) *COVID-19 Testing*. The LTC facility must test residents and facility staff, including individuals providing services under arrangement and volunteers, for COVID-19. At a minimum, for all residents and facility staff, including individuals providing services under arrangement and volunteers, the LTC facility must:

(1) Conduct testing based on parameters set forth by the Secretary, including but not limited to:

(i) Testing frequency;

(ii) The identification of any individual specified in this paragraph diagnosed with COVID-19 in the facility;

(iii) The identification of any individual specified in this paragraph with symptoms consistent with COVID-19 or with known or suspected exposure to COVID-19;

(iv) The criteria for conducting testing of asymptomatic individuals specified in this paragraph, such as the positivity rate of COVID-19 in a county;

(v) The response time for test results; and

(vi) Other factors specified by the Secretary that help identify and prevent the transmission of COVID-19.

(2) Conduct testing in a manner that is consistent with current standards of practice for conducting COVID-19 tests;

(3) For each instance of testing:

(i) Document that testing was completed and the results of each staff test; and

(ii) Document in the resident records that testing was offered, completed (as appropriate to the resident's testing status), and the results of each test.

(4) Upon the identification of an individual specified in this paragraph with symptoms consistent with COVID-19, or who tests positive for COVID-19, take actions to prevent the transmission of COVID-19.

(5) Have procedures for addressing residents and staff, including individuals providing services under arrangement and volunteers, who refuse testing or are unable to be tested.

(6) When necessary, such as in emergencies due to testing supply shortages, contact state and local health departments to assist in testing efforts, such as obtaining testing supplies or processing test results.

F886

DEFINITIONS

"Close contact " *refers to someone who has been within 6 feet of a COVID-19 positive person for a cumulative total of 15 minutes or more over a 24-hour period.*

"Level of community transmission" *refers to facility's county level of COVID-19 transmission. This metric uses two indicators for categorization (1. Total number of new cases per 100,000 persons within the last 7 days and 2. Percentage of positive diagnostic and screening nucleic acid amplification tests (NAAT) during the last 7 days), which can be found on the Centers for Disease Control and Prevention (CDC) COVID-19 Integrated County View site at https://covid.cdc.gov/covid-data-tracker/#county-view.*

"Fully vaccinated" *refers to the CDC definition. The current definition can be found on CDC's website: Interim Public Health Recommendations for Fully Vaccinated People \| CDC.*

"Higher-risk exposure" *refers to exposure of an individual's eyes, nose, or mouth to material potentially containing SARS-CoV-2, particularly if present in the room for an aerosol-generating procedure. This can occur when staff do not wear adequate personal protective equipment during care or interaction with an individual. For more information, see CDC's "Interim Guidance for Managing Healthcare Personnel with SARS-CoV-2 Infection or Exposure to SARS-CoV-2."*

"Unvaccinated" refers to a person who does not fit the definition of "fully vaccinated," including people whose vaccination status is not known, for the purposes of this guidance.

GUIDANCE

Testing of Nursing Home Staff and Residents

To enhance efforts to keep COVID-19 from entering and spreading through nursing homes, facilities are required to test residents and staff based on parameters and a frequency set forth by the HHS Secretary.

Facilities can meet the testing requirements through the use of rapid point-of-care (POC) diagnostic testing devices or through an arrangement with an offsite laboratory. POC testing is diagnostic testing that is performed at or near the site of resident care. For a facility to conduct these tests with their own staff and equipment (including POC devices provided by the Department of Health and Human Services), the facility must have*, at a minimum,* a CLIA Certificate of Waiver. Information on obtaining a CLIA Certificate of Waiver can be found here.

Facilities without the ability to conduct COVID-19 POC testing should have arrangements with a laboratory to conduct tests to meet these requirements. Laboratories that can quickly process large numbers of tests with rapid reporting of results (e.g., within 48 hours) should be selected to rapidly inform infection prevention initiatives to prevent and limit transmission.

"Facility staff" includes employees, consultants, contractors, volunteers, and caregivers who provide care and services to residents on behalf of the facility, and students in the facility's nurse

aide training programs or from affiliated academic institutions. For the purpose of testing "individuals providing services under arrangement and volunteers," facilities should prioritize those individuals who are regularly in the facility (e.g., weekly) and have contact with residents or staff. We note that the facility may have a provision under its arrangement with a vendor or volunteer that requires them to be tested from another source (e.g., their employer or on their own). However, the facility is still required to obtain documentation that the required testing was completed during the timeframe that corresponds to the facility's testing frequency, as described in Table 2 below.

When prioritizing individuals to be tested, facilities should prioritize individuals with signs and symptoms of COVID-19 first, then perform testing triggered by an outbreak *investigation* (as specified below).

Table 1: Testing Summary

Testing Trigger	Staff	Residents
Symptomatic individual identified	Staff, vaccinated and unvaccinated, with signs *or* symptoms must be tested.	Residents, vaccinated and unvaccinated, with signs *or* symptoms must be tested.
Newly identified COVID-19 positive staff or resident in a facility that can identify close contacts	*Test all staff, vaccinated and unvaccinated, that had a higher-risk exposure with a COVID-19 positive individual.*	*Test all residents, vaccinated and unvaccinated, that had close contact with a COVID-19 positive individual.*
Newly identified COVID-19 positive staff or resident in a facility that is unable to identify close contacts	*Test all staff, vaccinated and unvaccinated, facility-wide or at a group level if staff are assigned to a specific location where the new case occurred (e.g., unit, floor, or other specific area(s) of the facility).*	*Test all residents, vaccinated and unvaccinated, facility-wide or at a group level (e.g., unit, floor, or other specific area(s) of the facility).*
Routine testing	According to Table 2 below	Not *generally* recommended

Testing of Staff and Residents with COVID-19 Symptoms or Signs

Staff with symptoms or signs of COVID-19, vaccinated or not vaccinated, must be tested immediately and are expected to be restricted from the facility pending the results of COVID-19 testing. If COVID-19 is confirmed, staff should follow Centers for Disease Control and Prevention (CDC) guidance "*Interim Guidance for Managing Healthcare Personnel with SARS-CoV-2 Infection or Exposure to SARS-CoV-2*." Staff who do not test positive for COVID-19 but have symptoms should follow facility policies to determine when they can return to work.

Residents who have signs or symptoms of COVID-19, vaccinated or not vaccinated, must be tested immediately. While test results are pending, residents with signs or symptoms should be placed on transmission-based precautions (TBP) in accordance with CDC guidance. Once test results are obtained, the facility must take the appropriate actions based on the results.

NOTE: Concerns related to initiating and/or maintaining TBP should be investigated under F880, Infection Control.

Testing of Staff with *a Higher-Risk* Exposure and Residents who had *a Close Contact*

For information on testing staff *with a higher-risk exposure* to COVID-19 and residents who *had close contact with a COVID-19 positive individual, when the facility is not in an outbreak status*, see the CDC's *"Interim Infection Prevention and Control Recommendations to Prevent SARS-CoV-2 Spread in Nursing Homes" and "Interim Guidance for Managing Healthcare Personnel with SARS-CoV-2 Infection or Exposure to SARS-CoV-2." Examples may include exposures from a visitor, while on a leave of absence, or during care of a resident on the COVID-19 unit.*

Testing of Staff and Residents *During* an Outbreak *Investigation*

A new COVID-19 infection in any *staff* or any nursing home-onset COVID-19 infection in a resident *triggers an outbreak investigation.* In an outbreak investigation, rapid identification and isolation of new cases is critical in stopping further viral transmission. A resident who is admitted to the facility with COVID-19 does not constitute a facility outbreak.

Upon identification of a single new case of COVID-19 infection in any staff or residents, *testing should begin* immediately. *Facilities have the option to perform outbreak testing through two approaches, contact tracing or broad-based (e.g. facility-wide) testing.*

If the facility has the ability to identify close contacts of the individual with COVID-19, they could choose to conduct focused testing based on known close contacts. If a facility does not have the expertise, resources, or ability to identify all close contacts, they should instead investigate the outbreak at a facility-wide or group-level (e.g., unit, floor, or other specific area(s) of the facility). Broader approaches might also be required if the facility is directed to do so by the jurisdiction's public health authority, or in situations where all potential contacts are unable to be identified, are too numerous to manage, or when contact tracing fails to halt transmission.

For further information on contact tracing and broad-based testing, including frequency of repeat testing, see CDC guidance "Interim Infection Prevention and Control Recommendations to Prevent SARS-CoV-2 Spread in Nursing Homes."

