Survey Management

The COVID-19 Focused Survey Process

A Compilation of Resources Used by the Survey Team in Conducting the Infection Control COVID-19 Focused Survey Process

Updated May 12, 2020

Provided Courtesy of

TEAMTSI

Coronavirus Disease 2019 (COVID-19)

Focused Survey for Nursing Homes

March 2020

Important Note: These slides and notes are the **actual** documents used by CMS to train the surveyors on **how** to conduct the **COVID-19** focused survey process. To enhance your use of these slides, we have **added** all the data referenced in the slide notes and added bold text to identify critical points.

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Today, I will review the Coronavirus Disease 2019 or "COVID-19 Focused Survey for Nursing Homes".

On March 23, 2020, CMS issued **QSO Memo 20-20-*Prioritization of Survey Activities*** announcing the release of a focused survey that can be used to **identify** and **correct** deficient practices in order to **control** and **prevent** the transmission of the virus. Over the next several slides, I will discuss relevant documents and instructions related to this focused survey.

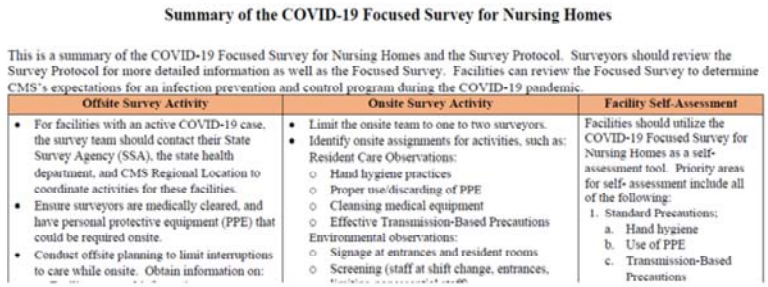
There are **four** documents associated with this training. The **four** documents **include**:

- The Summary Table;
- The Survey Protocol*;*
- The Entrance Conference Form*; and*
- The Survey Tool*.*

You will see each document as we go through the training. The four documents are located on QSEP training site. The four documents available in this training will also be available in a subfolder of the survey resource folder on the CMS DNH website. The resource folder will also include Appendix Z-Emergency Preparedness.

Summary Table of COVID-19 Focused Survey

- COVID-19 Focused Survey Protocol
- COVID-19 Focused Survey/Facility Self-Assessment

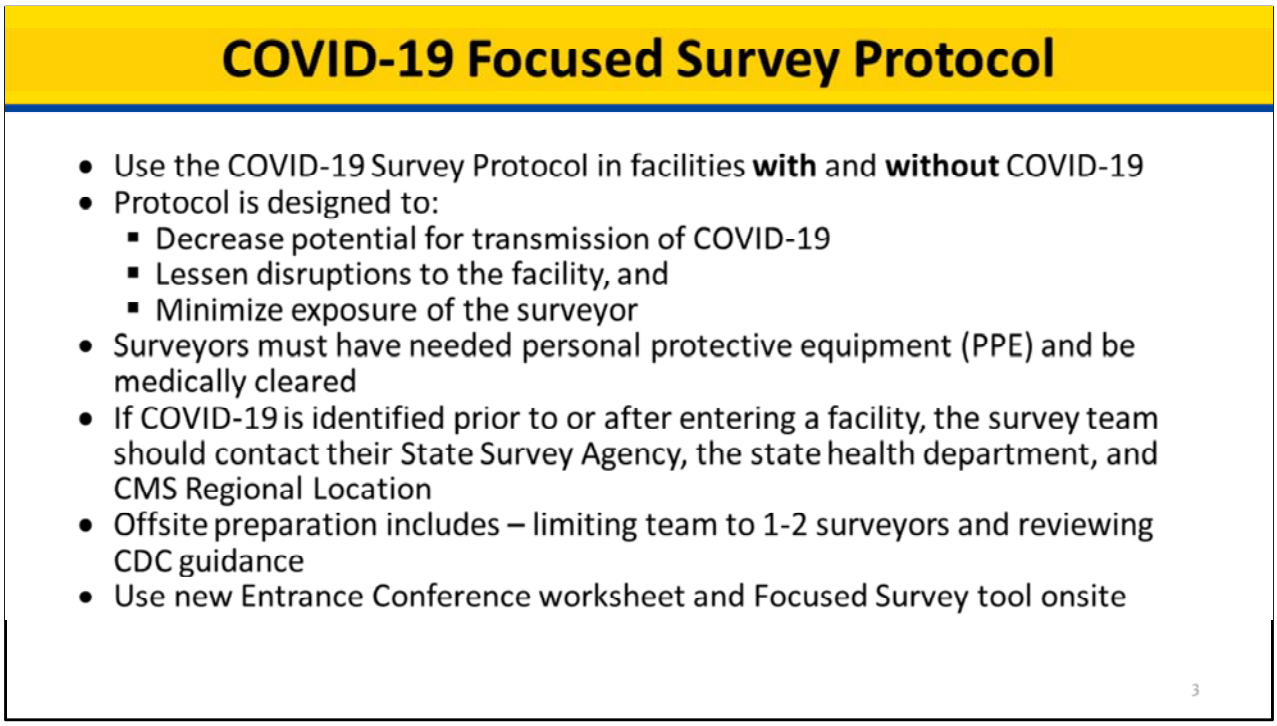


Summary of the COVID-19 Focused Survey for Nursing Homes

This is a summary of the COVID-19 Focused Survey for Nursing Homes and the Survey Protocol. Surveyors should review the Survey Protocol for more detailed information as well as the Focused Survey. Facilities can review the Focused Survey to determine CMS's expectations for an infection prevention and control program during the COVID-19 pandemic.

Offsite Survey Activity	Onsite Survey Activity	Facility Self-Assessment
• For facilities with an active COVID-19 case, the survey team should contact their State Survey Agency (SSA), the state health department, and CMS Regional Location to coordinate activities for these facilities. • Ensure surveyors are medically cleared, and have personal protective equipment (PPE) that could be required onsite. • Conduct offsite planning to limit interruptions to care while onsite. Obtain information on:	• Limit the onsite team to one to two surveyors. • Identify onsite assignments for activities, such as: Resident Care Observations: ○ Hand hygiene practices ○ Proper use/discarding of PPE ○ Cleansing medical equipment ○ Effective Transmission-Based Precautions Environmental observations: ○ Signage at entrances and resident rooms ○ Screening (staff at shift change, entrances,	Facilities should utilize the COVID-19 Focused Survey for Nursing Homes as a self-assessment tool. Priority areas for self- assessment include all of the following: 1. Standard Precautions; a. Hand hygiene b. Use of PPE c. Transmission-Based Precautions

Let's start with the one-page, three-column Summary Table that provides highlights of the COVID-19 Survey Protocol and Focused Survey for Nursing Homes. The Survey Protocol helps surveyors **prioritize** survey activities, with an emphasis on performing as much **offsite** as possible, as well as what activities must be performed **onsite**. This will be discussed further in the next slide. Likewise, detailed information on the COVID-19 Focused Survey will be discussed in a few moments. The Summary Table provides highlights of both of these documents and also emphasizes that facilities should use the Focused Survey, in conjunction with the latest guidance from the Centers for Disease Control and Prevention or CDC, to perform a self-assessment of their ability to prevent the transmission of COVID-19.



Next, we will discuss the Survey Protocol. When used in facilities **with** COVID-19, this Survey Protocol will help surveyors **prioritize** survey activities while **onsite** and **identify** those survey activities which can be accomplished **offsite**. The protocol is designed to **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.

For facilities **without** COVID-19, the use of this Survey Protocol and Focused Survey Tool will help **identify** and **correct** deficient practices in order to prevent the transmission of the virus.

State Survey Agencies should **ensure** surveyors have the personal protective equipment that is needed for the facility being surveyed. Surveyors **should** also be medically cleared, trained in the proper use, removal and disposal of respirators, and medical contraindications to respirator use.

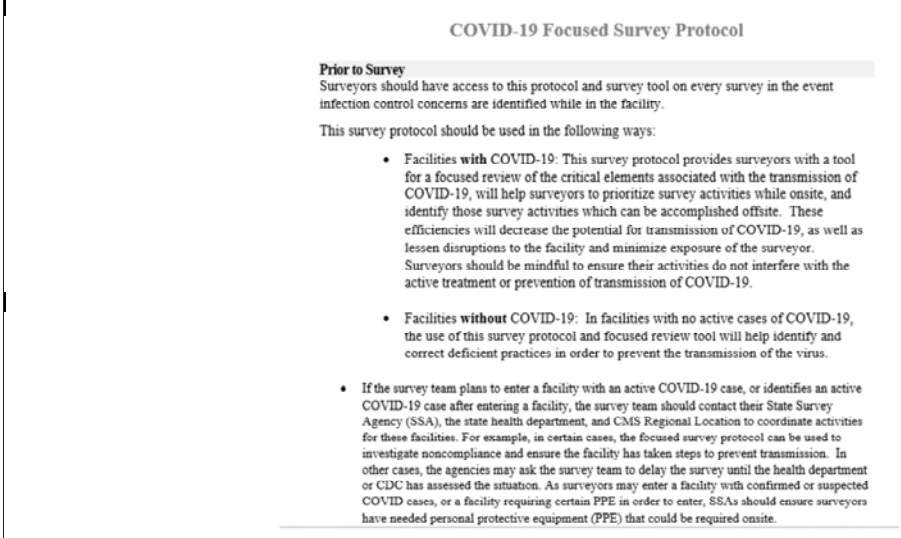
If the survey team plans to enter a facility **with** an active COVID-19 case, or identifies an active COVID-19 case after entering a facility, the survey team should contact their State Survey Agency, the state health department, and CMS Regional Location to coordinate activities for these facilities. In some cases, the Focused Survey Tool can be used to **investigate** noncompliance and ensure the facility has taken steps to **prevent** transmission. In other cases, the health department or CMS Branch may ask the survey team to delay the survey until the health department or CDC has assessed the situation.

Offsite preparation for this survey includes **limiting** the survey team to **one** to **two** surveyors. When creating the shell in ACO, (if you are aware the facility has COVID-19 before entry), make sure to designate the survey as COVID19 under Survey Properties. You can refer to the QTSO Memo 2020-017 for directions on how to create the special survey in ACO. **Offsite** prep also **includes** obtaining information from the facility, the CDC, state and local public health departments, and hospitals, as appropriate. Surveyors should also **review** CDC guidance and plan to do as many survey activities **offsite** as possible. The COVID-19 documents are located in the survey resource folder at the CMS DNH page, the survey resource folder should be on your desktop computers for ease of use. If you determine that COVID-19 is in the facility after entry, once the survey is completed, adjust ACO so that the COVID-19 indicator is checked.

The COVID-19 Focused Survey that is created in ACO will not have a LTCSP survey shell, which means you should document your investigation notes either on an electronic or paper version of a surveyor notes worksheet and/or the COVID-19 Focused Survey tool which I'll discuss in a minute. Ensure all documentation is archived. CMS recommends attaching the documents to the survey shell in ACO.

Surveyors **must** use the *COVID-19 Entrance Conference Worksheet* which we will discuss next.

COVID-19 Focused Survey Protocol Cont.



COVID-19 Focused Survey Protocol

Prior to Survey

Surveyors should have access to this protocol and survey tool on every survey in the event infection control concerns are identified while in the facility.

This survey protocol should be used in the following ways:

- Facilities **with** COVID-19: This survey protocol provides surveyors with a tool for 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.

- Facilities **without** COVID-19: In facilities with no active cases of COVID-19, the use of this survey protocol and focused review tool will help identify and correct deficient practices in order to prevent the transmission of the virus.

- If the survey team plans to enter a facility with an active COVID-19 case, or identifies an active COVID-19 case after entering a facility, the survey team should contact their State Survey Agency (SSA), the state health department, and CMS Regional Location to coordinate activities for these facilities. For example, in certain cases, the focused survey protocol can be used to investigate noncompliance and ensure the facility has taken steps to prevent transmission. In other cases, the agencies may ask the survey team to delay the survey until the health department or CDC has assessed the situation. As surveyors may enter a facility with confirmed or suspected COVID cases, or a facility requiring certain PPE in order to enter, SSAs should ensure surveyors have needed personal protective equipment (PPE) that could be required onsite.

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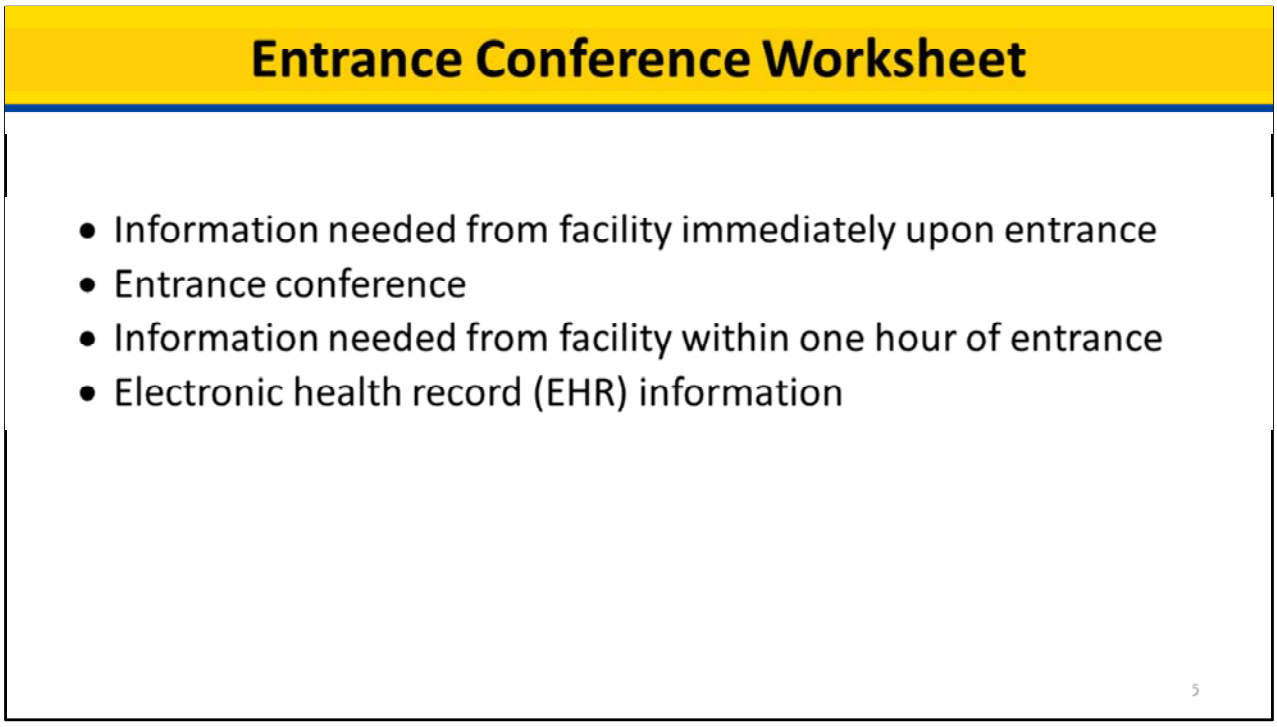


The **Entrance Conference Worksheet** has been **adjusted** for **this** focused survey and it will be used to request information from the facility, some of which is needed from the facility **immediately** upon entrance. This **includes** the census number, an alphabetical list of all residents and room numbers, a list of residents who are confirmed or presumptive positive for COVID-19, and the name of facility staff responsible for the facility's Infection Prevention and Control Program.

A **brief** Entrance Conference should be conducted. Notify the facility administrator of the **limited** nature of the COVID-19 focused survey while also **requesting** items on the Entrance Conference Worksheet. Request that **signs** announcing the survey be posted in high-visibility areas and also ask for a copy of an updated floor plan, **if** changes have been made.

Certain information is needed from the facility within **one hour** of entrance. Ask for the **actual** working schedules for licensed and registered nursing staff for the survey time period, along with a **list** of key personnel, their location and phone numbers.

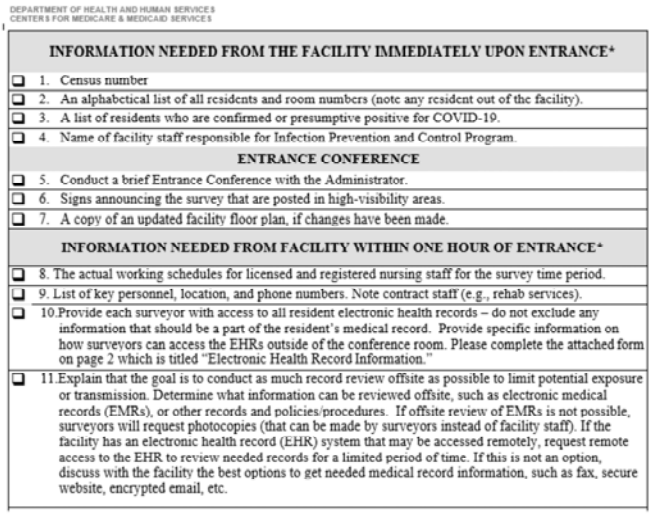
Contract staff, such a rehab services are to be **included** in this list.

In addition, the facility will need to provide each surveyor with **access to all resident electronic health records or EHRs**, including specific information on **how** surveyors can access the EHRs outside of the conference room. The facility is to provide record information that includes: infections, hospitalization, change of condition, medications, and diagnoses. Additionally, the survey team will need the **name** and **contact** information for the facility's IT and backup IT for questions.

During the Entrance Conference, it should be explained that the **goal** is to **conduct** as much record review **offsite** as is possible **and** determine **what** information can be reviewed **offsite**. If offsite review of electronic health records is **not** possible, then surveyors will request **photocopies**. These photocopied can be made by the surveyor if the facility permits, however the surveyor **should** only request those photocopies needed to determine compliance or to support identified noncompliance. If the facility has an electronic health record system that may be accessed **remotely**, request remote access but if this is **not** an option, **discuss** with the facility the best way to get needed health record information.

Lastly, **certain policies and procedures** will be needed from the facility **within one hour of entrance**. Specifically, **ask** for the Infection Prevention and Control Program policies and procedures, to include the Surveillance Plan. **Additionally** ask for the Emergency Preparedness Policy and Procedure, including Emergency Staffing Strategies. A **comprehensive review** of policies should be completed **offsite**.

Entrance Conference Worksheet Cont.



DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

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 presumptive positive for COVID-19.
❑	4. Name of facility staff responsible for Infection Prevention and Control Program.
ENTRANCE CONFERENCE	
❑	5. Conduct a brief Entrance Conference with the Administrator.
❑	6. Signs announcing the survey that are posted in high-visibility areas.
❑	7. A copy of an updated facility floor plan, if changes have been made.
INFORMATION NEEDED FROM FACILITY WITHIN ONE HOUR OF ENTRANCE*	
❑	8. The actual working schedules for licensed and registered nursing staff for the survey time period.
❑	9. List of key personnel, location, and phone numbers. Note contract staff (e.g., rehab services).
❑	10. Provide each surveyor with access to all resident electronic health records – do not exclude any information that should be a part of the resident's medical record. Provide specific information on how surveyors can access the EHRs outside of the conference room. Please complete the attached form on page 2 which is titled "Electronic Health Record Information."
❑	11. Explain that the goal is to conduct as much record review offsite as possible to limit potential exposure or transmission. Determine what information can be reviewed offsite, such as electronic medical records (EMRs), or other records and policies/procedures. If offsite review of EMRs is not possible, surveyors will request photocopies (that can be made by surveyors instead of facility staff). If the facility has an electronic health record (EHR) system that may be accessed remotely, request remote access to the EHR to review needed records for a limited period of time. If this is not an option, discuss with the facility the best options to get needed medical record information, such as fax, secure website, encrypted email, etc.

