Infection Control - COVID 19 Tool and Checklist for the COVID-19 Survey

Updated 05/14/2020

*This tool is not a stand-alone tool and should be used as a supplement to the attached CMS COVID-19 Survey for Nursing Homes tool.*

Policies and Procedures

- Do you have a policy and procedure for Infection Control and Prevention plan?
- Do you have an Emergency Preparedness plan that includes contingency staffing?

General Standard Precautions

- Have staff been trained on and demonstrated competency in the listed general standard precautions?

Hand Hygiene

- **New 05/14** Do you have a process for ongoing monitoring of appropriate hand hygiene practices?
- Do staff know when to use alcohol-based hand rub vs. washing with soap and water?
- Do staff know when they should be assisting residents with hand hygiene?

Personal Protective Equipment (PPE)

- **New 05/14** Do staff know how to appropriately use PPE, including appropriate donning and doffing?
  - Have you trained staff on appropriate use of PPE?
  - How are you monitoring for ongoing appropriate use?
- Do staff know what PPE should be used for which procedures, including guidance on optimization/prioritization?
- Where do staff dispose of PPE after use? Does it pose a transmission risk? Are hand hygiene supplies located proximally?
- Do you have record of:
  - Attempts to obtain adequate supplies of PPE
  - Notification to appropriate authorities of inadequate PPE supplies ([https://www.phe.gov/Preparedness/planning/hpp/Pages/find-hc-coalition.aspx](https://www.phe.gov/Preparedness/planning/hpp/Pages/find-hc-coalition.aspx))
- If PPE or supplies run out, do staff know who to contact?
Do front-line staff know who to notify within the facility?
• Who is responsible for ordering more supplies, implementing optimization strategies, and notifying outside authorities in the event of shortage?
• Who is responsible if the individual designated above is off shift or out sick?

Do you have alternative PPE and supply strategies?

Transmission-Based Precautions

• Do staff know the different types of transmission-based precautions?
• How do staff or visitors (permitted healthcare workers) know which residents require which precautions?
• Do staff know the difference between precautions for COVID-19 vs. precautions for an undiagnosed respiratory illness?
• How are staff monitored for compliance with precautions?

Resident Care

• Are you maintaining infection control practices, including social distancing and designated staff, when supplementing cancelled communal dining and group activities?
• Do you have a plan for resident isolation, including a plan to address wide-spread isolation needs (cohorting)?
  • New 05/14 What is your process for determining when to isolate or cohort a resident?
• What is your procedure for transporting a resident with known or suspected COVID-19? How have you notified appropriate staff of their responsibilities in these circumstances?
• How are you managing risks for residents who must leave and re-enter the facility for medical appointments, including dialysis or chemotherapy?

Infection Prevention and Control Program Standards, Policies, and Procedures

• Have you adapted your IPCP for undiagnosed respiratory illness and COVID-19?
• When/how are you reviewing and revising these plans?
• Are you reporting to local/state public health officials clusters of both COVID-19 and other respiratory illness?

Infection Surveillance

• Do you have an infection surveillance plan?
• How do you determine when this plan will be implemented?
• How is infection surveillance information, including any trends or changes, communicated within the facility?
• How are you communicating with collaborating providers, such as hospitals, regarding residents’ symptoms and status?
• Who will communicate infection information to local/state public health officials? Do these staff know what information to provide?
  • Who is responsible if the individual(s) designated above are off shift or out sick?

Visitor Entry

• Do you have a policy on visitor screening and entry, including special circumstances under which a visitor will be permitted?
• How have you communicated screening and restriction procedures?
• How are permitted visitors screened and provided education on infection control?
• How do permitted visitors, including visiting healthcare workers, know about monitoring for symptoms and who to contact if symptoms develop?

Education, Monitoring, and Screening of Staff
• Does staff have policy and procedure knowledge?
• Are there signs for surveillance for signs/symptoms if appropriate?
• Does staff know reporting procedures including reporting to the health department?
• Do you have record of staff training on:
  o COVID-19 symptoms, transmission, screening criteria, and work exclusions?
  o Updates to COVID-19 guidance and the local situation?
  o What to do if symptoms develop while working, including who to notify that they are leaving the floor?
• How do you maintain records of staff screening?
• Do you use supply optimization strategies as applicable for staff screening?