For individuals who test positive for COVID-19, repeat testing is not recommended *to discontinue TBP or work restrictions*. A symptom-based strategy is intended to replace the need for repeated testing. Facilities should follow the CDC guidance *"Interim Infection Prevention and Control Recommendations for Healthcare Personnel During the Coronavirus Disease 2019 (COVID-19) Pandemic"* for residents and *"Interim Guidance for Managing Healthcare Personnel with SARS-CoV-2 Infection or Exposure to SARS-CoV-2"for staff.*

Routine Testing of Staff

Routine testing of unvaccinated staff should be based on the extent of the virus in the community. Fully vaccinated staff do not have to be routinely tested. Facilities should use their *community transmission level* as the trigger for staff testing frequency. **Reports of COVID-19 *level of community transmission* are available on the *CDC COVID-19 Integrated County View site*: *https://covid.cdc.gov/covid-data-tracker/#county-view*.** *Please see the COVID-19 Testing section on the CMS COVID-19 Nursing Home Data webpage: https://data.cms.gov/covid-19/covid-19-nursing-home-data for information on how to obtain current and historic levels of community transmission on the CDC website.*

Table 2: Routine Testing Intervals by *County COVID-19 Level of Community Transmission*

Level of COVID-19* Community *Transmission	**Minimum Testing Frequency of Unvaccinated Staff[+]**
Low *(blue)*	***Not recommended***
Moderate *(yellow)*	***Once a week****
Substantial *(orange)*	***Twice* a week***
High *(red)*	**Twice a week***

[+]Vaccinated staff do not need *to* be routinely tested.
***This frequency presumes availability of Point of Care testing on-site at the nursing home or where off-site testing turnaround time is <48 hours.**

If the 48-hour turn-around time cannot be met due to community testing supply shortages, limited access or inability of laboratories to process tests within 48 hours, the facility should have documentation of its efforts to obtain quick turnaround test results with the identified laboratory or laboratories and contact with the local and state health departments.

The facility should test all unvaccinated staff at the frequency prescribed in the Routine Testing table based on the *level of community transmission* reported in the past week. Facilities should monitor their *level of community transmission* every other week (e.g., first and third Monday of every month) and adjust the frequency of performing staff testing according to the table above.

- If the *level of community transmission* increases to a higher level of activity, the facility should begin testing staff at the frequency shown in the table above as soon as the criteria for the higher activity *level* are met.
- If the *level of community transmission* decreases to a lower level of activity, the facility should continue testing staff at the higher frequency level until the *level of community transmission* has remained at the lower activity level for at least two weeks before reducing testing frequency.

The guidance above represents the minimum testing expected. Facilities may consider other factors, such as the *level of community transmission* in an adjacent (i.e., neighboring) county to test at a frequency that is higher than required. For example, if a facility in a county with *a* low *level of community transmission* has many staff that live in a county with a *moderate level of community transmission*, the facility should consider testing based on the higher *level of community transmission* (in scenario described, weekly staff testing would be indicated).

State and local officials may also direct facilities to monitor other factors that increase the risk for COVID-19 transmission, such as rates of Emergency Department visits of individuals with COVID-19-like symptoms. Facilities should consult with state and local officials on these factors, and the actions that should be taken to reduce the spread of the virus.

NOTE: Routine testing of asymptomatic residents is not recommended unless prompted by a change in circumstances, such as the identification of a confirmed COVID-19 case in the facility. Facilities may consider testing asymptomatic residents who leave the facility frequently, such as for dialysis or chemotherapy. Facilities should inform resident transportation services (such as non-emergency medical transportation) and receiving healthcare providers (such as hospitals) regarding a resident's COVID-19 status to ensure appropriate infection control precautions are followed.

Routine communication between the nursing home and other entities about the resident's status should ideally occur prior to the resident leaving the nursing home for treatment. Coordination between the nursing home and the other healthcare entity is vital to ensure healthcare staff are informed of the most up to date information relating to the resident's health status, including COVID-19 status, and to allow for proper planning of care and operations. Additionally, facilities should maintain communications with the local ambulance and other contracted providers that transport residents between facilities, to ensure appropriate infection control precautions are followed as described by the CDC.

Refusal of Testing

Facilities must have procedures in place to address staff who refuse testing. Procedures should ensure that staff who have signs or symptoms of COVID-19 and refuse testing are prohibited from entering the building until the return to work criteria are met. If outbreak testing has been triggered and *an unvaccinated* staff member refuses testing, the staff member should be restricted from the building until the procedures for outbreak testing have been completed. The facility should follow its occupational health and local jurisdiction policies with respect to any asymptomatic *unvaccinated* staff who refuse routine testing.

Residents (or resident representatives) may exercise their right to decline COVID-19 testing in accordance with the requirements under 42 CFR § 483.10(c)(6). In discussing testing with residents, staff should use person-centered approaches when explaining the importance of testing for COVID-19. Facilities must have procedures in place to address residents who refuse testing. Procedures should ensure that residents who have signs or symptoms of COVID-19 and refuse testing are placed on TBP until the criteria for discontinuing TBP have been met. If outbreak testing has been triggered and an asymptomatic resident refuses testing, the facility should be extremely vigilant, such as through additional monitoring, to ensure the resident maintains appropriate distance from other residents, wears a face covering, and practices effective hand hygiene until the procedures for outbreak testing have been completed.

Clinical discussions about testing may include alternative specimen collection sources that may be more acceptable to residents than nasopharyngeal swabs (e.g., anterior nares). Providing information about the method of testing and reason for pursuing testing may facilitate discussions with residents or resident representatives.

Residents who refuse testing may require TBP based on symptoms or vaccination status. For further information, see CDC guidance "Interim Infection Prevention and Control Recommendations to Prevent SARS-CoV-2 Spread in Nursing Homes."

Other Testing Considerations

Although exceptions exist, generally staff and residents who have recovered from COVID-19 and are asymptomatic do not need to be retested for COVID-19 within 3 months after symptom onset. Until more is known, testing should be encouraged again (e.g., in response to an exposure) 3 months after the date of symptom onset with the prior infection. Facilities should continue to monitor the CDC webpages and FAQs for the latest information. The facility should consult with infectious diseases specialists and public health authorities to review all available information (e.g., medical history, time from initial positive test, Reverse Transcription-Polymerase Chain Reaction Cycle Threshold (RT-PCR Ct) values, and presence of COVID-19 signs or symptoms). Individuals who are determined to be potentially infectious should undergo evaluation and remain isolated until they meet criteria for discontinuation of isolation or discontinuation of transmission-based precautions, depending on their circumstances.

For residents or staff who test positive, facilities should contact the appropriate state or local entity for contact tracing.

While not required, facilities may test residents' visitors to help facilitate visitation while also preventing the spread of COVID-19. Facilities should prioritize resident and staff testing and have adequate testing supplies to meet required testing, prior to testing resident visitors.

Conducting Testing

In accordance with 42 CFR § 483.50(a)(2)(i), the facility must obtain an order from a physician, physician assistant, nurse practitioner, or clinical nurse specialist in accordance with state law, including scope of practice laws to provide or obtain laboratory services for a resident, which includes COVID-19 testing (see F773). This may be accomplished through the use of physician approved policies (e.g., standing orders), or other means as specified by scope of practice laws and facility policy.

NOTE: Concerns related to orders for laboratory and/or POC testing should be investigated under F773.

Rapid POC testing devices are prescription use tests under the Emergency Use Authorization and must be ordered by a healthcare professional licensed under the applicable state law or a pharmacist under HHS guidance. Accordingly, the facility must have an order from a healthcare professional or pharmacist, as previously described, to perform a rapid POC COVID-19 test on an individual.

Facilities must conduct testing according to nationally recognized guidelines, outlined by the Centers for Disease Control and Prevention (CDC). This would include the following *guidance*:

- Interim Infection Prevention and Control Recommendations to Prevent SARS-CoV-2 Spread in Nursing Homes: https://www.cdc.gov/coronavirus/2019-ncov/hcp/long-term-care.html
- *Interim Infection Prevention and Control Recommendations for Healthcare Personnel During the Coronavirus Disease 2019 (COVID-19) Pandemic: https://www.cdc.gov/coronavirus/2019-ncov/hcp/infection-control-recommendations.html*

A diagnostic test shows if a patient has an active coronavirus infection. As of the date of this guidance, there are two types of diagnostic tests which detect the active virus – molecular tests, such as RT-PCR tests, that detect the virus's genetic material, and antigen tests that detect specific proteins on the surface of the virus. An antibody test looks for antibodies that are made by the immune system in response to a threat, such as a specific virus. An antibody test does not identify an active coronavirus infection; therefore, conducting an antibody test on a staff or resident would not meet the requirements under this regulation.

Frequently asked questions related to the use of these testing devices in high-risk congregate settings such as nursing homes can be found here. In addition, when testing residents, a facility's selection of a test should be person-centered.

Collecting and handling specimens correctly and safely is imperative to ensure the accuracy of test results and prevent any unnecessary exposures. The specimen should be collected and, if necessary, stored in accordance with the manufacturer's instructions for use for the test and CDC guidelines.

During specimen collection, facilities must maintain proper infection control and use recommended personal protective equipment (PPE), which includes a *NIOSH-approved* N95 or *equivalent or* higher-level respirator (or facemask if a respirator is not available), eye protection, gloves, and a gown, when collecting specimens.