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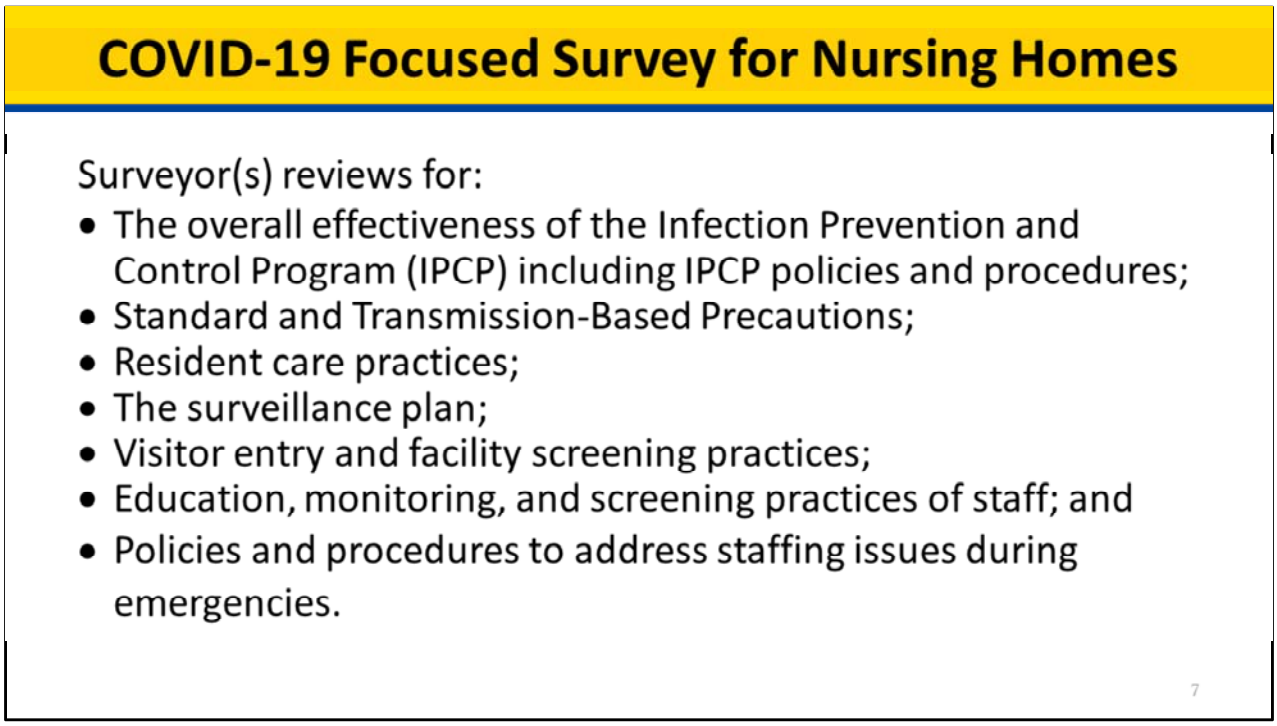
And this is what the Entrance Conference Worksheet looks like.

A copy of the *Entrance Conference Worksheet* is located on **page 19**.



Next, we will discuss the survey tool that will be used by surveyors to assess for compliance at tag **F880**, Infection Prevention and Control (beginning on page 51), as well as Emergency Preparedness tag **E0024** (tag E24) (see page 49), for policies and procedures that address staffing during an emergency. Surveyors must be familiar with QSO memos related to COVID-19 and nursing homes as this will provide context to some of the sections of the survey such as visitor and staff entry and screening practices (See **QSO 20-14** beginning on page 43). CMS understands that information related to clinical presentation of COVID-19 is evolving as well as national guidance on infection prevention and control practices. We also understand that medical supplies such as personal protective equipment or PPE may be in **short supply** and facilities may need to follow national recommendations for **optimization**. (See *CDC Optimization Guidance Documents* beginning on page 79.) Facilities **experiencing shortages** of PPE **should** reach out to their **healthcare coalition** to notify them of the shortage and **surveyors will assess** whether facilities are doing everything in their control to address this issue. In addition to QSO memos, **surveyors** should be familiar with **guidance** from the CDC, related to COVID-19 and healthcare professionals as well as healthcare facilities. Relevant websites are included in the survey tool. In addition, surveyors should be aware of infection prevention and control guidance provided by state or local public health authorities to surveyed facilities.

If surveyors **are citing** for noncompliance related to COVID-19, they *must* include the term "**COVID-19"** in the Deficient Practice Statement or other place determined appropriate on Form CMS-2567.

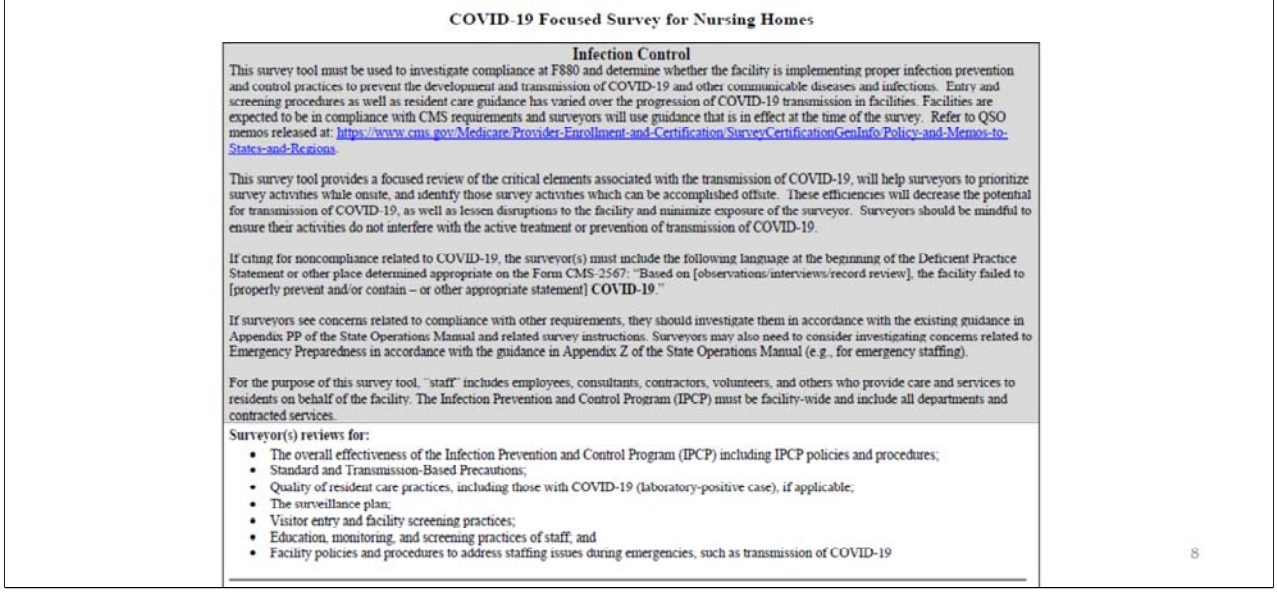
During the survey, surveyors will focus review on the **critical elements** associated with the **transmission** of COVID-19.

These areas include:

- Standard and Transmission-Based Precautions;
- Resident care;
- Infection prevention and control standards, policies and procedures;
- Infection surveillance;
- Visitor entry;
- Education, monitoring, and screening of staff; and
- Staffing in emergencies.

In **addition** to use by surveyors, a **facility** can use the survey tool as a **self-assessment** of infection prevention and control practices to **prevent** the development and transmission of COVD-19.

COVID-19 Focused Survey for Nursing Homes Cont.



COVID-19 Focused Survey for Nursing Homes

Infection Control

This survey tool must be used to investigate compliance at F880 and 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.

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.

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;
- Visitor entry and facility screening practices;
- Education, monitoring, and screening practices of staff; and
- Facility policies and procedures to address staffing issues during emergencies, such as transmission of COVID-19

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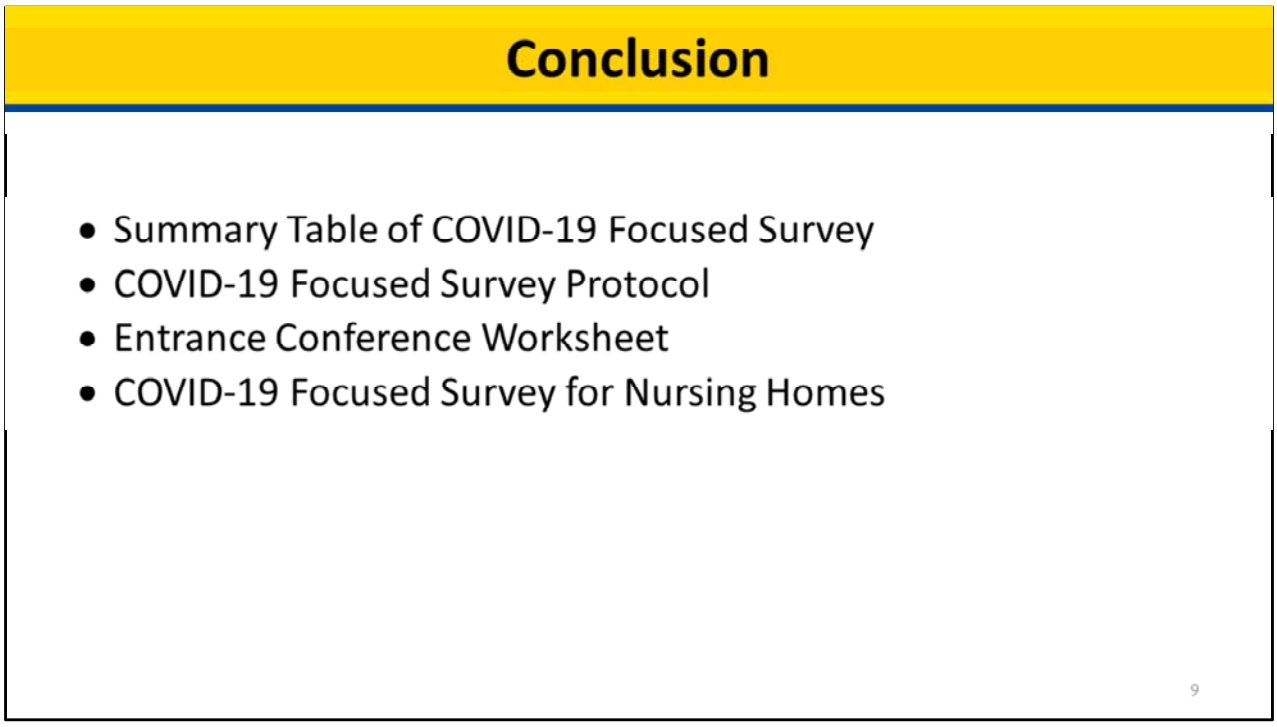
And this is what the COVID-19 Focused Survey for Nursing Homes looks like.

A copy of this *Focused Survey Tool* is located on **page 21****.**



Today we have reviewed the COVID-19 Focused Survey for Nursing Homes, a survey that can be used to identify and correct deficient practices in order to control and prevent the transmission of the virus.

Documents and instructions related to this focused survey covered included:

The Summary Table which includes relevant information from the Survey Protocol and Focused Survey (see **page 13**);

The COVID-19 Focused Survey Protocol which is to be used in facilities **with** and **without** COVID-19 (see **page 15**);

The Entrance Conference Worksheet used to request information from the facility (see **page 19**); and

The COVID-19 Focused Survey for Nursing Homes which is the survey tool that will be used by surveyors to assess for compliance at tags **F880** and **E0024** related to infection prevention and control as well as staffing during an emergency. In addition, it can also be used by facilities for self-assessment. (See **pages 21**, **49**, and **51**).

Used together, these documents will help to create an effective method for the investigation of COVID-19.

Thank you.

Summary of the COVID-19 Focused Survey for Nursing Homes

This is a summary of the COVID-19 Focused Survey for Nursing Homes and the Survey Protocol. Surveyors should review the Survey Protocol for more detailed information as well as the Focused Survey. Facilities can review the Focused Survey to determine CMS's expectations for an infection prevention and control program during the COVID-19 pandemic.

Offsite Survey Activity	Onsite Survey Activity	Facility Self-Assessment
• For facilities with an active COVID-19 case, the survey team should contact their State Survey Agency (SSA), the state health department, and CMS Regional Location to coordinate activities for these facilities. • Ensure surveyors are medically cleared, and have personal protective equipment (PPE) that could be required onsite. • Conduct offsite planning to limit interruptions to care while onsite. Obtain information on: o Facility-reported information; o CDC, state/local public health reports; o Available hospital information regarding patients transferred to the hospital; and/or o Complaint allegations. • Identify survey activities that will be conducted offsite, such as: o Medical record review o Telephonic interviews, such as: ▪ Surveillance policies ▪ First onset of symptoms ▪ Communication to facility leaders and health officials ▪ Resident, representatives and families (if feasible, otherwise conduct onsite) o Policy/Procedure Review ▪ Infect. Control/Prev. Plan ▪ Emerg. Prep. Plan, including contingency strategies (e.g., staffing) o Review communication(s) to residents, representatives and families (e.g., newsletter, etc) • Conduct survey exit discussion telephonically and draft the CMS-2567 offsite.	• Limit the onsite team to one to two surveyors. • Identify and prioritize onsite assignments for activities, such as: Resident Care Observations: o Hand hygiene practices o Proper use/discarding of PPE o Cleansing medical equipment o Effective Transmission-Based Precautions Environmental observations: o Signage at entrances and resident rooms o Screening (staff at shift change, entrances, limiting nonessential staff) o Hand hygiene stations Interviews with relevant staff: o Policy/Procedure knowledge o Surveillance for sign/symptoms o Notifying local health officials o Information provided to residents, their representatives, and families concerning COVID-19 activity in the facility • Adhere to all CDC guidance for infection prevention and control related to COVID-19. • Provide the facility with the COVID-19 Entrance Conference worksheet and utilize this to request necessary information. • Identify and arrange for interviews that can be done telephonically. • Be alert of other immediate jeopardy (IJ) situations that may be present, and investigate appropriately.	Facilities should utilize the COVID-19 Focused Survey for Nursing Homes as a self- assessment tool. Priority areas for self- assessment include all of the following: 1. Standard Precautions; a. Hand hygiene b. Use of PPE c. Transmission-Based Precautions 2. Resident care (including resident placement); 3. Infection prevention and control standards, policies and procedures; 4. Infection surveillance; 5. Visitor entry (i.e., screening, restriction, and education); 6. Education, monitoring, and screening of staff; 7. Reporting to residents, representatives, and families on COVID-19 activity in the facility and mitigating actions taken; 8. Reporting to CDC's National Healthcare Safety Network COVID-19 Module; and 9. Emergency preparedness – staffing in emergencies

COVID-19 Focused Survey Protocol

Prior to Survey

Surveyors should have access to this protocol and survey tool on every survey in the event infection control concerns are identified while in the facility.

- This survey protocol should be used in the following ways:
  - Facilities **with** COVID-19: This survey protocol provides surveyors with a tool for 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.
  - Facilities **without** COVID-19: In facilities with no active cases of COVID-19, the use of this survey protocol and focused review tool will help identify and correct deficient practices in order to prevent the transmission of the virus.
  - Data used to determine facility compliance at F884 is only available to the CMS locations. F884 will only be cited by CMS Federal Surveyors.
- If the survey team plans to enter a facility with an active COVID-19 case, or identifies an active COVID-19 case after entering a facility, the survey team should contact their State Survey Agency (SSA), the state health department, and CMS Regional Location to coordinate activities for these facilities. For example, in certain cases, the focused survey protocol can be used to investigate noncompliance and ensure the facility has taken steps to prevent transmission. In other cases, the agencies may ask the survey team to delay the survey until the health department or CDC has assessed the situation. As surveyors may enter a facility with confirmed or suspected COVID cases, or a facility requiring certain PPE in order to enter, SSAs should ensure surveyors have needed personal protective equipment (PPE) that could be required onsite.
- Refer to latest CDC guidance on use of Personal Protective Equipment at: https://www.cdc.gov/coronavirus/2019-ncov/infection-control/control-recommendations.html
- Ensure surveyors are:
  - Medically cleared; and
  - Trained in the proper use of respirators, safe removal and disposal, and medical contraindications to respirator use.

Offsite Preparation

- 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
    - The extent (if needed) should be marked as E=abbreviated survey
  - When conducting a Focused COVID-19 survey the SA will code the Type of Survey as U=COVID-19 (M will automatically be marked)
    - The extent (if needed) should be marked as E=abbreviated survey

  There should be no offsite surveys coded in ACO.
- Limit the team to one or two surveyors.
- Conduct offsite planning based on available information from:
  - Facility-reported information;
  - CDC, state/local public health information if available (in some cases CDC or public health will have gone onsite prior to the SA/CMS);

  - Available hospital information regarding patients transferred to the hospital; and/or
  - Complaint allegations.
- Identify surveyors who are remaining offsite to receive information from the surveyors or facility staff while onsite. List key survey activities that will be conducted onsite and offsite, with a plan for doing as much offsite as possible. For example:

  For onsite activities:
  - Prioritize observations to key areas and activities related to infection control;
  - Identify interviews that need to be conducted onsite, and make arrangements for those that can be conducted offsite telephonically; and
  - Identify the records that need to be reviewed onsite, and those that can be sent for offsite review.

  For offsite activities:
  - Medical record reviews;
  - Telephonic interviews, such as:
    - Surveillance policies
    - First onset of symptoms
    - Communication to facility leaders and health officials
    - Resident, representatives and families (if feasible, otherwise conduct onsite);
  - Facility Policy/Procedure Reviews (e.g., Infection Control and Prevention Program, Emergency Preparedness Plan); and
  - Review communication(s) to residents, representatives and families (e.g., listserv, newsletter, etc.).
- Surveyors should add the following to their desktop:
  - COVID-19 Focused Survey Protocol
  - COVID-19 Focused Survey
  - Surveyor Resources folder
- Refer to and review latest CDC guidance on use of personal protective equipment and Standard and Transmission-Based Precautions based on the CDC Interim Infection Prevention and Control Recommendations for Patients with Suspected or Confirmed Coronavirus Disease 2019 (COVID-19) in Healthcare Settings at the following link: https://www.cdc.gov/coronavirus/2019- ncov/infection-control/control-recommendations.html

Entrance Conference

- Notify the Facility administrator of the limited nature of the COVID-19 focused survey:
  - Prioritize observations on day one; and
  - Complete remaining observations and interviews on day two.
- Follow the COVID-19 Entrance Conference worksheet to request information.