New 05/08 Reporting to Residents, Representatives, and Families
• Have you begun notifying residents, representatives, and families of new COVID-19 cases and clusters of respiratory illness?
  o Are you counting both staff and residents in case and cluster notifications and updates?
• What is your process for providing ongoing updates?
• Does your notification format consider reasonable accommodations for low vision, low English proficiency, lack of access to technology, or other access issues common to your intended audience?
• Do you have a process in place, including a designated person(s), to ensure updates occur by 5pm the next calendar day following the identification of a new confirmed COVID-19 case among residents or staff or new clusters of respiratory symptoms among residents or staff?
• What is your back-up plan in case you experience any technical glitches or other roadblocks?
  o Does your back-up plan include a back-up designated person(s) for ensuring updates occur timely?
• Do notifications include the required information: mitigating actions, any alterations to normal operations (cancelling activities or dining, etc.), cumulative information on COVID-19 cases and clusters of respiratory symptoms?
• Do you have a process in place to ensure that updates are provided on at least a weekly basis, even if there have been no new confirmed cases or clusters in that week?
• How do you know that residents, representatives, and families are receiving the information you are providing?

New 05/08 Reporting to the Centers for Disease Control & Prevention (CDC)
• Do you have a process in place, including a designated person(s), to ensure data is submitted at least once every 7 days into the NHSN system?
• What is your back-up plan in case you experience any technical glitches or other roadblocks?
Does your back-up plan include a back-up designated person(s) to ensure data is submitted timely?

- How is data collected, tracked, and utilized internally by your organization?

Emergency Preparedness – Staffing in Emergencies

- Do you have a plan for a widespread staff shortage?
  - Have you cross-trained staff to take on critical responsibilities in the event of a staff shortage (i.e. can your Accounts Payable staff assist with housekeeping services? Can your social worker help serve meals?)?
  - What specialized training is available online, such as infection control or feeding certification?
- Have you coordinated with any outside entities (other facilities, staffing agencies, hospitals, etc.)?
- Do you have a plan for specialized staff shortages (i.e. infection preventionist, physician, etc.)?
- Is there a backup or second staff member trained in infection control?
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**Infection Control**

This survey tool must be used to investigate compliance at F880, F884 (CMS Federal surveyors only), F885, and E0024. Surveyors must determine whether the facility is implementing proper infection prevention and control practices to prevent the development and transmission of COVID-19 and other communicable diseases and infections. Entry and screening procedures as well as resident care guidance has 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](https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Policy-and-Memos-to-States-and-Regions).

This survey tool provides a focused review of the critical elements associated with the transmission of COVID-19, will help surveyors to prioritize survey activities while onsite, and identify those survey activities which can be accomplished offsite. These efficiencies will decrease the potential for transmission of COVID-19, as well as lessen disruptions to the facility and minimize exposure of the surveyor. Surveyors should be mindful to ensure their activities do not interfere with the active treatment or prevention of transmission of COVID-19.

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.”

If surveyors see concerns related to compliance with other requirements, they should investigate them in accordance with the existing guidance in Appendix PP of the State Operations Manual and related survey instructions. Surveyors may also need to consider investigating concerns related to Emergency Preparedness in accordance with the guidance in Appendix Z of the State Operations Manual (e.g., for emergency staffing).

For the purpose of this survey tool, “staff” includes employees, consultants, contractors, volunteers, and others who provide care and services to residents on behalf of the facility. The Infection Prevention and Control Program (IPCP) must be facility-wide and include all departments and contracted services.

**Critical Element #8 is only for consideration by CMS Federal Survey staff. Information to determine the facility’s compliance at F884 is only reported to each of the 10 CMS locations.**

**Surveyor(s) reviews for:**
- The overall effectiveness of the Infection Prevention and Control Program (IPCP) including IPCP policies and procedures;
- Standard and Transmission-Based Precautions;
- Quality of resident care practices, including those with COVID-19 (laboratory-positive case), if applicable;
- The surveillance plan;
COVID-19 Focused Survey for Nursing Homes

- Visitor entry and facility screening practices;
- Education, monitoring, and screening practices of staff;
- Facility policies and procedures to address staffing issues during emergencies, such as transmission of COVID-19; and
- How the facility informs residents, their representatives, and families of suspected or confirmed COVID-19 cases in the facility.