The CDC has provided guidance on proper specimen collection:

- Influenza Specimen Collection: https://www.cdc.gov/flu/pdf/professionals/flu-specimen-collection-poster.pdf.
- Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens from Persons for Coronavirus Disease 2019 (COVID-19): https://www.cdc.gov/coronavirus/2019-ncov/lab/guidelines-clinical-specimens.html.
- CDC's Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with Coronavirus Disease 2019 (COVID-19): https://www.cdc.gov/coronavirus/2019-ncov/lab/lab-biosafety-guidelines.html.

For additional considerations for antigen testing, see CDC's *"SARS-CoV-2 Antigen Testing in Long Term Care Facilities."*

As a reminder, per 42 CFR § 483.50(a), the facility must provide or obtain laboratory services to meet the needs of its residents. If a facility provides its own laboratory services or performs any laboratory tests directly (e.g., SARS-CoV-2 point-of-care test) the provisions of 42 CFR Part 493 apply and the facility must have a current CLIA certificate appropriate for the level of testing performed within the facility. Surveyors should only verify that the facility has a current CLIA certificate and not attempt to determine compliance with the requirements in 42 CFR Part 493.

Reporting Test Results

Facilities conducting tests *are required to have* a CLIA certificate *and* are subject to regulations that require laboratories to report *results* for all testing completed, for each individual tested, *to state or local health departments*. For additional information on reporting requirements see:

- Frequently Asked Questions: COVID-19 Testing at Skilled Nursing Facilities/Nursing Homes
- CMS memorandum: Interim Final Rule (IFC), CMS-3401-IFC, Updating Requirements for Reporting of SARS-CoV-2 Test Results by Clinical Laboratory Improvement Amendments of 1988 (CLIA) Laboratories, and Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency

Surveyors should report concerns related to CLIA certificates or laboratory reporting requirements to their *CLIA State Agency contact*. When reporting concerns include the CLIA number; name and address of laboratory (facility); number of days that results were not reported, if known; and number of results not reported, if known.

In addition to reporting in accordance with CLIA requirements, facilities must continue to report COVID-19 information to the CDC's National Healthcare Safety Network (NHSN), in accordance with 42 CFR § 483.80(g)(1)–(2). See "Interim Final Rule Updating Requirements for Notification of Confirmed and Suspected COVID-19 Cases Among Residents and Staff in Nursing Homes," CMS Memorandum QSO-20-29-NH (May 6, 2020).

NOTE: Concerns related to informing residents, their representatives and families of new or suspected cases of COVID-19 should be investigated under F885.

NOTE: Concerns related to the reporting to state and local public health authority of communicable diseases and outbreaks, including for purposes such as contact tracing, should be investigated under F880.

Documentation of Testing

Facilities must demonstrate compliance with the testing requirements. To do so, facilities should do the following:

- For symptomatic residents and staff, document the date(s) and time(s) of the identification of signs or symptoms, when testing was conducted, when results were obtained, and the actions the facility took based on the results.
- Upon identification of a new COVID-19 case in the facility, document the date the case was identified, the date that other residents and staff are tested, the dates that staff and residents who tested negative are retested, and the results of all tests (see section "Testing of Staff and Residents *During* an Outbreak *Investigation"* above).

- For staff routine testing, document the facility's *level of community transmission*, the corresponding testing frequency indicated (e.g., every week), and the date each *level of community transmission* was collected. Also, document the date(s) that testing was performed for *unvaccinated* staff, and the results of each test.
- Document the facility's procedures for addressing residents and staff that refuse testing or are unable to be tested, and document any staff or residents who refused or were unable to be tested and how the facility addressed those cases.
- When necessary, such as in emergencies due to testing supply shortages, document that the facility contacted state and local health departments to assist in testing efforts, such as obtaining testing supplies or processing test results.

Facilities may document the conducting of tests in a variety of ways, such as a log of *community transmission levels*, schedules of completed testing, and/or staff and resident records. However, the results of tests must be done in accordance with standards for protected health information. For residents, the facility must document testing results in the medical record. For staff, including individuals providing services under arrangement and volunteers, the facility must document testing results in a secure manner consistent with requirements specified in 483.80(h)(3).

Surveying for Compliance

Compliance will be assessed through the following process using the COVID-19 Focused Survey *and during the Standard Survey* for Nursing Homes:

1. Surveyors will ask for the facility's documentation noted in the "Documentation of Testing" section above, and review the documentation for compliance.
2. Surveyors will also review records of those residents and staff selected as a sample as part of the survey process.
3. If possible, surveyors should observe how the facility conducts testing in real-time. In this process, surveyors will assess if the facility is conducting testing and specimen collection in a manner that is consistent with current standards of practice for conducting COVID-19 tests, such as ensuring PPE is used correctly to prevent the transmission of the virus. If observation is not possible, surveyors should interview an individual responsible for testing and inquire on how testing is conducted (e.g., "what are the steps taken to conduct each test?").
4. If the facility has a shortage of testing supplies, or cannot obtain test results within 48 hours, the surveyor should ask for documentation that the facility contacted state and local health departments to assist with these issues.

Facilities that do not comply with the testing requirements in § 483.80(h) will be cited for noncompliance at F886. Additionally, enforcement remedies (such as civil money penalties) will be imposed based on the resident outcome (i.e., the scope and severity of the noncompliance), in accordance with Chapter 7 of the State Operations Manual.

If the facility has documentation that demonstrates their attempts to perform and/or obtain testing in accordance with these guidelines (e.g., timely contacting state officials, multiple attempts to identify a laboratory that can provide testing results within 48 hours), surveyors should not cite

the facility for noncompliance. Surveyors should also inform the state or local health authority of the facility's lack of resources.

The current Survey/Infection Prevention, Control & Immunization Pathway (CMS-20054) can be found in the LTC Survey Pathways zipfile located at https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/GuidanceforLawsAndRegulations/Downloads/LTC-Survey-Pathways.zip.

Contact: Questions related to the nursing home testing requirement may be submitted to: DNH_TriageTeam@cms.hhs.gov.

Effective Date: Immediately. This policy should be communicated with all survey and certification staff, their managers and the State Agency/CMS Branch Location training coordinators immediately.

/s/
David R. Wright

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
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Center for Clinical Standards and Quality/Quality, Safety & Oversight Group

Ref: QSO-21-19-NH

DATE: **May 11, 2021**

TO: State Survey Agency Directors

FROM: Director
Quality, Safety & Oversight Group

SUBJECT: Interim Final Rule - COVID-19 Vaccine Immunization Requirements for Residents and Staff

Memorandum Summary

- CMS is committed to continually taking critical steps to ensure America's healthcare facilities continue to respond effectively to the Coronavirus Disease 2019 (COVID-19) Public Health Emergency (PHE).
- On May 11, 2021, CMS published an interim final rule with comment period (IFC). This rule establishes **Long-Term Care (LTC) Facility Vaccine Immunization Requirements for Residents and Staff.** This includes new requirements for educating residents or resident representatives and staff regarding the benefits and potential side effects associated with the COVID-19 vaccine, and offering the vaccine. Furthermore, LTC facilities must report COVID-19 vaccine and therapeutics treatment information to the Centers for Disease Control and Prevention's (CDC) National Healthcare Safety Network (NHSN).
- Transparency: CMS will post the new information reported to the NHSN for viewing by facilities, stakeholders, or the general public on CMS's COVID-19 Nursing Home Data website.
- **Updated Survey Tools:** CMS has updated tools used by surveyors to assess compliance with these new requirements.

Background

On December 1, 2020, the Advisory Committee in Immunization Practices (ACIP) recommended that health care personnel (HCP) and long-term care (LTC) facility residents be offered COVID-19 vaccination first (Phase 1a).[1] Ensuring LTC residents receive COVID-19 vaccinations will help protect those who are most at risk of severe infection or death from COVID-19.

To support this, on May 11, 2021, CMS published an interim final rule with comment period (IFC), CMS-3414-IFC , entitled "Medicare and Medicaid Programs; COVID-19 Vaccine Requirements for Long-Term Care (LTC) Facilities and Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICFs-IID) Residents, Clients, and Staff." CMS added new requirements at §483.80(d)(3)(i)-(vii) for LTC facilities to develop policies and procedures

[1] https://www.cdc.gov/mmwr/volumes/69/wr/mm6949e1.htm

to educate residents or resident representatives and staff regarding the benefits and potential side effects associated with the COVID-19 vaccine and offer the vaccine unless it is medically contraindicated or the resident or staff member has already been immunized. Additionally, the facility must maintain appropriate documentation to reflect that the facility provided the required COVID-19 vaccine education, and whether the resident and staff member received the vaccine.