COVID-19 Focused Survey Protocol

Onsite Survey Activities

- Adhere to Standard and Transmission-Based Precautions and refer to the CDC Interim Infection Prevention and Control Recommendations for Patients with Suspected or Confirmed Coronavirus Disease 2019 (COVID-19) in Healthcare Settings.
- Refer to the COVID-19 focused survey to guide your investigation and make compliance determinations.
- Identify onsite assignments for activities, such as:
  Resident Care Observations:
  - Hand hygiene practices
  - Proper use/discarding of PPE
  - Cleansing medical equipment
  - Effective Transmission-Based Precautions

  Environmental observations:
  - Signage at entrances and resident rooms
  - Screening (staff at shift change, entrances, limiting nonessential staff)
  - Hand hygiene stations

  Interviews with relevant staff:
  - Policy/Procedure knowledge
  - Surveillance for sign/symptoms
  - Notifying local health officials
  - Information provided to residents, their representatives, and families concerning COVID-19 activity in the facility
  - NOTE: Identify and arrange for interviews that can be done telephonically offsite.
- Document your investigation on the electronic version of the COVID-19 focused survey and/or electronic or paper-based surveyor notes worksheets.
- While the primary focus is COVID-19, you should investigate any other areas of potential noncompliance where there is a likelihood of immediate jeopardy. 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.
- Determine what information can be reviewed offsite (e.g., electronic medical records, EP plan for staffing and other policies or photocopies). NOTE: Surveyors should limit photocopies to only those records necessary for confirming noncompliance or to support findings of deficient practice.

Concluding the Survey

- Conduct any survey exit discussion with the facility by telephone (unless requested in person by facility).
- Draft the CMS-2567 offsite. 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."

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. Conduct a brief Entrance Conference with the Administrator.
❑ 6. Signs announcing the survey that are posted in high-visibility areas.
❑ 7. A copy of an updated facility floor plan, if changes have been made.
❑ 8. The actual working schedules for licensed and registered nursing staff for the survey time period.
❑ 9. 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.
❑ 10. Provide each surveyor with access to all resident electronic health records – do not exclude any information that should be a part of the resident's medical record. Provide specific information on how surveyors can access the EHRs outside of the conference room. Please complete the attached form on page 2 which is titled "Electronic Health Record Information."
❑ 11. Explain that the goal is to conduct as much record review offsite as possible to limit potential exposure or transmission. Determine what information can be reviewed offsite, such as electronic medical records (EMRs), or other records and policies/procedures. If offsite review of EMRs is not possible, surveyors will request photocopies (that can be made by surveyors instead of facility staff). If the facility has an electronic health record (EHR) system that may be accessed remotely, request remote access to the EHR to review needed records for a limited period of time. If this is not an option, discuss with the facility the best options to get needed medical record information, such as fax, secure website, encrypted email, etc.
❑ 12. Facility Policies and Procedures: • Infection Prevention and Control Program Policies and Procedures, to include the Surveillance Plan. • Emergency Preparedness Policy and Procedure to include Emergency Staffing Strategies **NOTE**– A comprehensive review of policies should be completed offsite.
❑ 13. The facility's mechanism(s) used to inform residents, their representatives, and families of confirmed or suspected COVID-19 activity 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 updates.

*__NOTE__: 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.

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	

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: _____

COVID-19 Focused Survey for Nursing Homes

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.

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;

- 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.

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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), 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 and healthcare facilities is located at: 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. 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?

- ☐ If there are shortages of ABHR, are staff performing hand hygiene using soap and water instead?
- ☐ Are staff washing hands with soap and water when their hands are visibly soiled (e.g., blood, body fluids)?
- ☐ Do 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, 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, is resident hand hygiene performed after toileting and before meals?
- ☐ 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):

- ☐ Determine if staff appropriately use 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;
  - Gloves are removed after contact with blood or body fluids, mucous membranes, or non-intact skin;
  - Gloves are changed and hand hygiene is performed before moving from a contaminated body site to a clean body site during resident care; and
  - An isolation gown is worn for direct resident contact if the resident has uncontained secretions or excretions.
- ☐ 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?
- ☐ 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?
- ☐ Interview appropriate staff to determine if PPE is available, accessible and used by staff.
  - 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?
  - Do staff know how to obtain PPE supplies before providing care?
  - Do they know who to contact for replacement supplies?

COVID-19 Focused Survey for Nursing Homes

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-levelrespirator 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)?

☐ 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**

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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**

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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?

☐ 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

- Signage posted at facility entrances for screening and restrictions as well as a communication plan to alert visitors ofnew 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?

☐ 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)?

☐ Did the information include personally identifiable information?

☐ 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?

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

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 ☐ **No F885**

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

☐ Review CDC data files provided to CMS to determine if the facility is reporting at least once a week.

☐ Review data files to determine if all data elements required in the National Healthcare Safety Network (NHSN) COVID-19 Module are completed.

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 ☐ **No F884**

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9. Emergency Preparedness – Staffing in Emergencies

☐ 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?

☐ 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).

9. Did the facility develop and implement policies and procedures for staffing strategies during an emergency?
☐ Yes ☐ **No E0024** ☐ N/A

COVID-19 Focused Survey for Nursing Homes

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.

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-20-29-NH

DATE: **May 6, 2020**

TO: State Survey Agency Directors

FROM: Director
Quality, Safety & Oversight Group

SUBJECT: Interim Final Rule Updating Requirements for Notification of Confirmed and Suspected COVID-19 Cases Among Residents and Staff in Nursing Homes

Memorandum Summary

- CMS is committed to taking critical steps to ensure America's healthcare facilities are prepared to respond to the Coronavirus Disease 2019 (COVID-19) Public Health Emergency (PHE).
- On May 8, 2020, CMS will publish an interim final rule with comment period.
- **COVID-19 Reporting Requirements**: CMS is requiring nursing homes to report COVID-19 facility data to the Centers for Disease Control and Prevention (CDC) and to residents, their representatives, and families of residents in facilities.
- **Enforcement:** Failure to report in accordance with 42 CFR §483.80(g) can result in an enforcement action.
- **Updated Survey Tools:** CMS has updated the COVID-19 Focused Survey for Nursing Homes, Entrance Conference Worksheet, COVID-19 Focused Survey Protocol, and Summary of the COVID-19 Focused Survey for Nursing Homes to reflect COVID-19 reporting requirements.
- **COVID-19 Tags**: F884 and F885.
- **Transparency:** CMS will begin posting data from the CDC National Healthcare Safety Network (NHSN) for viewing by facilities, stakeholders, or the general public. The COVID-19 public use file will be available on https://data.cms.gov/.

Background

On April 19, 2020, CMS released memo QSO-20-26, "Upcoming Requirements for Notification of Confirmed COVID-19 (or COVID-19 Persons under Investigation) Among Residents and Staff in Nursing Homes," summarizing new facility reporting requirements that would soon be released through rulemaking.

On May 8, 2020, CMS will publish an interim final rule with comment period, titled "Medicare and Medicaid Programs, Basic Health Program, and Exchanges; Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency and Delay of

Certain Reporting Requirements for the Skilled Nursing Facility Quality Reporting Program". The unpublished rule is available for public inspection at the Federal Register website (Agency Docket: CMS-5531-IFC and Regulation ID Number (RIN): 0938-AU32).

Prior to the COVID-19 PHE and this interim final rule, regulations at 42 CFR §483.80(a)(2)(ii), already required LTC facilities (i.e., skilled nursing facilities and/or nursing facilities) to have written standards, policies and procedures regarding infection control, to include when and to whom possible incidents of communicable disease or infections should be reported, such as to local/state health authorities. In an effort to support surveillance of COVID-19 cases and increase transparency for residents, their representatives, and families, we have added to the infection control requirements provisions to establish reporting for confirmed or suspected COVID-19 cases at new §483.80(g), as follows:

§ 483.80 Infection control.

(g) *COVID-19 Reporting*. The facility must—

(1) Electronically report information about COVID-19 in a standardized format specified by the Secretary. This report must include but is not limited to--

(i) Suspected and confirmed COVID-19 infections among residents and staff, including residents previously treated for COVID-19;
(ii) Total deaths and COVID-19 deaths among residents and staff;
(iii) Personal protective equipment and hand hygiene supplies in the facility;
(iv) Ventilator capacity and supplies in the facility;
(v) Resident beds and census;
(vi) Access to COVID-19 testing while the resident is in the facility;
(vii) Staffing shortages; and
(viii) Other information specified by the Secretary.

(2) Provide the information specified in paragraph (g)(1) of this section at a frequency specified by the Secretary, but no less than weekly to the Centers for Disease Control and Prevention's National Healthcare Safety Network. This information will be posted publicly by CMS to support protecting the health and safety of residents, personnel, and the general public.

(3) Inform residents, their representatives, and families of those residing in facilities by 5 p.m. the next calendar day following the occurrence of either a single confirmed infection of COVID-19, or three or more residents or staff with new-onset of respiratory symptoms occurring within 72 hours of each other. This information must—

(i) Not include personally identifiable information;
(ii) Include information on mitigating actions implemented to prevent or reduce the risk of transmission, including if normal operations of the facility will be altered; and
(iii) Include any cumulative updates for residents, their representatives, and families at least weekly or by 5 p.m. the next calendar day following the subsequent occurrence of either: each time a confirmed infection of COVID-19 is identified, or whenever three or more residents or staff with new onset of respiratory symptoms occur within 72 hours of each other.

We understand that state and local health departments may currently require nursing homes to report certain COVID-19 related information to them. A key difference between the state/local reporting and this new national reporting requirement is that reporting to state/local health departments allows them to understand the status of their local environment and intervene (e.g., direct staffing and supplies), whereas this national requirement provides standardized information to assist with national surveillance on the status of COVID-19 in all nursing homes. State and local health departments are also able to submit the required data on behalf of a nursing homes, although this does not relieve facilities of their accountability to report in accordance with the regulation.

Reporting COVID-19 Information to CDC's NHSN

The NHSN Long-Term Care Facility COVID-19 Module is available. Facilities should immediately gain access to the NHSN system and visit the home page for important information, including how to register: https://www.cdc.gov/nhsn/. The following provides an overview of the registration process:

Step 1 – Prepare your computer to interact with NHSN

You may need to change your email and internet security settings to receive communications from NHSN during the enrollment process

Step 2A – Register Facility with NHSN

The person who will serve as the NHSN Facility Administrator must access and read the NHSN Facility/Group Administrator Rules of Behavior from https://nhsn.cdc.gov/RegistrationForm/index

Step 2B – Register with SAMS (Security Access Management System)

After CDC receives your completed registration, you will receive an ***Invitation to Register with SAMS*** via email

Step 3 – Complete NHSN Enrollment

On the SAMS homepage, click the link to the NHSN labeled **NHSN Enrollment** and Complete Facility Contact Information

Step 4 – Electronically Accept the NHSN Agreement to Participate and Consent

After successfully completing enrollment, the NHSN Facility Administrator and Component Primary Contact (may be the same person) will receive an NHSN email with instructions on how to electronically accept the *NHSN Agreement to Participate and Consent*.

Please note: It is critical for facilities to ensure their CMS Certification Number (CCN) is entered correctly into the NHSN system, so CMS can confirm the facility has met the reporting requirement.

For NHSN questions, please email: NHSN@cdc.gov and add "LTCF" in the subject header.

Facilities must submit their first set of data by 11:59 p.m. Sunday, May 17, 2020. To be compliant with the new requirement, 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. CMS is not prescribing which day of the week the data must be submitted, although reporting should remain consistent with data being submitted on the same day(s) each week. The collection period should also remain consistent (e.g., Monday through Sunday). Each Monday,

CMS will review the data submitted to assess if each facility submitted data at least once in the previous seven days. The data pulled each Monday will also be used to update the data that is publicly reported.

Updates to the COVID-19 Focused Survey for Nursing Homes

CMS has updated the "COVID-19 Focused Survey for Nursing Homes," "Entrance Conference Worksheet," "COVID-19 Focused Survey Protocol," and "Summary of the COVID-19 Focused Survey for Nursing Homes" to include an updated assessment of the new requirements for facilities to report to the NHSN and to residents, their representatives, and their families. These updated forms are posted to the Survey Resources folder in the COVID-19 Focused Survey sub-folder on the CMS Nursing Homes website. Surveyors should begin using these revised documents immediately, and facilities should also begin using the revised "COVID-19 Focused Survey for Nursing Homes" to perform their self-assessment. The documents include the following new deficiency tags for citing noncompliance with the new requirements:

F884: COVID-19 Reporting to CDC as required at §483.80(g)(1)-(2)

Review for F884 will be conducted offsite by CMS Federal surveyors (state surveyors should not cite this F-tag). Following an initial reporting grace period granted to facilities, CMS will receive the CDC NHSN COVID-19 reported data and review for timely and complete reporting of all data elements. Facilities identified as not reporting will receive a deficiency citation at F884 on the CMS-2567 with a scope and severity level at an F (no actual harm with a potential for more than minimal harm that is not an Immediate Jeopardy [IJ] and that is widespread; this is a systemic failure with the potential to affect a large portion or all of the residents or employees), and be subject to an enforcement remedy imposed as described below.

F885: COVID-19 Reporting to Residents, their Representatives, and Families as required at §483.80(g)(3)(i)-(iii)

Review for F885 is included in the "COVID-19 Focused Survey Protocol" and will occur onsite by State and/or Federal surveyors. If the survey finds noncompliance with this requirement, a deficiency citation at this tag will be recorded on the CMS-2567 and enforcement actions will follow the memo QSO-20-20-All. We note that there are a variety of ways that facilities can meet this requirement, such as informing families and representatives through email listservs, website postings, paper notification, and/or recorded telephone messages. We do not expect facilities to make individual telephone calls to each resident's family or responsible party to inform them that a resident in the facility has laboratory-confirmed COVID-19. However, we expect facilities to take reasonable efforts to make it easy for residents, their representatives, and families to obtain the information facilities are required to provide.

In addition, when the State Survey Agency is planning to conduct these surveys, the COVID-19 Focused Survey should be coded in the Automated Survey Process Environment (ASPEN) under "Survey Type" as U=COVID-19. If the survey is taking place with an IJ complaint investigation, the survey should be coded in ASPEN under "Survey Type" as A=complaint and U=COVID-19. This will help ensure consistent, accurate reporting.

Enforcement for F884

A determination that a facility failed to comply with the requirement to report COVID-19 related information to the CDC pursuant to §483.80(g)(1)-(2) (tag F884) will result in an enforcement action. These regulations require a minimum of weekly reporting, and noncompliance with this requirement will receive a deficiency citation and result in a civil money penalty (CMP) imposition.

CMS will provide facilities with an initial two-week grace period to begin reporting cases in the NHSN system (which ends at 11:59 p.m. on May 24, 2020). Facilities that fail to begin reporting after the third week (by 11:59 p.m. on May 31st) will receive a warning letter reminding them to begin reporting the required information to CDC. For facilities that have not started reporting in the NHSN system by 11:59 p.m. on June 7th, ending the fourth week of reporting, CMS will impose a per day (PD) CMP of $1,000 for one day for the failure to report that week. For each subsequent week that the facility fails to submit the required report, the noncompliance will result in an additional one-day PD CMP imposed at an amount increased by $500. For example, if a facility fails to report in week four (following the two week grace period and receipt of the warning letter), it will be imposed a $1,000 one-day PD CMP for that week. If it fails to report again in week five, the noncompliance will lead to the imposition of another one-day PD CMP in the amount of $1,500 for that failure to report (for a CMP total of $2,500). In this example, if the facility complies with the reporting requirements and submits the required report in week six, but then subsequently fails to report as required in week seven, a one-day PD CMP amount of $2,000 will be imposed (which is $500 more than the last imposed PD CMP amount) for a total of $4,500 imposed CMPs.

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

Posting Facility-Level COVID-19 Data

Reporting COVID-19 data supports CMS's responsibility to protect and ensure the health and safety of residents and is necessary to ensure the appropriate tracking, response, and mitigation of the spread and impact of COVID-19 on our most vulnerable citizens, personnel who care for them, and the general public. The information provided may be used to inform residents, families, and communities of the status of COVID-19 infections in their area. We believe that this action strengthens CMS's response to the COVID-19 pandemic, and reaffirms our commitment to transparency and protecting the health and safety of nursing home residents. CMS anticipates publicly posting CDC's NHSN data (including facility names, number of COVID-19 suspected and confirmed cases, deaths, and other data as determined appropriate) weekly on https://data.cms.gov/ by the end of May.

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

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

/s/
David R. Wright

Attachments:
COVID-19 Focused Survey for Nursing Homes
Long-term Care Facility Notification Frequently Asked Questions

cc: Survey & Operations Group (SOG) Management

Long-term Care (LTC) Facility Requirements for Notification of Confirmed and Suspected Coronavirus Disease 2019 (COVID-19) Cases Among Residents and Staff: Frequently Asked Questions (FAQs)

May 6, 2020

The purpose of this FAQ is to provide additional information on the updated reporting requirements for LTC facilities at 42 CFR §483.80(g), which will be published on May 8, 2020, in an interim final rule with comment period. The unpublished rule is available for public inspection at the Federal Register website. The new reporting requirements specify that facilities must report COVID-19 data to the Centers for Disease Control and Prevention (CDC), and to all residents, their representatives, and families.

Note: The terms "nursing home" and "long-term care facility" are used interchangeably in this document, and both refer to a facility that is certified to provide Medicare skilled nursing facility (SNF) services, and/or Medicaid nursing facility (NF) services.

Reporting to CDC's National Healthcare Safety Network (NHSN)

1. **Q: What actions are the Centers for Medicare & Medicaid Services (CMS) taking by revising the Requirements for Participation for LTC facilities?**

   A: CMS is requiring facilities to report COVID-19 facility data on residents and staff to CDC and to residents, their representatives, and families of residents in facilities. CMS has updated the COVID-19 Focused Survey for Nursing Homes, Entrance Conference Worksheet, COVID-19 Focused Survey Protocol, and Summary of the COVID-19 Focused Survey for Nursing Homes to reflect these COVID-19 reporting requirements and created two new deficiency tags (F884 and F885). Facilities must submit data through CDC NHSN Long-Term Care Facility COVID-19 Module at least once a week. CMS will begin posting aggregated data from CDC NHSN to https://data.cms.gov/ by the end of May for viewing by LTC facilities, stakeholders, and the general public.

2. **Q: How will CMS and CDC use this information?**

   A: CDC will use information collected through the new NHSN Long-Term Care Facility COVID-19 Module to strengthen COVID-19 surveillance locally and nationally. Nursing home reporting to CDC is a critical component of national COVID-19 surveillance efforts and is consistent with White House guidelines, Opening Up America Again. CMS will use the information to ensure nursing homes are following all requirements for participation, specifically those focused on infection control. CMS may also use the information to determine survey prioritization.