### 1. Standard and Transmission-Based Precautions (TBPs)

CMS is aware that there is a scarcity of some supplies in certain areas of the country. State and Federal surveyors should not cite facilities for not having certain supplies (e.g., PPE such as gowns, N95 respirators, surgical masks) if they are having difficulty obtaining these supplies for reasons outside of their control. 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. For example, if there is a shortage of PPE (e.g., due to supplier(s) shortage which may be a regional or national issue), the facility should contact their health department or healthcare coalition for assistance ([https://www.phe.gov/Preparedness/planning/hpp/Pages/find-hc-coalition.aspx](https://www.phe.gov/Preparedness/planning/hpp/Pages/find-hc-coalition.aspx)), follow national and/or local guidelines for optimizing their current supply or identify the next best option to care for residents. Among other practices, optimizing their current supply may mean prioritizing use of gowns based on risk of exposure to infectious organisms, blood or body fluids, splashes or sprays, high contact procedures, or aerosol generating procedures (AGPs), as well as possibly extending use of PPE (follow national and/or local guidelines). Current CDC guidance for healthcare professionals is located at: [https://www.cdc.gov/coronavirus/2019-nCoV/hcp/index.html](https://www.cdc.gov/coronavirus/2019-nCoV/hcp/index.html) and healthcare facilities is located at: [https://www.cdc.gov/coronavirus/2019-ncov/healthcare-facilities/index.html](https://www.cdc.gov/coronavirus/2019-ncov/healthcare-facilities/index.html). Guidance on strategies for optimizing PPE supply is located at: [https://www.cdc.gov/coronavirus/2019-ncov/hcp/ppe-strategy/index.html](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:**

- Are staff 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:**

- Are staff performing hand hygiene when indicated?
- If alcohol-based hand rub (ABHR) is available, is it readily accessible and preferentially used by staff for hand hygiene?
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<tr>
<th>Question</th>
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<tr>
<td>If there are shortages of ABHR, are staff performing hand hygiene using soap and water instead?</td>
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<tr>
<td>Are staff washing hands with soap and water when their hands are visibly soiled (e.g., blood, body fluids)?</td>
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<td>Do staff perform hand hygiene (even if gloves are used) in the following situations:</td>
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<td>• Before and after contact with the resident;</td>
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<td>• After contact with blood, body fluids, or visibly contaminated surfaces;</td>
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<tr>
<td>• After contact with objects and surfaces in the resident’s environment;</td>
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<tr>
<td>• After removing personal protective equipment (e.g., gloves, gown, facemask); and</td>
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<td>• 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)?</td>
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<td>When being assisted by staff, is resident hand hygiene performed after toileting and before meals?</td>
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<tr>
<td>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.</td>
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### Personal Protective Equipment (PPE):

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<tr>
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<tbody>
<tr>
<td>Determine if staff appropriately use PPE including, but not limited to, the following:</td>
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<tr>
<td>• Gloves are worn if potential contact with blood or body fluid, mucous membranes, or non-intact skin;</td>
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<tr>
<td>• Gloves are removed after contact with blood or body fluids, mucous membranes, or non-intact skin;</td>
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<tr>
<td>• Gloves are changed and hand hygiene is performed before moving from a contaminated body site to a clean body site during resident care;</td>
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<td>and</td>
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<td>• An isolation gown is worn for direct resident contact if the resident has uncontained secretions or excretions.</td>
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<td>Is PPE appropriately removed and discarded after resident care, prior to leaving room (except in the case of extended use of PPE per national/local recommendations), followed by hand hygiene?</td>
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<td>If PPE use is extended/reused, is it done according to national and/or local guidelines? If it is reused, is it cleaned/decontaminated/maintained after and/or between uses?</td>
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<tr>
<td>Interview appropriate staff to determine if PPE is available, accessible and used by staff.</td>
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<tr>
<td>• 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?</td>
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<tr>
<td>• Do staff know how to obtain PPE supplies before providing care?</td>
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<tr>
<td>• Do they know who to contact for replacement supplies?</td>
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Transmission-Based Precautions (Note: PPE use is based on availability and latest CDC guidance. See note on Pages 1-2):