Furthermore, CMS added a new requirement at §483.80(g)(1)(viii)-(ix) for LTC facilities to report COVID-19 vaccine status of residents and staff, each dose of vaccine received, COVID-19 vaccination adverse events, and therapeutics administered to residents for treatment of COVID-19. As already required at §483.80(g)(2), this data also must be reported to CDC's NHSN system and CMS intends to post the new information collected on the CMS COVID-19 Nursing Home Data website. This reporting will help public health agencies and stakeholders monitor the level of vaccinated residents and staff and target resources accordingly to improve vaccination rates. Additionally, reporting the use of therapeutics will help agencies and stakeholders monitor the prevalence of these treatments, their impact on reducing the effect of COVID-19 on nursing home residents, and support allocation efforts to ensure that nursing homes have access to supplies to meet their needs.

Noncompliance related to the new requirements for educating and offering COVID-19 vaccination to residents and staff will be cited at F-tag 887, and noncompliance related to COVID-19 vaccination reporting will be cited at F-tag 884.

§483.80 Infection control

(d) Influenza, pneumococcal, and COVID-19 immunizations. . .

(3) *COVID-19 immunizations*. The LTC facility must develop and implement policies and procedures to ensure all the following:

(i) When COVID-19 vaccine is available to the facility, each resident and staff member is offered the COVID-19 vaccine unless the immunization is medically contraindicated or the resident or staff member has already been immunized;

(ii) Before offering COVID-19 vaccine, all staff members are provided with education regarding the benefits and risks and potential side effects associated with the vaccine;

(iii) Before offering COVID-19 vaccine, each resident or the resident representative receives education regarding the benefits and risks and potential side effects associated with the COVID-19 vaccine;

(iv) In situations where COVID-19 vaccination requires multiple doses, the resident, resident representative, or staff member is provided with current information regarding those additional doses, including any changes in the benefits or risks and potential side effects, associated with the COVID-19 vaccine, before requesting consent for administration of any additional doses.

(v) The resident, resident representative, or staff member has the opportunity to accept or refuse a COVID-19 vaccine, and change their decision; and

(vi) The resident's medical record includes documentation that indicates, at a minimum, the following:

(A) That the resident or resident representative was provided education regarding the benefits and potential risks associated with COVID-19 vaccine; and

(B) Each dose of COVID-19 vaccine administered to the resident, or

(C) If the resident did not receive the COVID-19 vaccine due to medical contraindications or refusal.

(vii) The facility maintains documentation related to staff COVID-19 vaccination that includes at a minimum, the following:

(A) That staff were provided education regarding the benefits and potential risks associated with COVID-19 vaccine;

(B) Staff were offered the COVID-19 vaccine or information on obtaining COVID-19 vaccine; and

(C) The COVID-19 vaccine status of staff and related information as indicated by NHSN.

(g)(1)(viii) The COVID-19 vaccine status of residents and staff, including total numbers of residents and staff, numbers of residents and staff vaccinated, numbers of each dose of COVID-19 vaccine received, and COVID-19 vaccination adverse events; and

(ix) Therapeutics administered to residents for treatment of COVID-19.

F887: COVID-19 Immunization

DEFINITIONS

"Staff" means those individuals who work in the facility on a regular (that is, at least once a week) basis, including individuals who may not be physically in the LTC facility for a period of time due to illness, disability, or scheduled time off, but who are expected to return to work. This also includes individuals under contract or arrangement, including hospice and dialysis staff, physical therapists, occupational therapists, mental health professionals, or volunteers, who are in the facility on a regular basis, as the vaccine is available.

"Emergency Use Authorization (EUA)" is a mechanism to facilitate the availability and use of medical countermeasures, including vaccines, during public health emergencies, such as the current COVID-19 pandemic. The EUA process is a way to ensure safety while still expediting approval in emergent situations.

GUIDANCE

In order to protect LTC residents from COVID-19, each facility must develop and implement policies and procedures that meet each resident's, resident representative's, and staff member's information needs and provides vaccines to all residents and staff that elect them.

Education

All residents and/or resident representatives and staff must be educated on the COVID-19 vaccine they are offered, in a manner they can understand, and receive the FDA COVID-19 EUA Fact Sheet before being offered the vaccine. The Food and Drug Administration (FDA) requires that vaccine recipients or their representative are provided with certain vaccine-specific EUA information to help make an informed decision about vaccination. Fact Sheets can be found at the Center for Disease Control and Prevention's (CDC) COVID-19 Vaccine Emergency Use Authorization (EUA) Fact Sheets for Recipients and Caregivers website.

Education must cover the benefits and potential side effects of the vaccine. This should include common reactions, such as aches or fever, and rare reactions such as anaphylaxis.

If the vaccination requires multiple doses of vaccine, the resident or resident representative and staff are again provided with education regarding the benefits and potential side effects of the

vaccine and current information regarding those additional doses, including any changes in the benefits or potential side effects, before requesting consent for administration of any additional doses. The resident, resident representative, or staff member must be provided the opportunity to refuse the vaccine and to change their decision about vaccination at any time.

The CDC, FDA, Immunization Action Coalition (IAC), and vaccine manufacturers have developed a variety of educational and training resources for healthcare professionals related to COVID-19 vaccines. CMS recommends that staff work with their LTC facility's Medical Director and Infection Preventionist and use the CDC and FDA resources as the source of information for their vaccination education initiatives. The CDC's LTC Facility Toolkit: Preparing for COVID-19 Vaccination at Your Facility has information and resources to build confidence among staff and residents.

Offering Vaccinations

LTC facilities must offer residents and staff vaccination against COVID-19 when vaccine supplies are available to the facility. Screening individuals prior to offering the vaccination for prior immunization, medical precautions and contraindications is necessary for determining whether they are appropriate candidates for vaccination at any given time. The vaccine may be offered and provided directly by the LTC facility or indirectly, such as through an arrangement with a pharmacy partner, local health department, or other appropriate health entity.

The facility is not required to educate and offer COVID-19 vaccinations to individuals who enter the facility for specific purposes and for a limited amount of time, such as delivery and repair personnel or volunteers who may enter the LTC facility infrequently (meaning less than once weekly). However, if the facility has the availability, they may offer education and vaccination to these individuals.

If a resident or staff member requests vaccination against COVID-19, but missed earlier opportunities for any reason (including recent residency or employment, changing health status, overcoming vaccine hesitancy, or any other reason), we expect the facility to offer the vaccine to that individual as soon as possible. If the vaccine is unavailable in the facility, the facility should provide information on obtaining vaccination opportunities (e.g. health department or local pharmacy) to the individual, however it is expected that the facility will provide evidence, upon request, of efforts made to make the vaccine available to its staff and residents. Similar to influenza vaccines, if there is a manufacturing delay, the facility should provide evidence of the delay, including efforts to acquire subsequent doses as necessary.

Indications and contraindications for COVID-19 vaccination are evolving and facilities should be alert to any new or revised guidelines issued by the CDC, FDA, vaccine manufacturers, or other expert stakeholders.

Vaccination Administration

For residents and staff who opt to receive the vaccine, vaccination must be conducted in accordance with CDC, ACIP, FDA, and manufacturer guidelines. All facilities must adhere to current infection prevention and control recommendations when preparing and administering vaccines.

Administration of any vaccine includes appropriate monitoring of recipients for adverse reactions, and long-term care facilities must have strategies in place to appropriately evaluate and manage post-vaccination adverse reactions among their residents and staff, per 483.45(d), F757. Particularly for COVID-19 vaccines, safety monitoring is required under the associated EUAs.

Vaccination Adverse Event Reporting
In accordance with FDA requirements, select adverse events for COVID-19 vaccines must be reported to the Vaccine Adverse Event Reporting System (VAERS), (that is, vaccine administration errors, serious adverse events, multisystem inflammatory syndrome (MIS) in children or adults, and cases of COVID-19 that result in hospitalization or death). Any revised safety reporting requirements must also be followed. For additional information see VAERS – Vaccine Adverse Event Reporting System at https://vaers.hhs.gov.

Vaccination Refusal
Residents and their representatives have the right to refuse the COVID-19 vaccine in accordance with Resident Rights requirements at 42 CFR 483.10(c)(6) and tag F578. Additionally, the regulation at §483.10(b)(2) states "The resident has the right to be free of interference, coercion, discrimination, and reprisal from the facility in exercising his or her rights and to be supported by the facility in the exercise of his or her rights as required under this subpart." Therefore, facilities cannot take any adverse action against a resident or representative who refuses the vaccine, including social isolation, denied visitation and involuntary discharge.

Facilities should follow state law and facility policies with respect to staff refusal of vaccination.

Documentation
The resident's medical record must include documentation that indicates, at a minimum, that the resident or resident representative was provided education regarding the benefits and potential side effects of the COVID-19 vaccine, and that the resident (or representative) either accepted and received the COVID-19 vaccine or did not receive the vaccine due to medical contraindications, prior vaccination, or refusal. If there is a contraindication to the resident having the vaccination, the appropriate documentation must be made in the resident's medical record. Documentation should include the date the education and offering took place, and the name of the representative that received the education and accepted or refused the vaccine, if the resident has a representative that makes decisions for them. Facilities should also provide samples of the educational materials that were used to educate residents.