   Facility-level data collected through NHSN as part of the Long-Term Care Facility COVID-19 Module will also be available to a broader set of federal, state, and local agencies. Specifically, COVID-19 data at the state, county, territory, and facility level submitted to

NHSN will continue to be used for public health emergency response activities by CDC's emergency COVID-19 response, by the U.S. Department of Health and Human Services' (HHS') COVID-19 tracking system maintained in the Office of the Assistant Secretary of Preparedness and Response (ASPR) as part of the National Response Coordination Center at the Federal Emergency Management Agency (FEMA), and by the White House Coronavirus Task Force.[1]

3. **Q: If states are already collecting COVID-19 information from nursing homes, why is CMS requiring it to be reported to CDC?**

   A: The new reporting tool complements existing, state level reporting efforts. Due to variation in state and local reporting requirements for COVID-19, NHSN's Long-Term Care Facility Module aims to provide a standardized, national lens on the experience of long-term care facilities to support and inform the public health response at the local, state, and federal levels.

   The NHSN Module is not intended as a replacement for state and local public health reporting requirements, and nursing homes are required to continue to report COVID-19 data to state and local health departments in accordance with state and local requirements via existing mechanisms. In some public health jurisdictions, the data that nursing homes report to the new module may supplement the data that they already report to state and local public health authorities. NHSN uses existing functionality (NHSN's Group Function) to make COVID-19 data immediately accessible to state and local health departments for surveillance and public health response decisions. State and local health departments are also able to submit the required data on behalf of nursing homes, although this does not relieve facilities of their accountability to report in accordance with the regulation.

4. **Q. Will CDC offer technical assistance/user support to facilities to help them begin reporting data?**

   A: Yes, CDC will offer users training and technical support through a variety of mechanisms, including the following:
   - Detailed instructions and copies of the reporting forms, which will be posted on the NHSN Long-Term Care Facility COVID-19 Module webpage
   - Web-based trainings, which will be recorded and similarly posted to the NHSN Long-Term Care Facility webpage
   - Live office hours, which will offer participants an opportunity to ask detailed questions and receive answers from CDC subject matter experts
   - E-mail updates on new functions or resources available through NHSN
   - Response to questions submitted to: NHSN@cdc.gov

[1] Members of the White House Coronavirus Task Force are listed here:
https://www.whitehouse.gov/briefings-statements/vice-president-pence-secretary-azar-add-key-administration-officials-coronavirus-task-force-2/
https://www.whitehouse.gov/briefings-statements/statement-press-secretary-regarding-presidents-coronavirus-task-force/

5. **Q: Can state health departments report COVID-19 data to NHSN on a nursing home's behalf?**

   A: Yes. Each nursing home must first enroll in NHSN to submit its data. Once enrolled, state and local health departments may submit data on behalf of a nursing home. Additionally, data can be batched and submitted as a single file for multiple facilities. We note this does not relieve facilities of their accountability to report in accordance with the regulation. CDC and CMS will work with state health departments and other partners to enable batch data reporting by state health departments or other entities (such as state hospital associations, corporate headquarters and IT vendors). CDC and CMS will work with state health departments and other partners to communicate and help them utilize this option.

6. **Q: How will nursing homes know their data was received?**

   A: Nursing homes will be able to view their data in the NHSN application upon data submission. NHSN's analysis and reporting features allows nursing homes to quickly verify that their data have been received.

7. **Q: Will CMS cite facilities for noncompliance at F884 and penalize any nursing home with a case of COVID-19 reported to CDC's NHSN?**

   A: The presence of COVID-19 in a nursing home does not automatically mean that noncompliance exists. CMS will not use the data to penalize nursing homes for the presence of COVID-19. Until further notice, surveys will continue to be conducted in accordance with CMS memorandum QSO-20-20-All, which includes surveying for Immediate Jeopardy allegations and Focused Infection Control surveys. CMS has updated the COVID-19 Focused Survey for Nursing Homes with processes related to the new reporting requirements. Surveyors will only cite noncompliance with federal requirements for infection control and prevention based on their investigations, and not based on the COVID-19 information reported through the NHSN system.

   We note, however, that facilities will be cited and subject to enforcement action for not submitting complete data through the NHSN system in accordance with the new reporting requirements.

   CMS will provide facilities with an initial two-week grace period to begin reporting cases in the NHSN system (which ends at 11:59 p.m. on May 24, 2020). Facilities that fail to begin reporting after the third week (by 11:59 p.m. on May 31st) will receive a warning letter reminding them to begin reporting the required information to CDC. For facilities that have not started reporting in the NHSN system by 11:59 p.m. on June 7th, ending the fourth week of reporting, CMS will impose a per day (PD) civil money penalty (CMP) of $1,000 for one day for the failure to report that week. For each subsequent week that the facility fails to submit the required report, the noncompliance will result in an additional one-day PD CMP imposed at an amount increased by $500. For example, if a facility fails to report in week four (following the two week grace period and receipt of the warning letter), it will be

imposed a $1,000 one-day PD CMP for that week. If it fails to report again in week five, the noncompliance will lead to the imposition of another one-day PD CMP in the amount of $1,500 for that failure to report (for a CMP total of $2,500 in PD CMPs). In this example, if the facility complies with the reporting requirements and submits the required report in week six, but then subsequently fails to report as required in week seven, a one-day PD CMP amount of $2,000 will be imposed (which is $500 more than the last imposed PD CMP amount) for a total of $4,500 imposed CMPs.

8. **Q. What if a facility under-reports COVID-19 data to CDC's NHSN?**

   A: CMS expects facilities to submit complete and accurate information through the NHSN system. We understand identifying cases of COVID-19 in a nursing home can be challenging. However, accurate data is critical to directing public health action and ensuring critical resources and assistance are available to facilities that need them. If, upon further investigation, CMS identifies that a facility did not submit complete and accurate information, the facility would not be in compliance with the new reporting requirements and would be subject to enforcement actions.

9. **Q: How long will reporting to CDC's NHSN system and to residents, resident representatives, and families continue to be required?**

   A: These requirements go into effect with the publication of the interim final rule. CMS will inform the public and all stakeholders of any changes in the reporting requirements. Until any changes are announced, these requirements remain in effect.

10. **Q: Are facilities required to report data that predates the effective date of the interim final rule?**

    A: No, there is no requirement in the rule to collect older data. The NHSN system has capability for retrospective reporting from January 2020 onward, consistent with CDC's mission-critical work, but CMS will not take enforcement action if a nursing home is unable to accurately report information from that time. However, we encourage facilities to report older data as it will help with CDC's ongoing surveillance and response efforts to assess burden of COVID-19 in nursing homes, and support a comprehensive national surveillance of the pandemic.

11. **Q. Must a facility report deaths of residents which occur in hospitals to the NHSN's LTCF COVID-19 Module?**

    A: Yes, the LTCF COVID-19 Module does include reporting of deaths in another location. This is clarified in the COVID-19 module instructions that facilities will use when reporting on resident impact and facility capacity.

12. Q: Must the facility notify all residents, representatives, and families, or just those affected?

A: Facilities must notify all residents in the facility, their representatives, and families, not just those who are suspected or confirmed cases of COVID-19. Notification must include data when a confirmed COVID-19 case is identified or when three or more residents or staff have new onset of respiratory symptoms that occur within 72 hours of each other in the facility. Cumulative updates must be provided when other confirmed cases or clusters of three or more residents or staff with respiratory symptoms occur within 72 hours of each other, and at least weekly. We note that there are a variety of ways that facilities can meet this requirement, such as informing families and representatives through email listservs, website postings, and/or recorded telephone messages. We do not expect facilities to make individual telephone calls to each resident's family or responsible party to inform them that a resident in the facility has laboratory-confirmed COVID-19. However, we expect facilities to make all reasonable efforts to properly inform residents, their representatives, and families of the information facilities are required to provide.

13. Q: What information is required to be reported to residents, their representatives, and families? Will this information include new cases as well as total cases?

A: Cumulative, confirmed COVID-19 cases as well as clusters of three or more residents or staff with respiratory symptoms within 72 hours must be reported. The facility is not required to identify new versus total cases.

14. Q: Can you clarify what symptoms CMS is referring to in the requirement to report if three or more residents or staff have respiratory symptoms within 72 hours of each other?

A: Respiratory symptoms consistent with COVID-19 are shortness of breath, difficulty breathing, new or change in cough, sore throat, or new loss of taste or smell. To a lesser extent, symptoms have included new sputum production, rhinorrhea, or hemoptysis. For more information on updated symptoms, please view CDC's webpages: Symptoms of Coronavirus and Preparing for COVID-19: Long-term Care Facilities, Nursing Homes.

15. Q: Must the facility report any suspected case of COVID-19 of a resident or staff member to residents, their representatives, and families?

A: No. The regulation does not require facilities to report to residents, their representatives, and families every suspected case of COVID-19 in residents and staff of the facility. However, it does require facilities to report suspected cases when three or more occur within 72 hours of each other.

16. Q: For dedicated COVID-19 facilities and those with COVID-19 units, must they inform residents, their representatives, and families each time a new resident with confirmed COVID-19 is admitted or staff member tests positive? Similarly, what is the time frame for notifying residents, their representatives, and families for subsequent COVID-19 activity?

A: Yes. The facility must provide any cumulative updates for residents, their representatives, and families. Updates must occur at least weekly or by 5 PM the next calendar day following the subsequent occurrence of either: a confirmed infection of COVID-19 is identified (including new admissions), or whenever three or more residents or staff with new onset of respiratory symptoms occur within 72 hours of each other.

17. **Q: Who are considered "staff" for purposes of reporting confirmed cases or clusters of respiratory symptoms to residents, their representatives, and families?**
A: "Staff" includes employees, consultants, contractors, volunteers, and caregivers who provide care and services to residents in the facility, including nurse aides that have not yet completed a nurse aide training, competency, and evaluation program (NATCEP) but are providing services to residents.

18. **Q: When informing residents, their representatives, and families of suspected and confirmed COVID-19 cases in the facility, does the facility have to specify whether individual cases are residents or staff?**
A: No. CMS does not require this.

19. **Q: Do facilities need to inform anyone who walks through their doors (e.g., a hospice or other healthcare provider) of the same numbers of suspected and confirmed COVID-19 cases that they are sharing with residents, their representatives, and families?**
A: No. Facilities are not required to provide the same COVID-19 information reported to residents, their representatives, and families. However, facilities would share with the visiting healthcare provider, if the resident receiving care is suspected of, or has laboratory-confirmed COVID-19. Any precautions the provider should take while in the facility (e.g., specific personal protective equipment) will be communicated to that provider by the facility as part of their standard practices under the infection prevention and control program requirement.

20. **Q: What if a facility has never had a suspected or confirmed COVID-19 case? Is the facility required to inform all residents, their representatives, and families?**
A: No. CMS does not require this, however, we encourage facilities to transparently communicate regularly with residents, their representatives, and families about the status of the facility.

21. **Q: What if a facility has three or more residents or staff with new onset of respiratory symptoms but not within 72 hours of each other? Does the facility still need to report this to all residents, their representatives, and families?**
A: No. CMS does not require this.

22. Q: Does the reporting requirement at 42 CFR §483.80(g)(3)(i)-(iii) (F885) fulfill the requirement at §483.10(g)(14)(i)(B), Notification of Changes (F580)?

A: No. The new reporting requirement at §483.80(g)(3)(i)-(iii) (F885) requires facilities to notify residents, their representatives, and families of cumulative numbers of confirmed COVID-19 cases and clusters of three or more residents or staff with respiratory symptoms within 72 hours of each other. By way of comparison, §483.10(g)(14)(i)(B) requires nursing homes to notify the resident, the resident's physician and as applicable, the resident's representative(s) of an individual resident's change in condition (F580) if he/she is suspected or confirmed to have 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-20-26-NH

DATE: **April 19, 2020**

TO: State Survey Agency Directors

FROM: Director
Quality, Safety & Oversight Group

SUBJECT: Upcoming Requirements for Notification of Confirmed COVID-19 (or COVID-19 Persons under Investigation) Among Residents and Staff in Nursing Homes

Memorandum Summary

- ***CMS is committed*** to taking critical steps to ensure America's health care facilities are prepared to respond to the 2019 Novel Coronavirus (COVID-19) Public Health Emergency (PHE).
- ***Communicable Disease Reporting Requirements:*** To ensure appropriate tracking, response, and mitigation of COVID-19 in nursing homes, CMS is reinforcing an existing requirement that nursing homes must report communicable diseases, healthcare-associated infections, and potential outbreaks to State and Local health departments. In rulemaking that will follow, CMS is requiring facilities to report this data to the Centers for Disease Control and Prevention (CDC) in a standardized format and frequency defined by CMS and CDC. Failure to report cases of residents or staff who have confirmed COVID -19 and Persons under Investigation (PUI) could result in an enforcement action. This memorandum summarizes new requirements which will be put in place very soon.
- ***Transparency:*** CMS will also be previewing a new requirement for facilities to notify residents' and their representatives to keep them up to date on the conditions inside the facility, such as when new cases of COVID-19 occur.

Background

The Centers for Medicare & Medicaid Services (CMS) is responsible for ensuring the health and safety of nursing home residents by enforcing the standards required to help each resident attain or maintain their highest level of well-being. In light of the recent spread of COVID-19, we are providing additional direction to nursing homes to help control and prevent the spread of the disease.

To address this spread, CMS, which inspects Medicare and Medicaid-participating facilities in conjunction with State Survey Agencies to ensure compliance with Federal health and safety rules, has worked hand-in-hand with CDC to provide nursing homes with clear guidance on how they

can keep their residents safe.

Guidance

Nursing homes are currently required to establish and maintain an infection prevention and control program designed to provide a safe, sanitary, and comfortable environment and to help prevent the development and transmission of communicable diseases and infections.

This includes a system of surveillance designed to identify possible communicable diseases or infections before they can spread to other persons in the facility. Further, nursing homes are required to know when and to whom possible incidents of communicable disease or infections should be reported.

Facility Reporting

Current requirements at 42 CFR 483.30 and CDC guidance specify that nursing homes notify State or Local health department about residents or staff with suspected or confirmed COVID-19, residents with severe respiratory infection resulting in hospitalization or death, or ≥ 3 residents or staff with new-onset respiratory symptoms within 72 hours of each other.

At present, these data are not collected by CMS, CDC, or the Federal Emergency Management Agency (FEMA). CMS and CDC will soon provide nursing homes with specific direction on standard formatting and frequency for reporting this information through the CDC's National Health Safety Network (NHSN) system. Currently, this information is provided optionally by nursing homes. The required collection of this information will be used to support surveillance of COVID-19 locally and nationally, monitor trends in infection rates, and inform public health policies and actions. This information may be retained and publicly reported in accordance with law.

Resident and Resident Representative Reporting

In addition to requiring reporting to CDC, in rulemaking that will follow, we will also be requiring that facilities notify its residents and their representatives to keep them informed of the conditions inside the facility. This is separate from the reporting required to CDC in that this information will be shared by the nursing home directly with residents and their representatives. At a minimum, once these requirements are in place, nursing homes must inform residents and their representatives within 12 hours of the occurrence of a single confirmed infection of COVID-19, or three or more residents or staff with new-onset of respiratory symptoms that occur within 72 hours. Also, updates to residents and their representatives must be provided weekly, or each subsequent time a confirmed infection of COVID-19 is identified and/or whenever three or more residents or staff with new onset of respiratory symptoms occurs within 72 hours. Facilities will include information on mitigating actions implemented to prevent or reduce the risk of transmission, including if normal operations in the nursing home will be altered. This information must be reported in accordance with existing privacy regulations and statute.

In rulemaking that will follow this memorandum, failure to report resident or staff incidences of communicable disease or infection, including confirmed COVID-19 cases (or Persons Under Investigation for COVID-19), or provide timely notification to residents and their representatives of these incidences, as required, could result in an enforcement action against the nursing home by CMS.

Ongoing Public Health Surveillance

Finally, to ensure access by appropriate public health entities at the Federal, State or Local level, nursing homes are reminded of the requirement at 42 CFR 483.10(f) (4)(i)(A) and (B) which mandates immediate access to any residents by any representative of the Secretary or State. The purpose of these visits will be for CDC (or its agents) to perform on-site infectious disease surveillance, testing of healthcare personnel and residents, or other related activities, as permitted under law.

The full CDC guidance to prepare nursing homes for COVID-19 can be found here: 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#facilities-should-do

These actions are necessary to ensure Federal, State and Local public health surveillance systems, and residents and their representatives, have the most complete information on COVID-19 cases in nursing homes to mitigate the spread and impact of COVID-19 on our most vulnerable citizens.

Contact

Questions about this memorandum should be addressed to DNH_TriageTeam@cms.hhs.gov.

Effective Date

This memorandum should be communicated with all survey and certification staff, their managers and the State/Regional Office training coordinators immediately.

/s/
David R. Wright

cc: Survey and Operations Group Management

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-20-20-All

DATE: **March 23, 2020**

TO: State Survey Agency Directors

FROM: Director
Quality, Safety & Oversight Group

SUBJECT: Prioritization of Survey Activities

Memorandum Summary

- ***The Centers for Medicare & Medicaid Services (CMS) is committed*** to taking critical steps to ensure America's health care facilities are prepared to respond to the threat of disease caused by the 2019 Novel Coronavirus (COVID-19).
- On Friday, March 13, 2020, the President declared a national emergency, which triggers the Secretary's ability to authorize waivers or modifications of certain requirements pursuant to section 1135 of the Social Security Act (the Act). Under section 1135(b)(5) of the Act, CMS is prioritizing surveys by authorizing modification of timetables and deadlines for the performance of certain required activities, delaying revisit surveys, and generally exercising enforcement discretion for three weeks.
- During this three-week timeframe, **only** the following types of surveys will be prioritized and conducted:
    - Complaint/facility-reported incident surveys: State survey agencies (SSAs) will conduct surveys related to complaints and facility-reported incidents (FRIs) that are triaged at the Immediate Jeopardy (IJ) level. A streamlined Infection Control review tool will also be utilized during these surveys, regardless of the Immediate Jeopardy allegation.
    - Targeted Infection Control Surveys: Federal CMS and State surveyors will conduct targeted Infection Control surveys of providers identified through collaboration with the Centers for Disease Control and Prevention (CDC) and the HHS Assistant Secretary for Preparedness and Response (ASPR). They will use a streamlined review checklist to minimize the impact on provider activities, while ensuring providers are implementing actions to protect the health and safety of individuals to respond to the COVID-19 pandemic.
    - Self-assessments: The Infection Control checklist referenced above will also be shared with all providers and suppliers to allow for voluntary self-assessment of their Infection Control plan and protections.

Memorandum Summary Continued

- During the prioritization period, the following surveys will not be authorized: Standard surveys for long term care facilities (nursing homes), hospitals, home health agencies (HHAs), intermediate care facilities for individuals with intellectual disabilities (ICF/IIDs), and hospices. This includes the life safety code and Emergency Preparedness elements of those standard surveys; and revisits that are not associated with IJ.
- Furthermore, for Clinical Laboratory Improvement Amendments (CLIA), we intend to prioritize immediate jeopardy situations over recertification surveys, and generally intend to use enforcement discretion, unless immediate jeopardy situations arise.
- Finally, initial certification surveys will continue to be authorized in accordance within current guidance and prioritization.