- Determine if appropriate Transmission-Based Precautions are implemented:
  - 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 within six feet of a resident;
  - For a resident on Airborne Precautions: staff don an N95 or higher level respirator prior to room entry of a resident;
  - For a resident with an undiagnosed respiratory infection: 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. Additionally, if there are COVID-19 cases in the facility or sustained community transmission, staff implement universal use of facemasks while in the facility (based on availability). When COVID-19 is identified in the facility, staff wear all recommended PPE (i.e., gloves, gown, eye protection and respirator or facemask) for the care of all residents on the unit (or facility-wide based on the location of affected residents), regardless of symptoms (based on availability).
    - 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.
      - Clean and disinfect the room surfaces promptly and with appropriate disinfectant. Use disinfectants on List N of the EPA website for EPA-registered disinfectants that have qualified under EPA’s emerging viral pathogens program for use against SARS-COV-2 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 equipment is cleaned and disinfected according to manufacturers’ instructions using an EPA-registered disinfectant for healthcare setting 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 setting (effective against the organism identified if known) at least daily and when visibly soiled; and
  - Is signage on the use of specific PPE (for staff) posted in appropriate locations in the facility (e.g., outside of a resident’s room, wing, or facility-wide)?
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☐ 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 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

2. Resident Care

☐ If there is sustained community transmission or case(s) of COVID-19 in the facility, is the facility restricting residents (to the extent possible) to their rooms except for medically necessary purposes? If there is a case in the facility, and residents have to leave their room, are they wearing a facemask, 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). If PPE shortage is an issue, facemasks should be limited to residents diagnosed with or having signs/symptoms of respiratory illness or COVID-19.

☐ Has the facility cancelled group outings, group activities, and communal dining?

☐ Has the facility isolated residents with known or suspected COVID-19 in a private room (if available), or taken other actions based on national (e.g., CDC), state, or local public health authority recommendations?

☐ For the resident who develops severe symptoms of illness and requires transfer to a hospital for a higher level of care, did the facility alert emergency medical services and the receiving facility of the resident’s diagnosis (suspected or confirmed COVID-19) and precautions to be taken by transferring and receiving staff as well as place a facemask on the resident during transfer (as supply allows)?

☐ For residents who need to leave the facility for care (e.g. dialysis, etc.), did the facility notify the transportation and receiving health care team of the resident’s suspected or confirmed COVID-19 status?

☐ Does the facility have residents who must leave the facility regularly for medically necessary purposes (e.g., residents receiving hemodialysis and chemotherapy) wear a facemask (if available) whenever they leave their room, including for procedures outside of the facility?

2. Did staff provide appropriate resident care?  ☐ Yes  ☐ No F880

3. IPCP Standards, Policies and Procedures

☐ Did the facility establish a facility-wide IPCP including standards, policies, and procedures that are current and based on national standards for undiagnosed respiratory illness and COVID-19?
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☐ Does the facility’s policies or procedures include when to notify local/state public health officials if there are clusters of respiratory illness or cases of COVID-19 that are identified or suspected?
☐ 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, and procedures that are current and based on national standards for undiagnosed respiratory illness and COVID-19? ☐ Yes ☐ No F880

4. Infection Surveillance

☐ How many residents and staff in the facility have fever, respiratory signs/symptoms, or other signs/symptoms related to COVID-19?
☐ How many residents and staff have been diagnosed with COVID-19 and when was the first case confirmed?
☐ How many residents and staff have been tested for COVID-19? What is the protocol for determining when residents and staff should be tested?
☐ Has the facility established/implemented a surveillance plan, based on a facility assessment, for identifying (i.e., screening), tracking, monitoring and/or reporting of fever (at a minimum, temperature is taken per shift), respiratory illness, and/or other signs/symptoms of COVID-19 and immediately isolate anyone who is symptomatic?
☐ Does the plan include early detection, management of a potentially infectious, symptomatic resident that may require laboratory testing and/or Transmission-Based Precautions/PPE (the plan may include tracking this information in an infectious disease log)?
☐ Does the facility have a process for communicating the diagnosis, treatment, and laboratory test results when transferring a resident to an acute care hospital or other healthcare provider; and obtaining pertinent notes such as discharge summary, lab results, current diagnoses, and infection or multidrug-resistant organism colonization status when residents are transferred back from acute care hospitals?
☐ Can appropriate staff (e.g., nursing and unit managers) identify/describe the communication protocol with local/state public health officials?
☐ 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

5. Visitor Entry

☐ Review for compliance of:
  • Screening processes and criteria (i.e., screening questions and assessment of illness);
  • Restriction criteria; and

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- Signage posted at facility entrances for screening and restrictions as well as a communication plan to alert visitors of new procedures/restrictions.