The facility must maintain documentation that each staff member was educated on the benefits and potential side effects of the COVID-19 vaccine and offered vaccination unless medically contraindicated or the staff member has already been immunized. Compliance can be demonstrated by providing a roster of staff that received education (e.g., a sign-in sheet), the date of the education, and samples of the educational materials that were used to educate staff. The facility must document the vaccination status of each staff member (i.e., immunized or not), including whether fully immunized (i.e., completed the series of multi-dose vaccines).

If a staff member is not eligible for COVID-19 vaccination because of previous immunization at another location or outside of the facility, the facility should request vaccination documentation from the staff member to confirm vaccination status.

LTC administrators and clinical leadership are encouraged to track vaccination coverage in their facilities and adjust communication with residents and staff accordingly to facilitate understanding and knowledge of the benefits of vaccination.

Resources for COVID-19 Vaccines

- COVID-19 Vaccination Training Programs and Reference Materials for Healthcare Professionals: https://www.cdc.gov/vaccines/covid-19/downloads/COVID-19-Clinical-Training-and-Resources-for-HCPs.pdf
- Immunization Action Coalition - for education and implementation materials: https://www.immunize.org/handouts/covid19-vaccines.asp
- CDC's Clinical Resources for COVID-19 Vaccine https://www.cdc.gov/vaccines/covid-19/index.html
- Long-Term Care Facilities COVID-19 Vaccination (landing page for LTC information, including the toolkit): https://www.cdc.gov/coronavirus/2019-ncov/hcp/nursing-home-long-term-care/vaccination.html
- Understanding the Pharmacy Partnership for Long-Term Care Program: https://www.cdc.gov/vaccines/covid-19/long-term-care/pharmacy-partnerships.html
- COVID-19 Vaccine Emergency Use Authorization (EUA) Fact Sheets for Recipients and Caregivers https://www.cdc.gov/vaccines/covid-19/eua/index.html#:~:text=For%20each%20COVID%2D19%20vaccine,an%20informed%20decision%20about%20vaccination
- Post Vaccine Considerations for Residents and HCP: https://www.cdc.gov/coronavirus/2019-ncov/hcp/post-vaccine-considerations-residents.html, https://www.cdc.gov/coronavirus/2019-ncov/hcp/post-vaccine-considerations-healthcare-personnel.html
- General Best Practice Guidelines for Immunization: Best Practices Guidance of the Advisory Committee on Immunization Practices (ACIP) www.cdc.gov/vaccines/hcp/acip-recs/general-recs/index.html

INVESTIGATIVE PROCEDURES

Use the Infection Prevention, Control & Immunizations Facility Task, along with the above interpretive guidance, when determining if the facility meets the requirements for, or investigating concerns related to COVID-19 vaccination of residents and staff.

POTENTIAL TAGS FOR ADDITIONAL INVESTIGATION

- F658: for concerns related to professional standards of practice for the provision of vaccines;
- F880: for concerns related to infection prevention and control;
- F660: for concerns related to provision of documentation of the resident's vaccination status to the next provider and follow-up vaccination instructions to the resident when the resident is transferred or discharged.

Updates to the Survey Process for F887

To determine compliance with §483.80(d)(3), surveyors will request a facility point of contact to provide information on how residents and staff are educated about and offered the COVID-19 vaccine, including samples of educational materials. Surveyors will also request a list of residents and staff and their COVID-19 vaccination status from which they will select a sample of residents and staff to review records and conduct interviews to confirm they were educated on and offered the COVID-19 vaccine in accordance with the new requirements. CMS will update the CMS-20054: "Infection Prevention, Control & Immunizations" Facility Task to include the new requirement at F887 for educating residents or resident representatives and staff and offering the COVID-19 vaccine. Additionally, CMS will update associated survey documents, which will be found under the "Survey Resources" link in the Downloads Section of the CMS Nursing Homes website. The updated documents will also be added to the Long-Term Care Survey Process software application.

F884: Reporting – National Healthcare Safety Network (NHSN)

42 CFR 483.80(g)(1)(viii)-(ix) requires LTC facilities report, on a weekly basis, the COVID-19 vaccination status of residents and staff, total numbers of residents and staff vaccinated, each dose of vaccine received, COVID-19 vaccination adverse events, and therapeutics administered to residents for treatment of COVID-19 through NHSN's LTCF COVID-19 Module.

LTC facility administrators and clinical leadership are encouraged to track vaccination coverage in their facility, which can help them target efforts to improve vaccination coverage. Facilities may use the COVID-19 Vaccination module in NHSN to track aggregate vaccination coverage.

Refer to CMS memorandum QSO-20-29-NH for additional NHSN reporting requirements under F884 as well as instructions on registering, enrolling, and reporting to NHSN. For NHSN questions, please email: NHSN@cdc.gov and add "Weekly COVID-19 Vaccination" in the subject header.

Facilities must continue submitting their COVID-19 data to NHSN at least weekly, but no later than Sunday at 11:59 p.m., each week. Facilities must begin including vaccination and therapeutic data reporting in facility NHSN submissions by 11:59 p.m. Sunday, June 13, 2021. To be compliant with the new reporting requirements, facilities must submit the data through the NHSN reporting system at least once every seven days. Facilities may choose to submit multiple times a week.

Enforcement for F884

Compliance with F884 requires facilities to continue to report COVID-19 data through NHSN's LTCF COVID-19 Module, and now, with finalization of the new reporting requirements at §483.80(g)(viii) and (ix), they must begin reporting vaccination data for residents and staff and the use of therapeutics for residents. **CMS will begin reviewing for compliance with the new vaccination reporting requirements Monday, June 14, 2021.**

As has been done since June 2020, CMS will continue to receive the CDC NHSN reported data and review for timely and complete reporting of **all** data elements. Facilities identified as not meeting the all reporting requirements under the provisions at §483.80(g)(1), including the new vaccination reporting requirements, will receive a deficiency citation at F884 on the CMS 2567, Statement of Deficiencies, at a scope and severity level of F (no actual harm with a potential for more than minimal harm that is not an Immediate Jeopardy [IJ] and that is widespread).

Failure to report the required elements to NHSN (including the new vaccination reporting requirements) will result in a single deficiency at F884 for that reporting week. In accordance with §488.447, a determination that a facility has failed to comply with the requirements to report weekly to the CDC pursuant to §483.80(g)(1)-(2) (tag F884) will result in a civil money penalty (CMP) imposition. Enforcement for F884 follows a progressive pattern, which leads to an increase of the CMP amount for each subsequent occurrence of noncompliance, not to exceed the maximum amount set forth in §488.408(d)(1)(iii), as specified in §488.447(a)(2).[2] The amount of the CMP imposed is incrementally increased based on the provider's history of noncompliance with F884 since June 2020 when providers were first required to start reporting COVID-19 related data to the CDC.

Per enforcement requirements at §488.447, failure to meet reporting requirements at §483.80(g)(1) will result in a CMP starting at $1,000 for the first occurrence of a failure to report. For each subsequent week that the facility fails to submit the required report, the noncompliance will result in an additional CMP imposed at an amount increased by $500 and added to the previously imposed CMP amount for each subsequent occurrence. Please refer to QSO 20-29-NH, which detailed how CMS will enforce the new reporting requirement.

CMS will continue to provide notification of noncompliance and imposition of a CMP, along with the CMS 2567 to facilities via their CASPER shared folders.

NHSN Resources for Providers

- LTCF COVID19 Module webpage (https://www.cdc.gov/nhsn/ltc/covid19/index.html): Visit this website before submitting questions to the NHSN help desk.

- Enrollment help: https://www.cdc.gov/nhsn/pdfs/covid19/ltcf/covid19-enrollment-508.pdf or https://www.cdc.gov/nhsn/ltc/covid19/enroll.html. If you still need help with enrollment/data submission, contact NHSN@cdc.gov "LTCF" in the subject line.

- To correct facility type: https://www.cdc.gov/nhsn/pdfs/covid19/ltcf/change-ltcf-508.pdf.

- To change/update your NHSN facility administrator: https://www.cdc.gov/nhsn/facadmin/index.html

- For enforcement-related questions, please email: DNH_Enforcement@cms.hhs.gov

Contact: For questions or concerns regarding this memo, please contact DNH_TriageTeam@cms.hhs.gov.

Effective Date: This policy should be communicated with all survey and certification staff, their managers and the State/CMS Location training coordinators immediately. The effective dates of the specific actions are specified above.

[2] See Medicare and Medicaid Programs, Clinical Laboratory Improvement Amendments (CLIA), and Patient Protection and Affordable Care Act; Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency, Interim Final Rule, 85 FR 54820, at 54823-54825 (Sept. 2, 2020).