Background

CMS is committed to taking critical steps to ensure America's health care facilities, providers, and clinical laboratories are prepared to respond to the threat of COVID-19 and other respiratory illness. Specifically, under section 1135(b)(5) of the Act, CMS is prioritizing and suspending certain federal and SSA surveys, and delaying revisit surveys, pursuant to federal requirements for the next three weeks, beginning March 20, 2020, for all certified provider and supplier types. Also, for Clinical Laboratory Improvement Amendments (CLIA), we intend to prioritize immediate jeopardy situations over recertification surveys, and generally intend to use enforcement discretion, unless immediate jeopardy situations arise. During this three-week timeframe, SSAs and CMS surveyors will prioritize and conduct surveys (including revisit surveys) related to complaints and facility-reported incidents (FRIs) that are triaged at the Immediate Jeopardy (IJ) level, for all allegations, in addition to a review with a Focused Infection Control survey. Federal surveyors will perform targeted Infection Control surveys of facilities in those areas most in need of additional oversight, as identified through collaboration with the CDC and ASPR.

If state or federal surveyors are unable to meet the Personal Protective Equipment (PPE) expectations outlined by the latest CDC guidance to safely perform an onsite survey due to lack of appropriate PPE supplies, they are instructed to refrain from entering the /provider, and obtain information necessary remotely, to the extent possible. Surveyors should continue the survey once they have the necessary PPE to do so safely.

The Focused Infection Control Survey is available to every provider in the country to make them aware of Infection Control priorities during this time of crisis, and providers and suppliers may perform a voluntary self-assessment of their ability to meet these priorities.

This shift in approach will allow health care providers time to implement the most recent infection control guidance from both CMS and the Centers for Disease Control and Prevention (CDC). At the same time, we are doing our duty to protect patients from harm, and ensuring providers are implementing actions to prevent the spread of COVID-19.

Therefore, during the prioritization period, the following surveys will **not** be authorized:

- Standard surveys for long term care facilities (nursing homes), hospitals, home health agencies (HHAs), intermediate care facilities for individuals with intellectual disabilities (ICF/IIDs), and hospices. This includes the life safety code and Emergency Preparedness elements of those standard surveys;

- Revisits that are not associated with IJ. As a result, the following enforcement actions will be suspended, until revisits are again authorized:
    - For nursing homes – Imposition of Denial of Payment for New Admissions (DPNA), including situations where facilities that are not in substantial compliance at 3 months, will be lifted to allow for new admissions during this time;
    - For HHAs – Imposition of suspension of payments for new admissions (SPNA) following the last day of the survey when termination is imposed will be lifted to allow for new admissions during this time;
    - For nursing homes and HHAs – Suspend per day civil money penalty (CMP) accumulation, and imposition of termination for facilities that are not in substantial compliance at 6 months.

- For CLIA, we intend to prioritize immediate jeopardy situations over recertification surveys.

This announcement follows previous action to focus survey activity on infection control. On March 4, 2020, CMS announced a suspension of inspections for federal and state inspectors (https://www.cms.gov/medicareprovider-enrollment-and-certificationsurveycertificationgeninfopolicy-and/suspension-survey-activities). This earlier announcement focused on immediate jeopardy complaints, complaints alleging infection control concerns – especially COVID-19 – statutorily required surveys, revisit surveys to resolve enforcement actions, initial certifications, inspections for facilities with histories of infection control deficiencies in the last three years, and inspections of facilities with histories of infection control deficiencies at low levels of severity. This action supersedes the March 4th announcement, and prioritizes surveys related to complaints and FRIs triaged at the IJ level, while suspending the other types of surveys.

Prioritization of Surveys

When conducting surveys related to complaints and facility-reported incidents (FRIs) that are triaged at the Immediate Jeopardy (IJ) level, and revisit surveys necessary to verify removal of IJ which has been previously cited, surveyors and CMS Regional Offices should adhere to the following guidelines:

1. SSAs follow their normal process for triaging complaints and FRIs:
    a. If a complaint or FRI is triaged at the IJ level, the state should follow the normal policies and procedures for surveying the provider. For example, a survey of a long term care facility (LTC) would be conducted within two business days of receipt of the allegation (State Operations Manual (SOM), Chapter 5, Section 5075.9).

b. If a complaint or FRI is triaged at the non- IJ level, the state would enter the allegation into the ASPEN Complaints/Incidents Tracking System (ACTS) per the instructions in the SOM Chapter 5. An onsite survey will not be conducted during the prioritization period. CMS will issue guidance related to these non-IJ complaints or FRIs in the next few weeks.
c. This normal complaint triaging process also applies to CLIA complaints.

2. For facilities that have been cited for IJ-level deficiencies and that surveyors have not verified that the IJ has been removed, surveyors would proceed as normal, and conduct a revisit survey to verify the IJ is removed.
    a. If the revisit survey determines there is continuing noncompliance, but not at the IJ level, surveyors would not conduct another onsite revisit survey. The provider may submit a plan of correction (POC), but an onsite revisit survey will not be conducted during the prioritization period, and these cases will be held. The provider may delay submission of a plan of correction until this prioritization period is over.
    b. If a survey is conducted because a complaint or FRI was triaged at the IJ level, and the provider is cited for noncompliance, but not at the IJ level (e.g., Level 3 – actual harm), surveyors would not conduct a revisit survey. The provider may submit a plan of correction (POC), but an onsite revisit survey will not be conducted during the prioritization period, and these cases will be held. The provider may delay submission of a plan of correction until this prioritization period is over.
    c. For level-3 (LTC) or condition level (Non-LTC) citations (for which an onsite revisit survey would normally be conducted), the provider <u>may</u> submit a plan of correction (POC), but an onsite revisit survey will not be conducted during the prioritization period, and these cases will be held. The provider may delay submission of a plan of correction until this prioritization period is over. CMS will issue guidance on how to verify compliance with these citations in the next few weeks.
    d. For level-2 (LTC) or standard level (non-LTC) citations, the provider <u>may</u> submits a POC, and providers and survey agencies could verify compliance through normal procedures through a desk review. The provider may delay submission of a plan of correction until this prioritization period is over.
    e. For clinical laboratories, surveyors will conduct a revisit survey to verify removal of IJ once a credible allegation of compliance has been received.

3. Federal CMS and State Surveyors will conduct focused Infection Control surveys in areas deemed necessary through collaboration with CDC and ASPR. *Please note this workload for SSAs is contingent on their ability to perform surveys based on PPE availability and fulfillment of other State Emergency Response responsibilities (such as staffing medical shelters or testing stations).*
    a. Revisit surveys: Surveyors will follow the same guidance for revisit surveys explained in section 2 above.
    b. Enforcement actions will also follow the guidance for all other surveys during the prioritization period explained in section 4 below.

4. Enforcement Actions:
    a. For pending enforcement cycles during the prioritization period where the provider is currently not in substantial compliance or has not had a revisit

survey to verify substantial compliance, and a per day civil money penalty (CMP), or DPNA (for nursing homes) or SPNA (for HHAs) was imposed for noncompliance that occurred prior to the prioritization date of surveys: These remedies will be suspended (stopped) as of the start of the survey prioritization date. In other words, the CMP will stop accruing and the DPNA/SPNA will end as of the suspension date. Additionally, CMS will not impose any new remedies to address noncompliance that occurred prior to the start of the survey prioritization period. NOTE: This does not apply to unremoved IJs. Enforcement actions will proceed as usual per the SOM for unremoved IJ deficiencies. CMS will issue guidance on how to reconcile these actions in the next few weeks.

b. For pending enforcement cycles during the prioritization period where the provider is currently not in substantial compliance or has not had a revisit survey to verify substantial compliance, and for pending enforcement cycles with new noncompliance cited after the issuance of this memo, and a per day CMP, or DPNA (for nursing homes) or SPNA (for HHAs) was imposed for IJ level noncompliance (where the IJ has not been removed): Surveyors will follow normal policies and procedures for removing the IJ. CMS will also follow normal policies and procedures for imposing enforcement remedies for remediating the noncompliance. For example, for noncompliance cited at the IJ level, that has not been removed at the time of the survey exit, the CMS Office will impose an enforcement remedy (e.g., CMP, 23 day termination), and the state surveyors will conduct a revisit survey. On the revisit survey, surveyors will either verify substantial compliance, or cite noncompliance at a lower level if warranted.
    i. If the IJ noncompliance is reduced and cited at level 3 (LTC) or condition level (non-LTC), an onsite revisit survey will not be conducted during the prioritization period, and these cases will be held. CMS will issue guidance on how to impose enforcement and verify compliance with these in the next few weeks (see 2.c.).
    ii. If the IJ noncompliance is reduced and cited at level 2 (LTC) or standard level (non-LTC), facilities and survey agencies would verify compliance through normal procedures through a desk review (see 2.d.). However, CMS should not impose remedies during the prioritization period for any noncompliance that was identified before or after the start of the survey prioritization period, unless the noncompliance is an unremoved IJ.
c. The three-month mandatory DPNA and six-month mandatory termination (nursing homes) for not being in substantial compliance (for nursing homes and HHAs) will not take place, and be deferred for an evaluation at a later date. However, enforcement actions related to IJ remain and continue under normal procedures.
d. If CMS has previously imposed an alternative sanction (e.g., SPNA, CMP) on a HHA for noncompliance identified prior to the suspension, the six-month mandatory termination will not take place, and be deferred for an evaluation at a later date.

e. For existing CLIA enforcement cases where a civil money penalty (CMP) per day of non-compliance was imposed, accrual of CMP will stop as of the survey COVID-19 suspension date. CMS will issue guidance on how to reconcile these actions in the next few weeks. Other CLIA enforcement actions that have been initiated will be handled on a case-by-case basis with consultation DCLIQ managers and staff.

5. If during an IJ complaint or FRI survey, the surveyor identifies that there is an active COVID-19 case in the facility:

   If the COVID-19 case is, or is not, related to the IJ, surveyors should report the case and facility to their agency, the state health department (to coordinate with the Centers for Disease Control and Prevention (CDC)), and the CMS Regional Office. These agencies should coordinate and decide on any further actions that should be taken. The Infection Control focused survey process can be used to investigate noncompliance and ensure the provider takes steps to minimize transmission.

For onsite surveys that were started prior to the prioritization period and don't fall under this guidance, survey teams should end the survey and exit the facility.

Lastly, any initial certification surveys remain authorized to increase the health care capacity of the country.

Note: While CMS' directive applies to the CMS' federal surveyors and state agency surveyors, CMS also urges other surveyors, including accrediting organizations (AOs), to follow suit. Additionally, CMS' survey prioritization applies to surveys for compliance with federal regulations, not state surveys pursuant to state licensure.

Additional Instructions for Nursing Homes

We are disseminating the Infection Control survey developed by CMS and CDC so facilities can educate themselves on the latest practices and expectations. We expect facilities to use this new process, in conjunction with the latest guidance from CDC, to perform a voluntary self-assessment of their ability to prevent the transmission of COVID-19. This document may be requested by surveyors, if an onsite investigation takes place. We also encourage nursing homes to voluntarily share the results of this assessment with their state or local health department Healthcare-Associated Infections (HAI) Program. Contact information for each state's health departments is identified on the Centers for Disease Control & Prevention's (CDC's) website at: https://www.cdc.gov/HAI/state-based/index.html.

Furthermore, we remind facilities that they are required to have a system of surveillance designed to identify possible communicable diseases or infections before they can spread to other persons in the facility, and when and to whom possible incidents of communicable disease or infections should be reported (42 CFR 483.80(a)(2)(i) and (ii)). CDC recommends that nursing homes notify their health department about residents with severe respiratory infection, or a cluster of respiratory illness (e.g., > or = 3 residents or HCP with new-onset respiratory symptoms within 72 hours). Local and state reporting guidelines or requirements may vary. Monitor the CDC website for information and resources to help prevent the introduction and spread of COVID-19 in nursing homes (CDC Preparing for COVID-19: Long-term Care Facilities, Nursing Homes: https://www.cdc.gov/coronavirus/2019-

ncov/healthcare-facilities/prevent-spread-in-long-term-care-facilities.html). We urge providers to review the tools and implement actions to protect the health and safety of individuals to respond to the COVID-19 pandemic.

Additional Instructions for Other (Non-Long Term Care) Provider Types

Education and Signage

Where the patient/resident is sleeping at the health care facility, signage on the patient's room is important to ensuring that all staff are aware of the necessary infection control steps. https://www.cdc.gov/infectioncontrol/pdf/droplet-precautions-sign-P.pdf

In the home setting, health care staff may have little control over the home environment, but must 1) educate staff, patients and family members regarding infection control procedures and how to avoid transmission of COVID-19, and 2) maintain clean equipment and supplies and follow appropriate infection control procedures during home visits and transport of reusable patient care items. For further information refer to CDC's interim guidance for home care of people not requiring hospitalization for COVID-19 (https://www.cdc.gov/coronavirus/2019-ncov/hcp/guidance-home-care.html).

Limitations on Visitors

To mitigate the spread of the COVID-19 virus, CMS is providing guidance to restrict visitation in health care facilities such as hospitals, critical access hospitals, psychiatric hospitals, inpatient hospice units, and intermediate care facilities for individuals with developmental disabilities. For CMS restrictions on visitation in nursing homes, see QSO-20-14 https://www.cms.gov/files/document/qso-20-14-nh-revised.pdf.

CMS is providing the following expanded guidance to prevent the spread of COVID-19:

a) Visitors should receive the same screening as patients, including whether they have had:
- Fever or symptoms of a respiratory infection, such as a cough and sore throat.
- International travel within the last 14 days to CDC Level 3 risk countries. For updated information on restricted countries visit: https://www.cdc.gov/coronavirus/2019-ncov/travelers/index.html
- Contact with someone with known or suspected COVID-19.

b) Health care facilities should set limitations on visitation. For example, limitations may include restricting the number of visitors per patient, or limiting visitors to only those that provide assistance to the patient, or limiting visitors under a certain age.

c) Health care facilities should provide signage at entrances for screening individuals, provide temperature checks/ ask about fever, and encourage frequent hand washing and use of hand sanitizer before entering the facility and before and after entering patient rooms

d) If visiting and not seeking medical treatment themselves, individuals with fevers, cough, sore throat, body aches or runny nose or not following infection control guidance should be restricted from entry.

e) Facilities should screen and limit visitors for any recent trips (within the last 30 days) on cruise ships as well as close contact with a suspect or laboratory-confirmed COVID-19 patient within the last 14 days, or overseas travel from certain countries.

https://www.cdc.gov/coronavirus/2019-ncov/travelers/after-travel-precautions.html, https://wwwnc.cdc.gov/travel/page/covid-19-cruise-ship

f) Facilities should instruct visitors to limit their movement within the facility (e.g., reduce walking the halls, trips to cafeteria, etc.)
g) Facilities should establish limited entry points for all visitors and/or establish alternative sites for screening prior to entry.
h) Facilities can implement measures to:
   - Increase communication with families (phone, face-time, skype, etc.).
   - Potentially offer a hotline for with a recording that is updated at set times so families can get an update on the facility's general status.
   - If appropriate, consider offering telephonic screening of recent travel and wellness prior to coming in for scheduled appointments. This may help limit the amount of visitor movement throughout the organization and congestion at entry points.
i) Consider closing common visiting areas and encouraging patients to visit with loved ones in their patient rooms.

In home and community-based settings, health care providers should advise patients with COVID-19 of the CDC guidance to mitigate transmission of the virus. This includes isolating at home during illness, restricting activities except for medical care, using a separate bathroom and bedroom if possible, and prohibiting visitors who do not have an essential need to be in the home. The certified Medicare/Medicaid provider is expected to share this information with patients with the COVID-19 virus and his/her caregiver. https://www.cdc.gov/coronavirus/2019-ncov/hcp/guidance-prevent-spread.html

Some states have chosen to establish more restrictive criteria than described above. Health care providers to follow the more restrictive criteria when present.

Access for Healthcare Staff

CMS is aware that some providers (nursing homes, assisted living facilities, etc.) have significantly restricted entry for staff from other Medicare/Medicaid certified providers who are providing direct care to patients. In general, if the staff is appropriately wearing PPE, and do not meet criteria for restricted access, they should be allowed to enter and provide services to the patient (interdisciplinary hospice care, dialysis, organ procurement, home health, etc.).

For hospitals, this would also apply to organ procurement coordinators. Ensuring that individuals have continued access to life-saving organs is critical. We understand that hospitals are preparing for a potential surge in COVID-19 patients however, we would ask that donor hospitals continue with operations in regards to allowing organ procurement coordinators into hospitals to discuss organ donation with families. Hospital and OPO leadership should communicate on risk assessments in their communities and any potential impacts for organ recovery operations.

CMS will continue to evaluate the survey prioritization in light of the situation on the ground in areas with large numbers of COVID-19 cases, to determine if CMS needs to continue this past the initial three weeks.

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 .

Contact: Questions about this document should be addressed to QSOG_EmergencyPrep@cms.hhs.gov.

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

/s/
David R. Wright

cc: Survey and Operations Group Management

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-20-17-ALL

DATE: **March 10, 2020**

TO: State Survey Agency Directors

FROM: Director
Quality, Safety & Oversight Group

SUBJECT: Guidance for use of Certain Industrial Respirators by Health Care Personnel

Memorandum Summary

- The Centers for Medicare & Medicaid Services (CMS) CMS is committed to taking critical steps to ensure America's health care facilities are prepared to respond to the threat of the Coronavirus Disease 2019 (COVID-19) and other respiratory illnesses.

- The memo clarifies the application of CMS policies in light of recent Centers for Disease Control and Prevention (CDC) and Food and Drug Administration (FDA) guidance expanding the types of facemasks healthcare workers may use in situations involving COVID-19 and other respiratory infections.

Background

CMS is committed to taking critical steps to ensure America's health care facilities are prepared to respond to the threat of the COVID-19 and other respiratory illness. With this announcement, health care workers in providers and suppliers certified by CMS will have a more expansive range of options to protect themselves and those receiving their care. CMS will continue to explore flexibilities and innovative approaches within our regulations to allow health care entities to meet the critical health needs of the country.

Guidance

The Centers for Disease Control and Prevention (CDC) have updated their Personal Protective Equipment (PPE) recommendations for health care workers involved in the care of patients with known or suspected COVID-19. At this time, these recommendations will be considered by CMS surveyors to determine if Medicare and Medicaid providers and suppliers are complying with infection control protocols:

- Based on local and regional situational analysis of PPE supplies, facemasks are an acceptable temporary alternative when the supply chain of respirators cannot meet the demand. During this time, available respirators should be prioritized for procedures that

are likely to generate respiratory aerosols, which would pose the highest exposure risk to Health Care Providers (HCP).
    - Facemasks protect the wearer from splashes and sprays.
    - Respirators, which filter inspired air, offer respiratory protection.
- When the supply chain is restored, facilities with a respiratory protection program should return to use of respirators for patients with known or suspected COVID-19. Facilities that do not currently have a respiratory protection program, but care for patients infected with pathogens for which a respirator is recommended, should implement a respiratory protection program.
- Eye protection, medical gown, and gloves continue to be recommended.
    - If there are shortages of medical gowns, they should be prioritized for aerosol-generating procedures, care activities where splashes and sprays are anticipated, and high-contact patient care activities that provide opportunities for transfer of pathogens to the hands and clothing of HCP.
- Updated recommendations regarding the need for an airborne infection isolation room (AIIR).
    - Patients with known or suspected COVID-19 should be cared for in a single-person room with the door closed. AIIRs should be reserved for patients undergoing aerosol-generating procedures.
- Updated information based on currently available information about COVID-19 and the current situation in the United States, which includes reports of cases of community transmission, infections identified in HCP, and shortages of facemasks, N95 filtering facepiece respirators (FFRs) (commonly known as N95 respirators), and gowns.
- Increased emphasis on early identification and implementation of source control (i.e., putting a face mask on patients presenting with symptoms of respiratory infection).