☐ For those permitted entry, are they instructed 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 offered PPE (e.g., facemask) as supply allows? What is the facility’s process for communicating this information?

☐ For those permitted entry, are they advised to monitor for signs and symptoms of COVID-19 and appropriate actions to take if signs and/or symptoms occur?

5. Did the facility perform appropriate screening, restriction, and education of visitors? ☐ Yes ☐ No F880

6. Education, Monitoring, and Screening of Staff

☐ Is there evidence the facility has provided education to staff on COVID-19 (e.g., symptoms, how it is transmitted, screening criteria, work exclusions)?

☐ How does the facility convey updates on COVID-19 to all staff?

☐ Is the facility screening all staff at the beginning of their shift for fever and signs/symptoms of illness? Is the facility actively taking their temperature and documenting absence of illness (or signs/symptoms of COVID-19 as more information becomes available)?

☐ If staff develop symptoms at work (as stated above), does the facility:
  - Place them in a facemask and have them return home;
  - Inform the facility’s infection preventionist and include information on individuals, equipment, and locations the person came in contact with; and
  - Follow current guidance about returning to work (e.g., local health department, CDC: https://www.cdc.gov/coronavirus/2019-ncov/healthcare-facilities/hcp-return-work.html).

6. Did the facility provide appropriate education, monitoring, and screening of staff? ☐ Yes ☐ No F880

7. Reporting to Residents, Representatives, and Families

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

☐ Did the facility inform 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?
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<tr>
<th>Question</th>
<th>Yes</th>
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<tr>
<td>Did the information include 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., restrictions to visitation or group activities)?</td>
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<tr>
<td>Did the information include personally identifiable information?</td>
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<td>Is the facility providing 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 occur within 72 hours of each other?</td>
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<tr>
<td>Interview a resident and a resident representative or family member to determine whether they are receiving timely notifications.</td>
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7. 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**

8. Reporting to the Centers for Disease Control and Prevention (CDC) – Performed Offsite by CMS. For consideration by CMS Federal Surveyors only.

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<th>Question</th>
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<tr>
<td>Review CDC data files provided to CMS to determine if the facility is reporting at least once a week.</td>
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<tr>
<td>Review data files to determine if all data elements required in the National Healthcare Safety Network (NHSN) COVID-19 Module are completed.</td>
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8. Did the facility report at least once a week to CDC on all of the data elements required in the NHSN COVID-19 Module? **Yes**


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<tr>
<td>Policy development: Does the facility have a policy and procedure for ensuring staffing to meet the needs of the residents when needed during an emergency, such as COVID-19 outbreak?</td>
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<td>Policy implementation: In an emergency, did the facility implement its planned strategy for ensuring staffing to meet the needs of the residents? (N/A if an emergency staff was not needed).</td>
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9. Did the facility develop and implement policies and procedures for staffing strategies during an emergency? **Yes**

05/08/2020
Section 3087 of the 21st Century Cures Act, signed into law in December 2016, added subsection (f) to section 319 of the Public Health Service Act. This new subsection gives the HHS Secretary the authority to waive Paperwork Reduction Act (PRA) (44 USC 3501 et seq.) requirements with respect to voluntary collection of information during a public health emergency (PHE), as declared by the Secretary, or when a disease or disorder is significantly likely to become a public health emergency (SLPHE). Under this new authority, the HHS Secretary may waive PRA requirements for the voluntary collection of information if the Secretary determines that: (1) a PHE exists according to section 319(a) of the PHS Act or determines that a disease or disorder, including a novel and emerging public health threat, is a SLPHE under section 319(f) of the PHS Act; and (2) the PHE/SLPHE, including the specific preparation for and response to it, necessitates a waiver of the PRA requirements. The Office of the Assistant Secretary for Planning and Evaluation (ASPE) has been designated as the office that will coordinate the process for the Secretary to approve or reject each request.

The information collection requirements contained in this information collection request have been submitted and approved under a PRA Waiver granted by the Secretary of Health and Human Services. The waiver can be viewed at https://aspe.hhs.gov/public-health-emergency-declaration-pra-waivers.