/s/
David R. Wright

cc: Survey and Operations Group Management

DEPARTMENT OF HEALTH & HUMAN SERVICES
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Center for Clinical Standards and Quality/Quality, Safety & Oversight Group

Ref: QSO-22-07-ALL

DATE: **December 28, 2021**

TO: State Survey Agency Directors

FROM: Directors
Quality, Safety & Oversight Group (QSOG) and Survey & Operations Group (SOG)

SUBJECT: Guidance for the Interim Final Rule - Medicare and Medicaid Programs; Omnibus COVID-19 Health Care Staff Vaccination

Memorandum Summary

- CMS is committed to ensuring America's healthcare facilities respond effectively in an evidence-based way to the Coronavirus Disease 2019 (COVID-19) Public Health Emergency (PHE).
- On November 05, 2021, CMS published an interim final rule with comment period (IFC). This rule establishes requirements regarding COVID-19 vaccine immunization of staff among Medicare- and Medicaid-certified providers and suppliers.
- CMS is providing guidance and survey procedures for assessing and maintaining compliance with these regulatory requirements.
- The guidance in this memorandum does not apply to the following states at this time: Alabama, Alaska, Arizona, Arkansas, Georgia, Idaho, Indiana, Iowa, Kansas, Kentucky, Louisiana, Mississippi, Missouri, Montana, Nebraska, New Hampshire, North Dakota, Ohio, Oklahoma, South Carolina, South Dakota, Texas, Utah, West Virginia and Wyoming. **Surveyors in these states should not undertake any efforts to implement or enforce the IFC.**

Background

Since the beginning of the Public Health Emergency, CMS and the Centers for Disease Control and Prevention (CDC) data show as of mid-October, over 44 million COVID-19 cases, 3 million COVID-19 related hospitalization, and 720,000 COVID-19 deaths have been reported. The CDC has reported that COVID-19 vaccines are safe and effective at preventing severe illness from COVID-19 and limiting the spread of the virus that causes it. On December 11, 2020, the Advisory Committee in Immunization Practices (ACIP) recommended, as interim guidance, that both 1) health care personnel, and 2) residents of long-term care (LTC) facilities be offered COVID-19 vaccine in the initial phase of the vaccination program. To support this recommendation, on May 13, 2021, CMS published an interim final rule with comment period (IFC), entitled "Medicare and Medicaid Programs; COVID-19 Vaccine Requirements for Long-

Term Care (LTC) Facilities and Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICFs-IID) Residents, Clients, and Staff" (86 FR 26306). Also, CMS released guidance for surveyors and LTC facilities in the CMS memo, QSO-21-19-NH, Interim Final Rule - COVID-19 Vaccine Immunization Requirements for Residents and Staff. This rule required all certified LTC facilities (i.e., nursing homes) to educate all residents and staff on the benefits and potential side effects associated with the COVID-19 vaccine, and offer the vaccine.

The regulation was intended to help increase vaccination rates among nursing home residents and staff to reduce the risk of infection and disease associated with COVID-19. Approximately two months after the publication of the rule, about 80 percent of nursing home residents were vaccinated. However, during that same time, roughly 60% of nursing home staff were vaccinated.[1] Therefore, more actions are warranted to increase vaccination rates among staff.

On August 18, 2021, CMS announced that it would be issuing a regulation that all nursing home staff would have to be vaccinated against COVID-19 as a requirement for LTC facilities participating with the Medicare and Medicaid programs. Subsequently, on September 9, 2021, CMS announced that this requirement would be extended to nearly all Medicare and Medicaid-certified providers and suppliers. These actions aim to support increasing vaccination rates among staff working in all facilities, providers, and certified suppliers that participate in Medicare and Medicaid.

Discussion

On November 5, 2021, CMS published an IFC with comment period (86 FR 61555), entitled "Medicare and Medicaid Programs; Omnibus COVID-19 Health Care Staff Vaccination," revising the infection control requirements that most Medicare- and Medicaid-certified providers and suppliers must meet to participate in the Medicare and Medicaid programs. These changes are necessary to protect the health and safety of patients and staff during the COVID-19 public health emergency. The COVID-19 vaccination requirements and policies and procedures required by this IFC must comply with applicable federal non-discrimination and civil rights laws and protections, including providing reasonable accommodations to individuals who are legally entitled to them because they have a disability or sincerely held religious beliefs, practices, or observations that conflict with the vaccination requirement. More information on federal non-discrimination and civil rights laws is available here: https://www.eeoc.gov/wysk/what-you-should-know-about-covid-19-and-ada-rehabilitation-act-and-other-eeo-laws.

Vaccination Enforcement– Surveying for Compliance

Medicare and Medicaid-certified facilities are expected to comply with all regulatory requirements, and CMS has a variety of established enforcement remedies. For nursing homes, home health agencies, and hospice (beginning in 2022), this includes civil monetary penalties, denial of payments, and—as a final measure—termination of participation from the Medicare and Medicaid programs. The sole enforcement remedy for non-compliance for hospitals and certain other acute and continuing care providers is termination; however, , CMS's primary goal is to bring health care facilities into compliance. Termination would generally occur only after providing a facility with an opportunity to make corrections and come into compliance.

[1] COVID-19 Nursing Home Data - Centers for Medicare & Medicaid Services Data (cms.gov)

CMS expects all providers' and suppliers' staff to have received the appropriate number of doses by the timeframes specified in the QSO-22-07 unless exempted as required by law, or delayed as recommended by CDC. **Facility staff vaccination rates under 100% constitute non-compliance under the rule.** Non-compliance does not necessarily lead to termination, and facilities will generally be given opportunities to return to compliance. Consistent with CMS's existing enforcement processes, this guidance will help surveyors determine the severity of a noncompliance deficiency finding at a facility when assigning a citation level. These enforcement action thresholds are as follows:

Within 30 days after issuance of this memorandum[2], if a facility demonstrates that:

- Policies and procedures are developed and implemented for ensuring all facility staff, regardless of clinical responsibility or patient or resident contact are vaccinated for COVID-19; **and**
- 100% of staff have received at least one dose of COVID-19 vaccine, or have a pending request for, or have been granted qualifying exemption, or identified as having a temporary delay as recommended by the CDC, the **facility is compliant under the rule; or**
- 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, the **facility is non-compliant under the rule.** The facility will receive notice[3] of their non-compliance with the 100% standard. A facility that is above 80% **and** has a plan to achieve a 100% staff vaccination rate within 60 days would not be subject to additional enforcement action. States should work with their CMS location for cases that exceed these thresholds, yet pose a threat to patient health and safety. Facilities that do not meet these parameters could be subject to additional enforcement actions depending on the severity of the deficiency and the type of facility (e.g., plans of correction, civil monetary penalties, denial of payment, termination, etc.).

Within 60 days after the issuance of this memorandum[4], if the facility demonstrates that:

- Policies and procedures are developed and implemented for ensuring all facility staff, regardless of clinical responsibility or patient or resident contact are vaccinated for COVID-19; **and**
- 100% of staff have received the necessary doses to complete the vaccine series (i.e., one dose of a single-dose vaccine or all doses of a multiple-dose vaccine series), or have been granted a qualifying exemption, or identified as having a temporary delay as recommended by the CDC, the **facility is compliant under the rule; or**
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[2] If 30 days falls on a weekend or designated federal holiday, CMS will use enforcement discretion to initiate compliance assessments the next business day.
[3] This information will be communicated through the CMS Form-2567, using the applicable Automated Survey Process Environment (ASPEN) federal tag.
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compliant under the rule. The facility will receive notice[5] of their non-compliance with the 100% standard. A facility that is above 90% **and** has a plan to achieve a 100% staff vaccination rate within 30 days would not be subject to additional enforcement action. States should work with their CMS location for cases that exceed these thresholds, yet pose a threat to patient health and safety. Facilities that do not meet these parameters could be subject to additional enforcement actions depending on the severity of the deficiency and the type of facility (e.g., plans of correction, civil monetary penalties, denial of payment, termination, etc.).

Within 90 days and thereafter following issuance of this memorandum, facilities failing to maintain compliance with the 100% standard may be subject to enforcement action.

Federal, state, Accreditation Organization, and CMS-contracted surveyors will begin surveying for compliance with these requirements as part of initial certification, standard recertification or reaccreditation, and complaint surveys 30 days following the issuance of this memorandum. Additional information and expectations for compliance can be found at the provider-specific guidance attached to this memorandum.

Provider-Specific Guidance:

Guidance specific to provider types and certified suppliers is provided in the following attachments. The provider-specific guidance should be used in conjunction with the information in this memo.

- Attachment A: LTC Facilities (nursing homes)
- Attachment B: ASC
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Enforcement Actions

CMS will follow current enforcement procedures based on the level of deficiency cited during a survey.

Contact:
DNH_TriageTeam@cms.hhs.gov for questions related to nursing homes;

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QSOG_Emergencyprep@cms.hhs.gov for question related to acute and continuing care providers.

Effective Date: This policy should be communicated with all survey and certification staff, their managers, and the State/CMS Location training coordinators immediately. The effective dates of the specific actions are specified above.