Additional information on CDC's recommendations above can be found here:

https://www.cdc.gov/coronavirus/2019-ncov/infection-control/control-recommendations.html

Further, the FDA approved the CDC request for an emergency use authorization (EUA) to allow health care personnel to use certain industrial respirators during the COVID-19 outbreak in health care settings. The FDA concluded that respirators approved by the National Institute for Occupational Safety and Health (NIOSH), but not currently meeting the FDA's requirements, may be effective in preventing health care personnel from airborne exposure, including COVID-19, which can cause serious or life-threatening disease, including severe respiratory illness.

This action allows the NIOSH-approved respirators not currently regulated by the FDA to be used in a health care setting by health care personnel during the COVID-19 outbreak, thereby maximizing the number of respirators available to meet the needs of the U.S. health care system.

PLEASE NOTE: Due to the updated CDC guidance and current supply demands of these devices (and the discards associated with testing), CMS is directing surveyors not to validate the date of the last FIT test for health care workers in Medicare and Medicaid certified facilities, until further notice.

The press release announcing FDA and CDC action to increase access to respirators, including N95s, for health care personnel, can be found at: https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-and-cdc-take-action-increase-access-respirators-including-n95s

The EUA letter can be found at https://www.fda.gov/media/135763/download.

- Appendix A: A list of approved Filtering Facepiece Respirators (FFRs) eligible for coverage under this EUA are posted on the FDA's website:
  https://www.fda.gov/media/135764/download

- Appendix B: A list of NIOSH-approved FFRs authorized under this EUA can be found here:
  https://www.fda.gov/media/135921/download

Therefore, any CMS guidance that explicitly, or by reference, indicates N-95 or PPE usage will automatically incorporate any FFRs authorized under this EUA and any guidance issued by the CDC. This memo is effective for all Medicare and Medicaid provider and certified supplier types:

1. Hospitals
2. Religious Nonmedical Health Care Institutions (RNHCIs)
3. Ambulatory Surgical Centers (ASCs)
4. Hospices
5. Psychiatric Residential Treatment Facilities (PRTFs)
6. Program of All-Inclusive Care for the Elderly (PACE)
7. Transplant Centers
8. Skilled Nursing Facilities (SNFs) and Nursing Facilities (NFs)
9. Intermediate Care Facilities for Individuals with Intellectual Disabilities- ICF/IID
10. Home Health Agencies (HHAs)
11. Comprehensive Outpatient Rehabilitation Facilities (CORFs)
12. Critical Access Hospitals (CAHs)
13. Clinics, Rehabilitation Agencies, and Public Health Agencies as Providers of Outpatient Physical Therapy and Speech-Language Pathology Services
14. Community Mental Health Centers (CMHCs)
15. Organ Procurement Organizations (OPOs)
16. Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs)
17. End-Stage Renal Disease (ESRD) Facilities

In addition, we're providing the following information about some specific areas related to COVID-19 and this EUA:

CDC Resources:

- Strategies for Optimizing the Supply of N95 Respirators: https://www.cdc.gov/coronavirus/2019-ncov/hcp/respirators-strategy/index.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fcoronavirus%2F2019-ncov%2Fhcp%2Frespirator-supply-strategies.html
- CDC Resources for Health Care Facilities: https://www.cdc.gov/coronavirus/2019-ncov/healthcare-facilities/index.html

- CDC Updates: https://www.cdc.gov/coronavirus/2019-ncov/whats-new-all.html
- CDC FAQ for COVID-19**:** https://www.cdc.gov/coronavirus/2019-ncov/infection-control/infection-prevention-control-faq.html
- CDC guidance for Infection Prevention and Control Recommendations for Patients with Confirmed Coronavirus Disease 2019: https://www.cdc.gov/coronavirus/2019-ncov/infection-control/control-recommendations.html

FDA Resources:

- Emergency Use Authorizations: https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations

Contact: Questions about this document should be addressed to QSOG_EmergencyPrep@cms.hhs.gov.

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

/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-20-14-NH

DATE: **March 13, 2020**

TO: State Survey Agency Directors

FROM: Director
Quality, Safety & Oversight Group

SUBJECT: Guidance for Infection Control and Prevention of Coronavirus Disease 2019 (COVID-19) in Nursing Homes ***(REVISED)***

Memorandum Summary

- ***CMS is committed*** to taking critical steps to ensure America's health care facilities and clinical laboratories are prepared to respond to the threat of the COVID-19.
- **Guidance for Infection Control and Prevention of COVID-19** - CMS is providing additional guidance to nursing homes to help them improve their infection control and prevention practices to prevent the transmission of COVID-19, *including revised guidance for visitation*.
- **Coordination with the Centers for Disease Control (CDC) and local public health departments** - We encourage all nursing homes to monitor the CDC website for information and resources and contact their local health department when needed (CDC Resources for Health Care Facilities: https://www.cdc.gov/coronavirus/2019-ncov/healthcare-facilities/index.html).

Background

The Centers for Medicare & Medicaid Services (CMS) is responsible for ensuring the health and safety of nursing home residents by enforcing the standards required to help each resident attain or maintain their highest level of well-being. In light of the recent spread of COVID-19, we are providing additional guidance to nursing homes to help control and prevent the spread of the virus.

Guidance

Facility staff should regularly monitor the CDC website for information and resources (links below). They should contact their local health department if they have questions or suspect a resident of a nursing home has COVID-19. Per CDC, prompt detection, triage and isolation of potentially infectious residents are essential to prevent unnecessary exposures among residents, healthcare personnel, and visitors at the facility. Therefore, facilities should continue to be vigilant in identifying any possible infected individuals. Facilities should consider frequent

monitoring for potential symptoms of respiratory infection as needed throughout the day. Furthermore, we encourage facilities to take advantage of resources that have been made available by CDC and CMS to train and prepare staff to improve infection control and prevention practices. Lastly, facilities should maintain a person-centered approach to care. This includes communicating effectively with residents, resident representatives and/or their family, and understanding their individual needs and goals of care.

Facilities experiencing an increased number of respiratory illnesses (regardless of suspected etiology) among patients/residents or healthcare personnel should immediately contact their local or state health department for further guidance.

In addition to the overarching regulations and guidance, we're providing the following information about some specific areas related to COVID-19:

Guidance for Limiting the Transmission of COVID-19 for Nursing Homes

For ALL facilities nationwide:

*Facilities should **restrict** visitation of **all** visitors and non-essential health care personnel, except for certain compassionate care situations, such as an end-of-life situation. In those cases, visitors will be limited to a specific room only. Facilities are expected to notify potential visitors to defer visitation until further notice (through signage, calls, letters, etc.). Note: If a state implements actions that exceed CMS requirements, such as a ban on all visitation through a governor's executive order, a facility would not be out of compliance with CMS' requirements. In this case, surveyors would still enter the facility, but not cite for noncompliance with visitation requirements.*

For individuals that enter in compassionate situations (e.g., end-of-life care), facilities should require visitors to perform hand hygiene and use Personal Protective Equipment (PPE), such as facemasks. Decisions about visitation during an end of life situation should be made on a case by case basis, which should include careful screening of the visitor (including clergy, bereavement counselors, etc.) for fever or respiratory symptoms. Those with symptoms of a respiratory infection (fever, cough, shortness of breath, or sore throat) should not be permitted to enter the facility at any time (even in end-of-life situations). Those visitors that are permitted, must wear a facemask while in the building and restrict their visit to the resident's room or other location designated by the facility. They should also be reminded to frequently perform hand hygiene.

Exceptions to restrictions:

- *Health care workers: Facilities should follow CDC guidelines for restricting access to health care workers found at https://www.cdc.gov/coronavirus/2019-ncov/hcp/guidance-risk-assesment-hcp.html. This also applies to other health care workers, such as hospice workers, EMS personnel, or dialysis technicians, that provide care to residents. They should be permitted to come into the facility as long as they meet the CDC guidelines for health care workers. Facilities should contact their local health department for questions, and frequently review the CDC website dedicated to COVID-19 for health care professionals (https://www.cdc.gov/coronavirus/2019-nCoV/hcp/index.html).*
- *Surveyors: CMS and state survey agencies are constantly evaluating their surveyors to ensure they don't pose a transmission risk when entering a facility. For example, surveyors may have been in a facility with COVID-19 cases in the previous 14 days, but because they were wearing PPE effectively per CDC guidelines, they pose a low risk to*

transmission in the next facility, and must be allowed to enter. However, there are circumstances under which surveyors should still not enter, such as if they have a fever.

Additional guidance:

1. *Cancel communal dining and all group activities, such as internal and external group activities.*
2. *Implement active screening of residents and staff for fever and respiratory symptoms.*
3. *Remind residents to practice social distancing and perform frequent hand hygiene.*
4. *Screen all staff at the beginning of their shift for fever and respiratory symptoms. Actively take their temperature and document absence of shortness of breath, new or change in cough, and sore throat. If they are ill, have them put on a facemask and self-isolate at home.*
5. *For individuals allowed in the facility (e.g., in end-of-life situations), provide instruction, before visitors enter the facility and residents' rooms, provide instruction on hand hygiene, limiting surfaces touched, and use of PPE according to current facility policy while in the resident's room. Individuals with fevers, other symptoms of COVID-19, or unable to demonstrate proper use of infection control techniques should be restricted from entry. Facilities should communicate through multiple means to inform individuals and non-essential health care personnel of the visitation restrictions, such as through signage at entrances/exits, letters, emails, phone calls, and recorded messages for receiving calls.*
6. *Facilities should identify staff that work at multiple facilities (e.g., agency staff, regional or corporate staff, etc.) and actively screen and restrict them appropriately to ensure they do not place individuals in the facility at risk for COVID-19.*
7. *Facilities should review and revise how they interact vendors and receiving supplies, agency staff, EMS personnel and equipment, transportation providers (e.g., when taking residents to offsite appointments, etc.), and other non-health care providers (e.g., food delivery, etc.), and take necessary actions to prevent any potential transmission. For example, do not have supply vendors transport supplies inside the facility. Have them dropped off at a dedicated location (e.g., loading dock). Facilities can allow entry of these visitors if needed, as long as they are following the appropriate CDC guidelines for Transmission-Based Precautions.*
8. *In lieu of visits, facilities should consider:*
    a) *Offering alternative means of communication for people who would otherwise visit, such as virtual communications (phone, video-communication, etc.).*
    b) *Creating/increasing listserv communication to update families, such as advising to not visit.*
    c) *Assigning staff as primary contact to families for inbound calls, and conduct regular outbound calls to keep families up to date.*
    d) *Offering a phone line with a voice recording updated at set times (e.g., daily) with the facility's general operating status, such as when it is safe to resume visits.*
9. *When visitation is necessary or allowable (e.g., in end-of-life scenarios), facilities should make efforts to allow for safe visitation for residents and loved ones. For example:*
    a) *Suggest refraining from physical contact with residents and others while in the facility. For example, practice social distances with no hand-shaking or hugging, and remaining six feet apart.*
    b) *If possible (e.g., pending design of building), creating dedicated visiting areas (e.g., "clean rooms") near the entrance to the facility where residents can meet with*

visitors in a sanitized environment. Facilities should disinfect rooms after each resident-visitor meeting.

c) *Residents still have the right to access the Ombudsman program. Their access should be restricted per the guidance above (except in compassionate care situations), however, facilities may review this on a case by case basis. If in-person access is not available due to infection control concerns, facilities need to facilitate resident communication (by phone or other format) with the Ombudsman program or any other entity listed in 42 CFR § 483.10(f)(4)(i).*

10. *Advise visitors, and any individuals who entered the facility (e.g., hospice staff), to monitor for signs and symptoms of respiratory infection for at least 14 days after exiting the facility. If symptoms occur, advise them to self-isolate at home, contact their healthcare provider, and immediately notify the facility of the date they were in the facility, the individuals they were in contact with, and the locations within the facility they visited. Facilities should immediately screen the individuals of reported contact, and take all necessary actions based on findings.*

When should nursing homes consider transferring a resident with suspected or confirmed infection with COVID-19 to a hospital?

Nursing homes with residents suspected of having COVID-19 infection should contact their local health department. Residents infected with COVID-19 may vary in severity from lack of symptoms to mild or severe symptoms or fatality. Initially, symptoms may be mild and not require transfer to a hospital as long as the facility can follow the infection prevention and control practices recommended by CDC. Facilities without an airborne infection isolation room (AIIR) are not required to transfer the resident assuming: 1) the resident does not require a higher level of care and 2) the facility can adhere to the rest of the infection prevention and control practices recommended for caring for a resident with COVID-19.

Please check the following link regularly for critical updates, such as updates to guidance for using PPE: https://www.cdc.gov/coronavirus/2019-ncov/infection-control/control-recommendations.html.

The resident may develop more severe symptoms and require transfer to a hospital for a higher level of care. Prior to transfer, emergency medical services and the receiving facility should be alerted to the resident's diagnosis, and precautions to be taken including placing a facemask on the resident during transfer. If the resident does not require hospitalization they can be discharged to home (in consultation with state or local public health authorities) if deemed medically and socially appropriate. Pending transfer or discharge, place a facemask on the resident and isolate him/her in a room with the door closed.

When should a nursing home accept a resident who was diagnosed with COVID-19 from a hospital?

A nursing home can accept a resident diagnosed with COVID-19 and still under Transmission-Based Precautions for COVID-19 as long as the facility can follow CDC guidance for Transmission-Based Precautions. If a nursing home cannot, it must wait until these precautions are discontinued. CDC has released Interim Guidance for Discontinuing Transmission-Based Precautions or In-Home Isolation for Persons with Laboratory-confirmed COVID-19. Information on the duration of infectivity is limited, and the interim guidance has been

developed with available information from similar coronaviruses. CDC states that decisions to discontinue Transmission-based Precautions in hospitals will be made on a case-by-case basis in consultation with clinicians, infection prevention and control specialists, and public health officials. Discontinuation will be based on multiple factors (see current CDC guidance for further details).

Note: Nursing homes should admit any individuals that they would normally admit to their facility, including individuals from hospitals where a case of COVID-19 was/is present. Also, if possible, dedicate a unit/wing exclusively for any residents coming or returning from the hospital. This can serve as a step-down unit where they remain for 14 days with no symptoms (instead of integrating as usual on short-term rehab floor, or returning to long-stay original room).

Other considerations for facilities:

- Review CDC guidance for Infection Prevention and Control Recommendations for Patients with Confirmed Coronavirus Disease 2019: https://www.cdc.gov/coronavirus/2019-ncov/infection-control/control-recommendations.html
- Increase the availability and accessibility of alcohol-based hand rubs (ABHRs), *reinforce strong hand-hygiene practices*, tissues, no touch receptacles for disposal, and facemasks at healthcare facility entrances, waiting rooms, resident check-ins, etc.
    - Ensure ABHR is accessible in all resident-care areas including inside and outside resident rooms.
- Increase signage for vigilant infection prevention, such as hand hygiene and cough etiquette.
- Properly clean, disinfect and limit sharing of medical equipment between residents and areas of the facility.
- Provide additional work supplies to avoid sharing (e.g., pens, pads) and disinfect workplace areas (nurse's stations, phones, internal radios, etc.).

Will nursing homes be cited for not having the appropriate supplies?

CMS is aware of 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 and ABHR) 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 ABHR, we expect staff to practice effective hand washing with soap and water. Similarly, 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 the local and state public health agency to notify them of the shortage, follow national guidelines for optimizing their current supply, or identify the next best option to care for residents. If a surveyor believes a facility should be cited for not having or providing the necessary supplies, the state agency should contact the CMS Branch Office.

What other resources are available for facilities to help improve infection control and prevention?

CMS urges providers to take advantage of several resources that are available:

CDC Resources:

- Infection preventionist training: https://www.cdc.gov/longtermcare/index.html
- CDC Resources for Health Care Facilities: https://www.cdc.gov/coronavirus/2019-ncov/healthcare-facilities/index.html
- CDC Updates: https://www.cdc.gov/coronavirus/2019-ncov/whats-new-all.html
- CDC FAQ for COVID-19**:** https://www.cdc.gov/coronavirus/2019-ncov/infection-control/infection-prevention-control-faq.html
- *Information on affected US locations: https://www.cdc.gov/coronavirus/2019-ncov/cases-in-us.html*

CMS Resources:

- Guidance for use of Certain Industrial Respirators by Health Care Personnel: https://www.cms.gov/files/document/qso-20-17-all.pdf
- Long term care facility – Infection control self-assessment worksheet: https://qsep.cms.gov/data/252/A._NursingHome_InfectionControl_Worksheet11-8-19508.pdf
- Infection control toolkit for bedside licensed nurses and nurse aides ("Head to Toe Infection Prevention (H2T) Toolkit"): https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/LTC-CMP-Reinvestment
- Infection Control and Prevention regulations and guidance: 42 CFR 483.80, Appendix PP of the State Operations Manual. See F-tag 880: https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/GuidanceforLawsAndRegulations/Downloads/Appendix-PP-State-Operations-Manual.pdf

Contact: Email DNH_TriageTeam@cms.hhs.gov

NOTE: The situation regarding COVID-19 is still evolving worldwide and can change rapidly. Stakeholders should be prepared for guidance from CMS and other agencies (e.g., CDC) to change. Please monitor the relevant sources regularly for updates.

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

/s/
David R. Wright

cc: Survey and Operations Group Management

Appendix Z - Emergency Preparedness

E-0024 – Policies and Procedures for Volunteers

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§483.73

[(b) Policies and procedures. The [facilities] must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, and the communication plan at paragraph (c) of this section. The policies and procedures must be reviewed and updated at least *every 2 years (annually for LTC)*.] At a minimum, the policies and procedures must address the following:]

(6) The use of volunteers in an emergency or other emergency staffing strategies, including the process and role for integration of State and Federally designated health care professionals to address surge needs during an emergency.

Interpretive Guidelines applies to:

§483.73(b)(6)

Guidance is pending and will be updated in future release.

F880 - Infection Prevention & Control

Old Tag Number: F441

§483.80 Infection Control

The facility must establish and maintain an infection prevention and control program designed to provide a safe, sanitary and comfortable environment and to help prevent the development and transmission of communicable diseases and infections.

§483.80(a) Infection prevention and control program.

The facility must establish an infection prevention and control program (IPCP) that must include, at a minimum, the following elements:

§483.80(a)(1) A system for preventing, identifying, reporting, investigating, and controlling infections and communicable diseases for all residents, staff, volunteers, visitors, and other individuals providing services under a contractual arrangement based upon the facility assessment conducted according to §483.70(e) and following accepted national standards;

§483.80(a)(2) Written standards, policies, and procedures for the program, which must include, but are not limited to:

(i) A system of surveillance designed to identify possible communicable diseases or infections before they can spread to other persons in the facility;

(ii) When and to whom possible incidents of communicable disease or infections should be reported;

(iii) Standard and transmission-based precautions to be followed to prevent spread of infections;

(iv) When and how isolation should be used for a resident; including but not limited to:

(A) The type and duration of the isolation, depending upon the infectious agent or organism involved, and

(B) A requirement that the isolation should be the least restrictive possible for the resident under the circumstances.