/s/

Karen L. Tritz
Director, Survey & Operations Group

David R. Wright
Director, Quality, Safety & Oversight Group

cc: Survey and Operations Group Management
Attachments: A through N

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop C2-21-16
Baltimore, Maryland 21244-1850

Center for Clinical Standards and Quality/Quality, Safety & Oversight Group

Ref: QSO-22-09-ALL

DATE: **January 14, 2022**

TO: State Survey Agency Directors

FROM: Directors
Quality, Safety & Oversight Group (QSOG) and Survey & Operations Group (SOG)

SUBJECT: Guidance for the Interim Final Rule - Medicare and Medicaid Programs; Omnibus COVID-19 Health Care Staff Vaccination

Memorandum Summary

- CMS is committed to ensuring America's healthcare facilities respond effectively in an evidence-based way to the Coronavirus Disease 2019 (COVID-19) Public Health Emergency (PHE).
- On November 05, 2021, CMS published an interim final rule with comment period (IFC). This rule establishes requirements regarding COVID-19 vaccine immunization of staff among Medicare- and Medicaid-certified providers and suppliers.
- CMS is providing guidance and survey procedures for assessing and maintaining compliance with these regulatory requirements.
- The guidance in this memorandum specifically applies to the following states: Alabama, Alaska, Arizona, Arkansas, Georgia, Idaho, Indiana, Iowa, Kansas, Kentucky, Louisiana, Mississippi, Missouri, Montana, Nebraska, New Hampshire, North Dakota, Ohio, Oklahoma, South Carolina, South Dakota, Utah, West Virginia and Wyoming.
- The guidance in this memorandum does not apply to the following state at this time: Texas. **Surveyors in Texas should not undertake any efforts to implement or enforce the IFC.**
- States that are not identified above are expected to continue under the timeframes and parameters identified in the December 28, 2021 memorandum (QSO-22-07-ALL).

Background

Since the beginning of the Public Health Emergency, CMS and the Centers for Disease Control and Prevention (CDC) data show as of mid-October, over 44 million COVID-19 cases, 3 million COVID-19 related hospitalization, and 720,000 COVID-19 deaths have been reported. The CDC has reported that COVID-19 vaccines are safe and effective at preventing severe illness from COVID-19 and limiting the spread of the virus that causes it. On December 11, 2020, the Advisory Committee in Immunization Practices (ACIP) recommended, as interim guidance, that both 1) health care personnel, and 2) residents of long-term care (LTC) facilities be offered COVID-19 vaccine in the initial phase of the vaccination program. To support this

recommendation, on May 13, 2021, CMS published an interim final rule with comment period (IFC), entitled "Medicare and Medicaid Programs; COVID-19 Vaccine Requirements for Long-Term Care (LTC) Facilities and Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICFs-IID) Residents, Clients, and Staff" (86 FR 26306). Also, CMS released guidance for surveyors and LTC facilities in the CMS memo, QSO-21-19-NH, Interim Final Rule - COVID-19 Vaccine Immunization Requirements for Residents and Staff. This rule required all certified LTC facilities (i.e., nursing homes) to educate all residents and staff on the benefits and potential side effects associated with the COVID-19 vaccine, and offer the vaccine.

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/s/

Karen L. Tritz
Director, Survey & Operations Group

David R. Wright
Director, Quality, Safety & Oversight Group

cc: Survey and Operations Group Management
Attachments: A through N

LINKS FROM THE MO REOPENING GUIDANCE DOCUMENT DATED 7/7/20 AND OTHER HELPFUL RESOURCES		REOPENING GUIDANCE FOR MO LTC HOMES
RESOURCE	**WEBSITE**	**PURPOSE**
CMS	**https://www.cms.gov/files/document/qso-20-39-nh-revised.pdf**	**Visitation Guidance**
CMS	**https://www.cms.gov/medicareprovider-enrollment-and-certificationsurveycertificationgeninfopolicy-and-memos-states-and/guidance-interim-final-rule-medicare-and-medicaid-programs-omnibus-covid-19-health-care-staff-2**	**Staff Vaccination QSO-22-11-ALL**
CDC	**https://www.cdc.gov/coronavirus/2019-ncov/hcp/assessment-tool-for-nursing-homes.html**	**Infection Prevention and Control Assessment Tool for Nursing Homes Preparing for COVID-19**
CDC	https://www.cdc.gov/coronavirus/2019-ncov/hcp/nursing-homes-testing.html	**Interim Infection Prevention and Control Recommendations to Prevent SARS-CoV-2 Spread in Nursing Homes**
CDC	https://www.cdc.gov/coronavirus/2019-ncov/lab/guidelines-clinical-specimens.html	**Interim Guidelines for Collecting, Handling, Testing Clinical Specimens for COVID-19**
CDC	**https://www.cdc.gov/coronavirus/2019-ncov/hcp/ppe-strategy/general-optimization-strategies.html**	**Optimizing PPE**
DHSS	https://health.mo.gov/living/lpha/pdf/printablelisting.pdf	**LPHA Listing**
DHSS/MHA	https://health.mo.gov/living/healthcondiseases/communicable/novel-coronavirus/pdf/hccs-contact-leads.pdf	**Healthcare Coalitions Contacts**
QIPMO	https://nursinghomehelp.org/educational/important-information-helpful-links-on-coronavirus-covid-19/	**COVID-19 Resource Page**

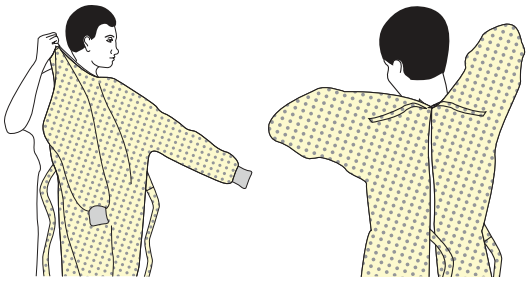
LINKS FROM THE MO REOPENING GUIDANCE DOCUMENT DATED 7/7/20 AND OTHER HELPFUL RESOURCES		REOPENING GUIDANCE FOR MO LTC HOMES
RESOURCE	**WEBSITE**	**PURPOSE**
CMS	https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Policy-and-Memos-to-States-and-Regions	**QSO's**
CMS	https://www.cms.gov/Outreach-and-Education/Outreach/OpenDoorForums/PodcastAndTranscripts	**Coronavirus COVID-19 Stakeholder Calls-Recordings and Transcripts**
CMS	https://www.cms.gov/files/document/covid-toolkit-states-mitigate-covid-19-nursing-homes.pdf	**Toolkit on State Actions to Mitigate COVID-19 Prevalence in Nursing Homes**
CMS	https://www.cms.gov/newsroom	**CMS Newsroom**
CMS	https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/GuidanceforLawsAndRegulations/Nursing-Homes	**Survey Resources (Including COVID Survey Pathway and Resources)**
HHS	https://www.hhs.gov/coronavirus/cares-act-provider-relief-fund/index.html	**CARES Act Relief Fund**
CDC	https://www.cdc.gov/nhsn/ltc/covid19/index.html	**NHSN LTCF COVID-19 Module**
CDC	https://www.cdc.gov/coronavirus/2019-ncov/hcp/long-term-care.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fcoronavirus%2F2019-ncov%2Fhealthcare-facilities%2Fprevent-spread-in-long-term-care-facilities.html	**Preparing for COVID-19 in Nursing Homes**
CMS	https://www.cms.gov/about-cms/emergency-preparedness-response-operations/current-emergencies/coronavirus-waivers	**1135 Waivers**

SEQUENCE FOR PUTTING ON PERSONAL PROTECTIVE EQUIPMENT (PPE)

The type of PPE used will vary based on the level of precautions required, such as standard and contact, droplet or airborne infection isolation precautions. The procedure for putting on and removing PPE should be tailored to the specific type of PPE.

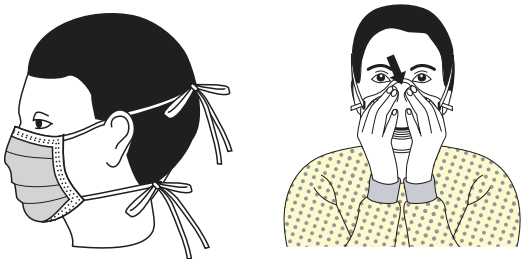
1. GOWN

- Fully cover torso from neck to knees, arms to end of wrists, and wrap around the back
- Fasten in back of neck and waist



2. MASK OR RESPIRATOR

- Secure ties or elastic bands at middle of head and neck
- Fit flexible band to nose bridge
- Fit snug to face and below chin
- Fit-check respirator

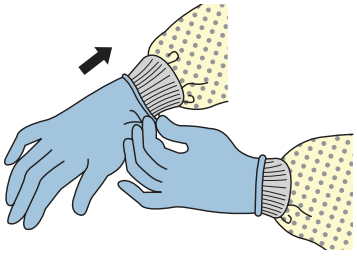


3. GOGGLES OR FACE SHIELD

- Place over face and eyes and adjust to fit

4. GLOVES

- Extend to cover wrist of isolation gown



USE SAFE WORK PRACTICES TO PROTECT YOURSELF AND LIMIT THE SPREAD OF CONTAMINATION

- Keep hands away from face
- Limit surfaces touched
- Change gloves when torn or heavily contaminated
- Perform hand hygiene