(v)The circumstances under which the facility must prohibit employees with a communicable disease or infected skin lesions from direct contact with residents or their food, if direct contact will transmit the disease; and

(vi) The hand hygiene procedures to be followed by staff involved in direct resident contact.

(vii) 483.80(a)(4) A system for recording incidents identified under the facility's IPCP and the corrective actions taken by the facility.

(viii) 483.80(e) Linens.

Personnel must handle, store, process, and transport linens so as to prevent the spread of infection.

§483.80(f) Annual review.

The facility will conduct an annual review of its IPCP and update their program, as necessary.

INTENT 483.80(a),(e),(f)

The intent of this regulation is to ensure that the facility:

- Develops and implements an ongoing infection prevention and control program (IPCP) to prevent, recognize, and control the onset and spread of infection to the extent possible and reviews and updates the IPCP annually and as necessary. This would include revision of the IPCP as national standards change;
- Establishes facility-wide systems for the prevention, identification, investigation and control of infections of residents, staff, and visitors. It must include an ongoing system of surveillance designed to identify possible communicable diseases or infections before they can spread to other persons in the facility and procedures for reporting possible incidents of communicable disease or infections; **NOTE**: For purposes of this guidance, "staff" includes employees, consultants, contractors, volunteers, 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.
- Develops and implements written policies and procedures for infection control that, at a minimum:
  - Explain how standard precautions and when transmission-based precautions should be utilized, including but not limited to the type and duration of precautions for particular infections or organisms involved and that the precautions should be the least restrictive possible for the resident given the circumstances and the resident's ability to follow the precautions;
  - Prohibit staff with a communicable disease or infected skin lesions from direct contact with residents or their food, if direct contact will transmit the disease; and
  - Require staff follow hand hygiene practices consistent with accepted standards of practice.
- Requires staff handle, store, process, and transport all linens and laundry in accordance with accepted national standards in order to produce hygienically clean laundry and prevent the spread of infection to the extent possible.

DEFINITIONS

"Airborne precautions": actions taken to prevent or minimize the transmission of infectious agents/organisms that remain infectious over long distances when suspended in the air. These infectious particles can remain suspended in the air for prolonged periods of time and can be carried on normal air currents in a room or beyond, to adjacent spaces or areas receiving exhaust air.[40]

"Alcohol-based handrub (ABHR)": a 60-95 percent ethanol or isopropyl alcohol- containing preparation base designed for application to the hands to reduce the number of viable microorganisms.

"Cleaning": removal of visible soil (e.g., organic and inorganic material) from objects and surfaces and is normally accomplished manually or mechanically using water with detergents or enzymatic products.

"Cohorting": the practice of grouping residents infected or colonized with the same infectious agent together to confine their care to one area and prevent contact with susceptible residents (cohorting residents).[40] During outbreaks, healthcare staff may be assigned to a specific cohort of residents to further limit opportunities for transmission (cohorting staff). The terms "cohort or cohorting" is standardized language used in the practice of infection prevention and control; the use of this terminology is not intended to offend residents or staff.

"Colonization": the presence of microorganisms on or within body sites without detectable host immune response, cellular damage, or clinical expression. [40]

"Communicable disease" (also known as [a.k.a.] "contagious disease"): an infection transmissible (e.g., from person-to-person) by direct contact with an affected individual or the individual's body fluids or by indirect means (e.g., contaminated object).

"Community-acquired infections" (a.k.a. "present on admission")**:** infections that are present or incubating at the time of admission and which generally develop within 72 hours of admission.

"Contact precautions": measures that are intended to prevent transmission of infectious agents which are spread by direct or indirect contact with the resident or the resident's environment.[40]

"Contaminated laundry": laundry which has been soiled with blood/body fluids or other potentially infectious materials or may contain sharps.

"Decontamination": the use of physical or chemical means to remove, inactivate, or destroy pathogenic organisms on a surface or item to the point where they are no longer capable of transmitting infectious particles and the surface or item is rendered safe for handling, use, or disposal.

"Disinfectant": usually a chemical agent (but sometimes a physical agent) that destroys disease-causing pathogens or other harmful microorganisms but might not kill bacterial spores. It refers to substances applied to inanimate objects. [41]

"Disinfection": thermal or chemical destruction of pathogenic and other types of microorganisms. Disinfection is less lethal than sterilization because it destroys most recognized pathogenic microorganisms but not necessarily all microbial forms (e.g., bacterial spores). [41]

40 Siegel, J.D., Rhinehart, E., Jackson, M., Chiarello, L., & the Healthcare Infection Control Practices Advisory Committee. (2007). *2007 Guideline for isolation precautions: Preventing transmission of infectious agents in healthcare settings.* Accessed on June 9, 2017 from https://www.cdc.gov/infectioncontrol/guidelines/isolation/index.html

"Disinfection": thermal or chemical destruction of pathogenic and other types of microorganisms. Disinfection is less lethal than sterilization because it destroys most recognized pathogenic microorganisms but not necessarily all microbial forms (e.g., bacterial spores). [41]

"Droplet precautions": actions designed to reduce/prevent the transmission of pathogens spread through close respiratory or mucous membrane contact with respiratory secretions.

"Hand hygiene": a general term that applies to hand washing, antiseptic hand wash, and alcohol-based hand rub.[42]

"Hand washing": the vigorous, brief rubbing together of all surfaces of hands with plain (i.e., nonantimicrobial) soap and water, followed by rinsing under a stream of water.[43]

"Healthcare-associated infection (HAI)": an infection that residents acquire, that is associated with a medical or surgical intervention (e.g., podiatry, wound care debridement) within a nursing home and was not present or incubating at the time of admission.

"Hygienically clean": being free of pathogens in sufficient numbers to cause human illness.[44]

"Infection": the establishment of an infective agent in or on a suitable host, producing clinical signs and symptoms (e.g., fever, redness, heat, purulent exudates, etc.).

"Infection preventionist": term used for the person(s) designated by the facility to be responsible for the infection prevention and control program. **NOTE:** Designation of a specific individual, detailed training, qualifications, and hourly requirements for an infection preventionist are not required until implementation of Phase 3.

"Personal protective equipment (PPE)": protective items or garments worn to protect the body or clothing from hazards that can cause injury and to protect residents from cross-transmission.

"(Regulated) Medical waste": liquid or semi-liquid blood or other potentially infectious materials; contaminated items that would release blood or other potentially infectious materials in a liquid or semi-liquid state if compressed; items that are caked with dried blood or other potentially infectious materials and are capable of releasing these materials during handling (e.g., blood-soaked bandages); contaminated sharps.[45]

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41 Centers for Disease Control and Prevention. (2008). Guideline for disinfection and sterilization in healthcare facilities, 2008. Accessed on June 9, 2017 from https://www.cdc.gov/hicpac/pdf/guidelines/Disinfection_Nov_2008.pdf

42 Centers for Disease Control and Prevention. (2002, October 25). Guideline for hand hygiene in health-care settings: Recommendations of The Healthcare Infection Control Practices Advisory Committee and the HICPAC/SHEA/APIC/IDSA Hand Hygiene Task Force. MMWR; 51(No.RR-16). Accessed on June 9, 2017 from http://www.cdc.gov/mmwr/PDF/rr/rr5116.pdf

43 Centers for Disease Control and Prevention (2009, July 20). OPRP – General information on hand hygiene.
Accessed on June 9, 2017 from https://www.cdc.gov/nceh/vsp/cruiselines/hand_hygiene_general.htm. 44 Association for the Advancement of Medical Instrumentation (AAMI). (2009). ANSI/AAMI ST65:2008/(R)2013. Processing of reusable surgical textiles for use in health care facilities, 2008. Arlington, VA.

NOTE: Authorities having jurisdiction may have more stringent regulations than OSHA.

"Standard Precautions": infection prevention practices that apply to all residents, regardless of suspected or confirmed diagnosis or presumed infection status. Standard precautions is based on the principle that all blood, body fluids, secretions, excretions except sweat, regardless of whether they contain visible blood, non-intact skin, and mucous membranes may contain transmissible infectious agents. Furthermore, equipment or items in the patient environment likely to have been contaminated with infectious body fluids must be handled in a manner to prevent transmission of infectious agents. Standard precautions include but are not limited to hand hygiene; use of gloves, gown, mask, eye protection, or face shield, depending on the anticipated exposure; safe injection practices, and respiratory hygiene/cough etiquette. Also, equipment or items in the patient environment likely to have been contaminated with infectious body fluids must be handled in a manner to prevent transmission of infectious agents (e.g., wear gloves for direct contact, properly clean and disinfect or sterilize reusable equipment before use on another patient).[40]

"Transmission-based precautions" (a.k.a. "Isolation Precautions"): actions (precautions) implemented, in addition to standard precautions, that are based upon the means of transmission (airborne, contact, and droplet) in order to prevent or control infections. **NOTE**: Although the regulatory language refers to "isolation," the nomenclature widely accepted and used in this guidance will refer to "transmission-based precautions" instead of "isolation".

NOTE: References to non-U. S. Department of Health and Human Services (HHS) sources or sites on the internet are provided as a service and do not constitute or imply endorsement of these organizations or their programs by CMS. CMS is not responsible for the content of pages found at these sites. URL addresses were current as of the date of this publication.

GUIDANCE §483.80(a),(e),(f)

INFECTION PREVENTION AND CONTROL PROGRAM

Healthcare-associated infections (HAIs) can cause significant pain and discomfort for residents in nursing homes and can have significant adverse consequences. The facility must establish and maintain an IPCP designed to provide a safe, sanitary, and comfortable environment and to help prevent the development and transmission of communicable diseases and infections. This program must include, at a minimum, a system for preventing, identifying, reporting, investigating, and controlling infections and communicable diseases for all residents, staff, and visitors. The IPCP must follow national standards and guidelines.

45 Occupational Safety and Health Administration. Title 29 Part 1910.1030. Bloodborne pathogens. Accessed on June 9, 2017 from http://www.ecfr.gov/cgi-bin/text-idx?SID=4e5245f66094d270bc2bd93105f6a92d&mc=true&node=se29.6.1910_11030&rgn=div8

For purposes of this guidance, we would expect facilities to tailor the emphasis of their IPCP for visitors. We expect facilities to work to prevent transmission of infection to the resident from the visitor using reasonable precautions and national standards.[40] For example, passive screening through the use of signs at the entrances to alert visitors with signs and symptoms of communicable diseases not to enter the facility.[40] If a facility has a visitor exception protocol (e.g., end-of-life care), this would need to be determined by the facility. In this case, if a symptomatic visitor/family member must enter the facility, the visitor must still follow the facility's policies for prevention of transmission (e.g., following respiratory hygiene/cough etiquette procedures).

The Infection Prevention and Control Program must include the following parts:

- A system for preventing, identifying, reporting, investigating, and controlling infections and communicable diseases that:
  - Covers all residents, staff, volunteers, visitors, and other individuals providing services under a contractual arrangement;
  - Is based on the individual facility assessment;
  - Follows accepted national standards;
- Written standards, policies and procedures in accordance with §483.80(a)(2);
- A system for recording incidents identified under the IPCP and corrective actions taken by the facility; and
- An antibiotic stewardship program (ASP) (F881).

FACILITY ASSESSMENT

Pursuant to §483.70(e) (F838), the facility must conduct and document a facility-wide assessment to determine what resources are necessary to care for its residents competently during both day-to-day operations and emergencies. The facility must review and update that assessment, as necessary, and at least annually. The facility must also review and update this assessment whenever there is, or the facility plans for, any change that would require a substantial modification to any part of this assessment. The facility assessment must address or include a facility-based and community-based risk assessment, utilizing an all-hazards approach. See §483.70(e) (F838) for guidance on the facility assessment. The results of the facility assessment must be used, in part, to establish and update the IPCP, its policies and/or protocols to include a system for preventing, identifying, reporting, investigating, and controlling infections and communicable diseases for residents, staff, and visitors.

NOTE: A community-based risk assessment should include review for risk of infections (e.g., multidrug-resistant organisms- MDROs) and communicable diseases such as tuberculosis and influenza. Appropriate resident tuberculosis screening should be performed based on state requirements.

NOTE: While not required for compliance, a sample tool of an infection control risk assessment is available for adaptation.[46]

INFECTION CONTROL POLICIES AND PROCEDURES

The facility must develop and implement written policies and procedures for the provision of infection prevention and control. The facility administration and medical director should ensure that current standards of practice based on recognized guidelines are incorporated in the resident care policies and procedures. These IPCP policies and procedures must include, at a minimum:

- As necessary, and at least annually, review and revision of the IPCP based upon the facility assessment (according to 483.70(e)) which includes any facility and community risk;
- An ongoing system of surveillance designed to identify possible communicable diseases or infections before they can spread to other persons in the facility;
- When and to whom possible incidents of communicable disease or infections should be reported within the facility;
- Which communicable diseases are reportable to local/state public health authorities;
- How to use standard precautions and how and when to use transmission-based precautions (i.e., contact precautions, droplet precautions, airborne isolation precautions). The areas described below are part of standard and transmission-based precautions[40] which are further described under their respective sections. For example:
    - Hand hygiene (HH) (e.g., hand washing and/or ABHR): consistent with accepted standards of practice such as the use of ABHR instead of soap and water in all clinical situations except when hands are visibly soiled (e.g., blood, body fluids), or after caring for a resident with known or suspected Clostridium (C.) difficile or norovirus infection during an outbreak, or if infection rates of C. difficile infection (CDI) are high; in these circumstances, soap and water should be used;[47] **NOTE:** According to the CDC, strict adherence to glove use is the most effective means of preventing hand contamination with C. difficile spores as spores are not killed by ABHR and may be difficult to remove even with thorough hand washing. For further information on appropriate hand hygiene practices see the following CDC website: http://www.cdc.gov/handhygiene/providers/index.html
- The selection and use of PPE (e.g., indications, donning/doffing procedures) and the clinical conditions for which specific PPE should be used (e.g., CDI, influenza);
- Addressing the provision of facemasks for residents with new respiratory symptoms;
- Addressing resident room assignment (e.g. single/private room/cohorted) as appropriate and/or available, based on a case by case analysis of the presence of risk factors for increased likelihood of transmission (e.g., uncontained drainage, stool incontinence);[40]
- The process to manage a resident on transmission-based precautions when a single/ private room is not available;

46 Association for Professionals in Infection Control and Epidemiology. IC risk assessment tool form and IC risk assessment analysis. Accessed on June 9, 2017 from

47 Dubberke, E.R., & Gerding, D.N. (2011). Rationale for hand hygiene recommendations after caring for a patient with Clostridium difficile infection. In A compendium of strategies to prevent healthcare-associated infections in acute care hospitals: A fall 2011 update. Accessed on June 9, 2017 from https://www.shea-online.org/images/patients/CDI-hand-hygiene-Update.pdf

- Limiting the movement of a resident with a highly infectious disease (e.g., norovirus, CDI) who is on transmission-based precautions with active symptoms (e.g., resident has diarrhea, vomiting, draining wounds, or other uncontained excretions or secretions) while outside of his/her room for medically necessary purposes only;[40] and
- Respiratory Hygiene/Cough Etiquette[40]: Implementing policies and procedures would include providing resources and instructions for performing HH in or near lobby areas or entrances; provide conveniently-located dispensers of ABHR and supplies for hand washing where sinks are available. During times of increased prevalence of respiratory infections in the community, facilities must have facemasks available and should offer facemasks to coughing or sneezing visitors and other symptomatic persons (e.g., family who accompany ill residents upon entry to the facility). Symptomatic (e.g., coughing) visitors should wear a facemask or maintain at least a three foot separation from others in common areas (e.g., admitting office). In addition, the facility should consider posting signs in the facility with instructions to family/ visitors with symptoms of respiratory infection to cover their mouth/nose when coughing or sneezing; use and dispose of tissues; perform hand hygiene after contact with respiratory secretions; and to take appropriate precautions if they are having symptoms of respiratory infection or other communicable diseases.

- Resident Care Activities:
  - The use and care of urinary catheters, which must include a written rationale for the use, consistent with evidence-based guidelines (e.g., acute urinary retention, bladder outlet obstruction, neurogenic bladder or terminally ill for comfort measures) (Refer to §483.25(e)(2)(i)(ii)&(iii) Incontinence, F690, for further information.);
  - Wound care, fecal/urinary incontinence care, and skin care. Since the IPCP must be based on the facility assessment, the presence of certain resident conditions would require that the facility have policies and procedures related to other specific services such as mechanical ventilation, infusion therapy, and/or dialysis either onsite or at an offsite dialysis facility;
  - Performing fingersticks and point-of-care testing (e.g., assisted blood glucose monitoring) to the extent identified as a resident need based on the facility assessment;
  - Preparation, administration, and care for medications administered by injection or peripheral and central venous catheters, if performed by the facility; and
  - Use and care of peripheral and central venous catheters, if performed by the facility.

- Environmental cleaning/disinfection:
  - Routine cleaning and disinfection of high-touch surfaces in common areas, resident rooms, and at the time of discharge; and

    NOTE: Privacy curtains in the resident's room should be changed when visibly dirty by laundering or cleaning with an Environmental Protection Agency (EPA)-registered disinfectant per manufacturer's instructions.
  - Cleaning/disinfection of resident care equipment including equipment shared among residents (e.g., blood pressure cuffs, rehabilitation therapy equipment, blood glucose meters, etc.).

- Written occupational health policies that address:
  - Reporting of staff illnesses and following work restrictions per nationally recognized standards and guidelines;[48]
  - Prohibiting contact with residents or their food when staff have potentially communicable diseases or infected skin lesions;
  - Assessing risks for tuberculosis (TB) based on regional/community data and screening staff to the extent permitted under applicable federal guidelines [49] and state law;
  - Monitoring and evaluating for clusters or outbreaks of illness among staff;
  - Implementing an exposure control plan in order to address potential hazards posed by blood and body fluids, from dialysis, glucose monitoring or any other point of care testing; and
  - Education and competency assessment: facilities must ensure staff follow the IPCP's standards, policies and procedures. Therefore, staff must be informed and competent. Knowledge and skills pertaining to the IPCP's standards, policies and procedures are needed by all staff in order to follow proper infection control practices (e.g., hand hygiene and appropriate use of personal protective equipment) while other needs are specific to particular roles, responsibilities, and situations (e.g., injection safety and point of care testing). Furthermore, residents and their representatives should receive education on the facility's IPCP as it relates to them (e.g., hand hygiene, cough etiquette) and to the degree possible/consistent with the resident's capacity. For example, residents should be advised of the IPCP's standards, policies and procedures regarding hand hygiene before eating and after using the restroom.

SURVEILLANCE

The facility must establish a system for surveillance based upon national standards of practice and the facility assessment, including the resident population and the services and care provided. The facility must establish routine, ongoing, and systematic collection, analysis, interpretation, and dissemination of surveillance data to identify infections (i.e., HAI and community-acquired), infection risks, communicable disease outbreaks, and to maintain or improve resident health status. As part of the system of surveillance, identification and prevention, the facility should determine how it will track the extent to which staff are following the facility's IPCP policies and procedures, and facilities would want to particularly address any areas that are related to a corrective action.