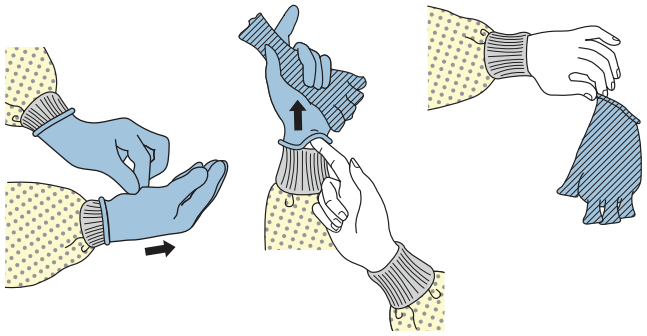
CS250672-E

HOW TO SAFELY REMOVE PERSONAL PROTECTIVE EQUIPMENT (PPE) EXAMPLE 1

There are a variety of ways to safely remove PPE without contaminating your clothing, skin, or mucous membranes with potentially infectious materials. Here is one example. **Remove all PPE before exiting the patient room** except a respirator, if worn. Remove the respirator **after** leaving the patient room and closing the door. Remove PPE in the following sequence:

1. GLOVES

- Outside of gloves are contaminated!
- If your hands get contaminated during glove removal, immediately wash your hands or use an alcohol-based hand sanitizer
- Using a gloved hand, grasp the palm area of the other gloved hand and peel off first glove
- Hold removed glove in gloved hand
- Slide fingers of ungloved hand under remaining glove at wrist and peel off second glove over first glove
- Discard gloves in a waste container

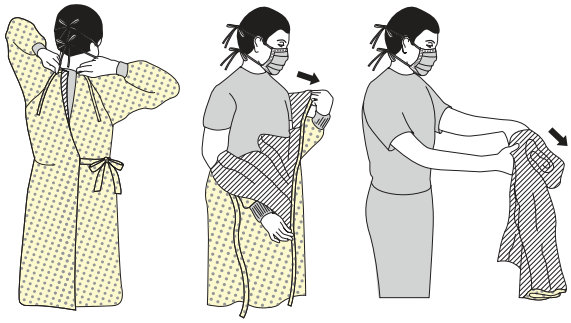


2. GOGGLES OR FACE SHIELD

- Outside of goggles or face shield are contaminated!
- If your hands get contaminated during goggle or face shield removal, immediately wash your hands or use an alcohol-based hand sanitizer
- Remove goggles or face shield from the back by lifting head band or ear pieces
- If the item is reusable, place in designated receptacle for reprocessing. Otherwise, discard in a waste container

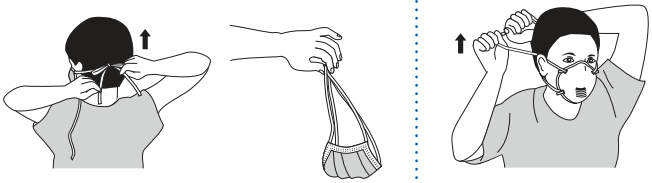
3. GOWN

- Gown front and sleeves are contaminated!
- If your hands get contaminated during gown removal, immediately wash your hands or use an alcohol-based hand sanitizer
- Unfasten gown ties, taking care that sleeves don't contact your body when reaching for ties
- Pull gown away from neck and shoulders, touching inside of gown only
- Turn gown inside out
- Fold or roll into a bundle and discard in a waste container

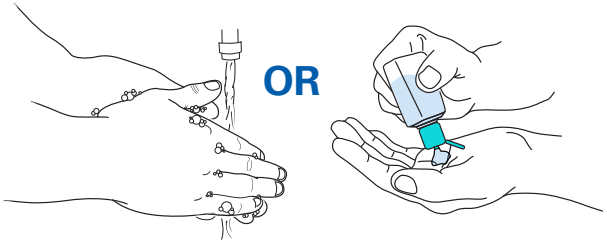


4. MASK OR RESPIRATOR

- Front of mask/respirator is contaminated — DO NOT TOUCH!
- If your hands get contaminated during mask/respirator removal, immediately wash your hands or use an alcohol-based hand sanitizer
- Grasp bottom ties or elastics of the mask/respirator, then the ones at the top, and remove without touching the front
- Discard in a waste container



5. WASH HANDS OR USE AN ALCOHOL-BASED HAND SANITIZER IMMEDIATELY AFTER REMOVING ALL PPE



PERFORM HAND HYGIENE BETWEEN STEPS IF HANDS BECOME CONTAMINATED AND IMMEDIATELY AFTER REMOVING ALL PPE

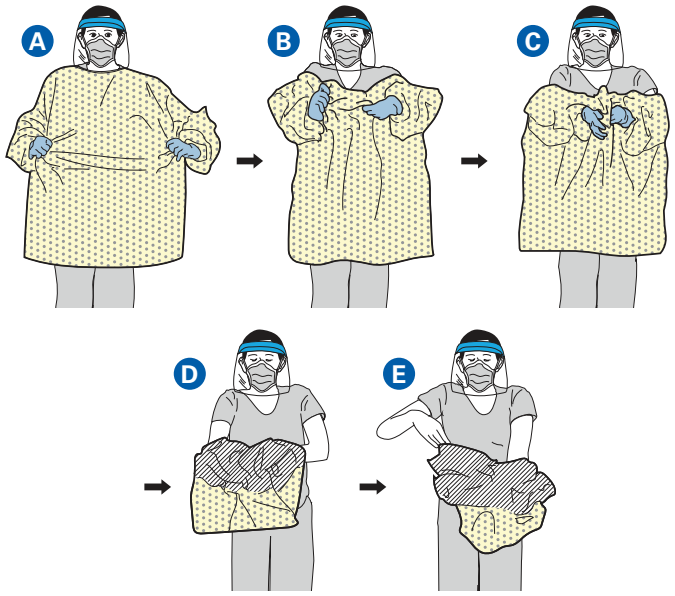
CS250672-E

HOW TO SAFELY REMOVE PERSONAL PROTECTIVE EQUIPMENT (PPE) EXAMPLE 2

Here is another way to safely remove PPE without contaminating your clothing, skin, or mucous membranes with potentially infectious materials. **Remove all PPE before exiting the patient room** except a respirator, if worn. Remove the respirator **after** leaving the patient room and closing the door. Remove PPE in the following sequence:

1. GOWN AND GLOVES

- Gown front and sleeves and the outside of gloves are contaminated!
- If your hands get contaminated during gown or glove removal, immediately wash your hands or use an alcohol-based hand sanitizer
- Grasp the gown in the front and pull away from your body so that the ties break, touching outside of gown only with gloved hands
- While removing the gown, fold or roll the gown inside-out into a bundle
- As you are removing the gown, peel off your gloves at the same time, only touching the inside of the gloves and gown with your bare hands. Place the gown and gloves into a waste container

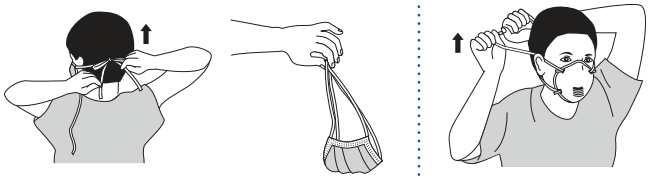


2. GOGGLES OR FACE SHIELD

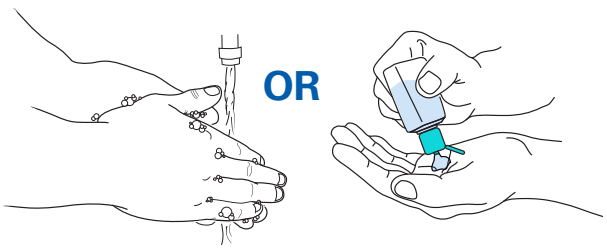
- Outside of goggles or face shield are contaminated!
- If your hands get contaminated during goggle or face shield removal, immediately wash your hands or use an alcohol-based hand sanitizer
- Remove goggles or face shield from the back by lifting head band and without touching the front of the goggles or face shield
- If the item is reusable, place in designated receptacle for reprocessing. Otherwise, discard in a waste container

3. MASK OR RESPIRATOR

- Front of mask/respirator is contaminated — DO NOT TOUCH!
- If your hands get contaminated during mask/respirator removal, immediately wash your hands or use an alcohol-based hand sanitizer
- Grasp bottom ties or elastics of the mask/respirator, then the ones at the top, and remove without touching the front
- Discard in a waste container



4. WASH HANDS OR USE AN ALCOHOL-BASED HAND SANITIZER IMMEDIATELY AFTER REMOVING ALL PPE



PERFORM HAND HYGIENE BETWEEN STEPS IF HANDS BECOME CONTAMINATED AND IMMEDIATELY AFTER REMOVING ALL PPE

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