48 Bolyard, E.A., Tablan, O.C., Williams, W.W., Pearson, M.L., Shapiro, C.N., Deitchman, S.D., & The Healthcare Infection Control Practices Advisory Committee. (1998). Guideline for infection control in health care personnel, 1998. American Journal of Infection Control 26, 289-354. Accessed on June 9, 2017 from https://www.cdc.gov/hicpac/pdf/InfectControl98.pdf

49 Jensen, P.A., Lambert, L.A., Iademarco, M.F., & Ridzon, R. (CDC's Division of Tuberculosis Elimination, National Center for HIV, STD, and TB Prevention). (2005, December 30). Guidelines for preventing the transmission of Mycobacterium tuberculosis in health-care settings, 2005. MMWR; 54 (No.RR-17). Accessed on June 9, 2017 from https://www.cdc.gov/mmwr/preview/mmwrhtml/rr5417a1.htm

The facility's surveillance system must include a data collection tool and the use of nationally-recognized surveillance criteria such as but not limited to CDC's National Healthcare Safety Network (NHSN) Long Term Care Criteria to define infections or updated McGeer criteria[50]. Furthermore, the facility must know when and to whom to report communicable diseases, healthcare-associated infections (as appropriate), and potential outbreaks (e.g., list of communicable diseases which are reportable to local/state public health authorities). The facility must document follow-up activity in response to important surveillance findings (e.g., outbreaks).

In addition, the facility must establish and implement a system, including who to notify (e.g. infection preventionist), for early detection and management of a potentially infectious, symptomatic resident at the time of admission. This includes the identification and use of appropriate transmission-based precautions.[40] This is important to incorporate into the resident's baseline care plan that must be developed within 48 hours of admission and include the minimum healthcare information necessary to properly care for a resident, including physician orders (e.g., medication orders). See §483.21, Comprehensive Person-Centered Care Planning for further information.

Furthermore, the facility must have a process for communicating information at the time of transfer (e.g., CDC, state, or other standardized inter-facility infection transfer form) when a resident has an infection or is colonized.[51] When a resident is transferred, the information provided to the receiving provider must include special instructions or precautions for ongoing care and other necessary information including a discharge summary. When a resident is discharged, the discharge summary must include the resident's disease diagnoses and health conditions, course of illness/treatment or therapy, medications, and pertinent lab, radiology, consultation results, and instructions or precautions for ongoing care. See §483.21(c)(2), Discharge Summary (F661) and §483.15(c)(2)(iii), Transfer and Discharge (F622) for further information on these requirements.

Additionally, as part of the overall IPCP for surveillance, the facility shall establish process and outcome surveillance.

Process Surveillance

Process surveillance is the review of practices by staff directly related to resident care.[52] The purpose is to identify whether staff implement and comply with the facility's IPCP policies and procedures. Some areas that facilities may want to consider for process surveillance are the following:

- *Hand hygiene;*
- *Appropriate use of personal protective equipment (e.g., gowns, gloves, facemask);*
- *Injection safety;*

50 Stone, N.D., Ashraf, M.S., Calder, J., Crnich, C. J., Crossley, K., Drinka, P.J., …Bradley, S.F. (2012). Surveillance definitions of infections in long-term care facilities: Revisiting the McGeer criteria. Infect Control Hosp Epidemiology. 33(10), 965-977.

51 Siegel, J.D., Rhinehart, E., Jackson, M., and Chiarello, L. (2006). Management of multidrug-resistant organisms in healthcare settings, 2006. Accessed on June 9, 2017 from https://www.cdc.gov/hicpac/pdf/mdro/mdroguideline2006.pdf

- Point-of-care testing (e.g., during assisted blood glucose monitoring);
- Implementation of infection control practices for resident care such as but not limited to urinary catheter care, wound care, injection/IV care, fecal/urinary incontinence care, skin care, respiratory care, dialysis care, and other invasive treatments;

- Managing a bloodborne pathogen exposure.

  NOTE: This may not lend itself to monitoring and feedback;

- Cleaning and disinfection products and procedures for environmental surfaces and equipment;
- Appropriate use of transmission-based precautions; and
- Handling, storing, processing, and transporting linens so as to prevent the spread of infection.

Outcome Surveillance

Another component of a system of identification is outcome surveillance. For example, this addresses the criteria that staff would use to identify and report evidence of a suspected or confirmed HAI or communicable disease. This process consists of collecting/documenting data on individual resident cases and comparing the collected data to standard written definitions (criteria) of infections.

NOTE: Refer to the CDC/SHEA Position Statement: Surveillance Definitions of Infections in Long-Term Care Facilities: Revisiting the McGeer Criteria[50] or NHSN at https://www.cdc.gov/nhsn/ for examples of nationally accepted surveillance definitions.

The following are some sources of data that can be utilized in outcome surveillance for infections, antibiotic use and susceptibility: Monitoring a resident(s) with fever or other signs or symptoms suspicious for infection;

- Laboratory cultures or other diagnostic test results consistent with potential infections to detect clusters, trends, or susceptibility patterns;
- Antibiotic orders;
- Medication regimen review reports;
- Documentation from the clinical record of residents with suspicion of an infection such as physician orders/progress notes; and/or
- Transfer/discharge summaries for new or readmitted residents for infections.[52]

52 Smith, P.W., Bennett, G., Bradley, S., Drinka, P., Lautenbach, E., Marx, J.... Stevenson, K. (2008). SHEA/APIC Guideline: infection prevention and control in the long-term care facility. *Infect Control Hosp Epidemiology. 29*(9), 785-814.

SYSTEM OF SURVEILLANCE: DATA ANALYSIS, DOCUMENTATION AND REPORTING

The facility's policies and procedures for a system of surveillance must include data to properly identify communicable diseases or infections before they spread. Therefore, the policies and procedures would include identifying:

- Data to be collected, including how often and the type of data to be documented, including:
  - The infection site (i.e., type of infection), pathogen (if available), signs and symptoms, and resident location, including summary and analysis of the number of residents
    (and staff, if applicable) who developed infections;
  - Observations of staff including the identification of ineffective practices (e.g., not practicing hand hygiene and/or using PPE when indicated as well as practices that do not follow the facility's IPCP policies and procedures), if any; and
  - The identification of unusual or unexpected outcomes (e.g. foodborne outbreak), infection trends and patterns.
- How the data will be used and shared with appropriate individuals (e.g., staff, medical director, director of nursing, quality assessment and assurance committee- QAA), when applicable, to ensure that staff minimize spread of the infection or disease (e.g., require revision of staff education and competency assessment).

The facility must identify how reports will be provided to staff and/or prescribing practitioners in order to revise interventions/approaches and/or re-evaluate medical interventions related to the infection rates and outcomes.

RECOGNIZING, CONTAINING AND REPORTING COMMUNICABLE DISEASE OUTBREAKS

The facility must know how to recognize and contain infectious disease outbreaks. An outbreak is the occurrence of more cases than expected in a given area or among a specific group of people over a particular period of time.[53] If a condition is rare or has serious health implications, an outbreak may involve only one case. While a single case of a rare infectious condition or one that has serious health implications may or may not constitute an outbreak, facilities should not wait for the definition of an outbreak to act. For example, one case of laboratory confirmed influenza in a resident should alert the facility to begin an outbreak investigation.[54] If an outbreak is identified, the facility must:

- Take the appropriate steps to diagnose and manage cases, implement appropriate precautions, and prevent further transmission of the disease as well as documentation of follow-up activity in response; and
- Comply with state and local public health authority requirements for identification, reporting, and containing communicable diseases and outbreaks.

53 Centers for Disease Control and Prevention. (2015, January 21). Epidemiology glossary. Accessed on June 9, 2017 from http://www.cdc.gov/reproductivehealth/data_stats/glossary.html#O

54 Schweon, S., Burdsall D., Hanchett, M., Hilley, S., Greene, D., Kenneley, I., Marx, J., Rosenbaum, P. (2013). Infection preventionist's guide to long-term care. Washington DC: APIC.

NOTE: Some states have specific regulations regarding responding to and reporting outbreaks that must be included in the IPCP.

PREVENTION AND CONTROL OF TRANSMISSION OF INFECTION

Infectious organisms (e.g., bacteria, viruses, or parasites) may be transmitted by direct contact (e.g., skin-to-skin) or indirect contact (e.g., inanimate objects). Healthcare staff and resident care equipment often move from resident to resident and therefore may serve as a vehicle for transferring infectious organisms.

Direct Contact Transmission (Person-to-Person) occurs when microorganisms such as methicillin-resistant Staphylococcus aureus (MRSA), vancomycin-resistant enterococci (VRE), carbapenem-resistant Enterobacteriaceae (CRE), influenza, or mites from a scabies-infected resident are transferred from an infected or colonized person to another person. In nursing homes, resident-to-resident direct contact transmission may occur in common areas of the facility such as the recreation room, rehabilitation area, and/or dining room.

Indirect Contact Transmission: involves the transfer of an infectious agent through a contaminated inanimate object or person.

The following are examples of opportunities for indirect contact transmission:

- Clothing, uniforms, laboratory coats, or isolation gowns used as PPE may become contaminated with potential pathogens after care of a resident colonized or infected with an infectious agent, (e.g., MRSA, VRE, and C. difficile); and
- Contamination of high touch environmental surfaces (e.g., bedside table, bed rails, toilets, sinks, and handrails), contributes to transmission of pathogens including C. difficile and norovirus.

Certain pathogens may contaminate and survive on equipment and environmental surfaces for long periods of time. Examples include, but are not limited to:

- C. difficile spores can live on inanimate surfaces for up to 5 months;[55]
- The hepatitis B virus can last up to a week on inanimate surfaces;[56] and
- The influenza virus can survive on fomites (e.g., any inanimate object or substance capable of carrying infectious organisms and transferring them from one individual to another) for up to 8 hours.[57]

Mechanisms to prevent and control transmission of infectious organisms through direct and indirect contact include standard and transmission-based precautions and are described in their subsequent sections.

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55 Kim, K.H., Fekety, R., Batts, D.H.,Brown, D., Cudmore , M., Silva, J. Jr., & Waters, D. (1981, January 1). Isolation of Clostridium difficile from the environment and contacts of residents with antibiotic-associated colitis. Journal of Infectious Disease. 143(1), 42-50.

56 Centers for Disease Control and Prevention (CDC). Hepatitis B FAQs for health professionals. Accessed on June 9, 2017 from http://www.cdc.gov/hepatitis/HBV/HBVfaq.htm

57 Centers for Disease Control and Prevention (CDC). (2007, February 15). Preventing seasonal flu. Accessed on June 9, 2017 from https://www.cdc.gov/flu/protect/vaccine/index.htm

STANDARD PRECAUTIONS

Standard precautions represent the infection prevention measures that apply to all resident care, regardless of suspected or confirmed infection status of the resident, in any setting where healthcare is being delivered. These evidence-based practices are designed to protect healthcare staff and residents by preventing the spread of infections among residents and ensuring staff do not carry infectious pathogens on their hands or via equipment during resident care. As mentioned in the definitions section, standard precautions include hand hygiene, use of PPE (e.g., gloves, gowns, facemasks), respiratory hygiene and cough etiquette, safe injection practices, and safe handling of equipment or items that are likely contaminated with infectious body fluids, as well as cleaning and disinfecting or sterilizing of potentially contaminated equipment.[40]

In order to perform hand hygiene appropriately, soap, water, ABHR, and a sink should be readily accessible in appropriate locations including but not limited to resident care areas, and food and medication preparation areas. Staff must perform hand hygiene (even if gloves are used):

- Before and after contact with the resident;
- Before performing an aseptic task;
- After contact with blood, body fluids, visibly contaminated surfaces or after contact with objects in the resident's room;
- After removing personal protective equipment (e.g., gloves, gown, facemask);
- After using the restroom; and
- Before meals.

If residents need assistance with hand hygiene, staff should assist with washing hands after toileting, before meals, and use of ABHR or soap and water at other times when indicated.

The use of PPE during resident care is determined by the nature of staff interaction and the extent of anticipated blood, body fluid, or pathogen exposure to include contamination of environmental surfaces. Furthermore, appropriate use of PPE includes but is not limited to the following:

- Gloves worn before and removed after contact with blood or body fluid, mucous membranes, or non-intact skin;
- Gloves changed and hand hygiene performed before moving from a contaminated-body site to a clean-body site during resident care;
- Gown worn for direct resident contact if the resident has uncontained secretions or excretions or with contaminated or potentially contaminated items;
- Appropriate mouth, nose, and eye protection (e.g., facemasks, face shield) is worn for procedures that are likely to generate splashes or sprays of blood or body fluids;
- PPE appropriately discarded after resident care prior to leaving room followed by hand hygiene; and
- Supplies necessary for adherence to proper PPE use (e.g., gloves, gowns, masks) are readily accessible in resident care areas (i.e., nursing units, therapy rooms) although, equipment supply carts should not be brought into the resident's room.

The facility must prevent infections through indirect contact transmission. This requires the decontamination (i.e., cleaning and/or disinfecting an object to render it safe for handling) of resident equipment, medical devices, and the environment. Alternatively, the facility may also consider using single-use disposable devices or designating reusable equipment for only an individual resident. **NOTE**: Refer to the CDC website for information on environmental cleaning - https://www.cdc.gov/hicpac/pdf/guidelines/eic_in_HCF_03.pdf

The facility must identify the decontamination method based upon the risk of infection to the resident coming into contact with equipment or medical devices. Equipment or items in the resident environment likely to have been contaminated with infectious fluids or other potentially infectious matter must be handled in a manner so as to prevent transmission of infectious agents, (e.g., wear gloves for handling soiled equipment and properly clean and disinfect or sterilize reusable equipment before use on another resident).[40]

The CDC has adopted the Spaulding classification system that identifies three risk levels associated with medical and surgical instruments: critical, semi-critical, and noncritical.[58] This includes:

- Critical items (e.g., needles, intravenous catheters, indwelling urinary catheters) enter sterile tissue or the vascular system. These items or equipment must be sterile when used, based on one of several accepted sterilization procedures. Most of the items in this category should be purchased as sterile or be sterilized;
- Semi-critical items (e.g., dental, podiatry equipment, electric razors) contact mucous membranes or non-intact skin. Such items require meticulous cleaning followed by high-level disinfection treatment using a Food and Drug Administration (FDA)- approved high-level chemical disinfectant, or they may be sterilized. High-level disinfection is traditionally defined as complete elimination of all microorganisms in or on an instrument, except for small numbers of bacterial spores. Refer to the specific disinfectant label claim to determine effectiveness; and
- Non-critical items are those that come in contact with intact skin but not mucous membranes. Noncritical items are divided into noncritical resident care items (e.g., blood pressure cuffs, stethoscopes, wheelchairs, therapy equipment) and noncritical environmental surfaces (e.g., bed rails, bedside tables). They require low level disinfection by cleaning periodically and after visible soiling, following manufacturer's instructions with an EPA-registered disinfectant, detergent or germicide that is approved for health care settings. All applicable label instructions on EPA-registered disinfectant products must be followed (e.g., use-dilution, shelf life, storage, material compatibility, safe use and disposal).

Single-use disposable equipment is an alternative to sterilizing reusable medical instruments. Single-use devices must be discarded after use and are never used for more than one resident. Nursing homes may purchase reprocessed single-use devices when these devices are reprocessed by an entity or a third party reprocessor that is registered with the FDA. The

58 Sehulster, L.M., Chinn, R.Y., Arduino, M.J., Carpenter, J., Donlan, R., Ashford, D., … Cleveland, J. (2003, June 6). Guidelines for environmental infection control in health-care facilities. Recommendations from CDC and the Healthcare Infection Control Practices Advisory Committee (HICPAC). *MMWR; 52(*No. RR-10). Accessed on June 9, 2017 from https://www.cdc.gov/hicpac/pdf/guidelines/eic_in_HCF_03.pdf

nursing home must have documentation from the third party reprocessor that indicates that it has been cleared by the FDA to reprocess the specific device in question.

NOTE: Refer to the CDC website for information on disinfection and sterilization – https://www.cdc.gov/infectioncontrol/guidelines/Disinfection/index.html

TRANSMISSION-BASED PRECAUTIONS

Transmission-based precautions must be used when a resident develops signs and symptoms of a transmissible infection, arrives at a nursing home with symptoms of an infection (pending laboratory confirmation), or has a laboratory confirmed infection and is at risk of transmitting the infection to other residents. For example, a resident with influenza and signs of infection should wear a facemask (e.g., surgical or procedure facemask) when leaving his/her room for medically-necessary care (i.e., droplet precautions for the duration of the illness). The diagnosis of many infections is based on clinical signs and symptoms, but often requires laboratory confirmation. However, since laboratory tests (especially those that depend on culture techniques) may require two or more days to complete, transmission-based precautions may need to be implemented while test results are pending, based on the clinical presentation and the likely category of pathogens.[40, 51]

Facility policies must identify the type (i.e., contact, droplet, airborne) and duration of the transmission-based precautions required, depending upon the infectious agent or organism involved. Furthermore, transmission-based precautions should be the least restrictive possible for the resident based on his/her clinical situation and used for the least amount of time. When used appropriately, transmission-based precautions is not to be considered involuntary seclusion. However, once the resident is no longer a risk for transmitting the infection (e.g., duration of the illness and/or can contain secretions), removing transmission-based precautions is required in order to avoid unnecessary involuntary seclusion. For example, a resident with vancomycin-resistant enterococci (VRE) who is colonized based on a urine culture, but is continent and cognizant, should be instructed regarding or as necessary, assisted with performing hand hygiene before leaving his/her room, but is not placed on transmission-based precautions.

Facility staff should take measures to reduce or minimize any potential psychosocial negative effects of isolation for whom transmission-based precautions are being used. Boredom, anger, withdrawal or depression are just some of the mood changes that could occur. The facility must pro-actively ensure that individualized needs (e.g., activities) are met.

Implementation of Transmission-Based Precautions

When implementing transmission-based precautions, consideration should be given to the following:[40]

- The identification of resident risk factors that increase the likelihood of transmission, (such as uncontained secretions or excretions, non-compliance, cognition deficits, incontinence, etc.);
- The provision of a private room as available/appropriate;
- Cohorting residents with the same pathogen; and
- Sharing a room with a roommate with limited risk factors (e.g., without indwelling or invasive devices, without open wounds, and not immunocompromised) as appropriate.

When a resident is placed on transmission-based precautions, the staff should implement the following:

- Clearly identify the type of precautions and the appropriate PPE to be used;
- Place signage in a conspicuous place outside the resident's room such as the door or on the wall next to the doorway identifying the CDC category of transmission-based precautions (e.g. contact, droplet, or airborne), instructions for use of PPE, and/or instructions to see the nurse before entering. Ensure that signage also complies with residents' rights to confidentiality and privacy;
- Make PPE readily available near the entrance to the resident's room;
- Don appropriate PPE upon entry into the environment (e.g., room or cubicle) of resident on transmission-based precautions (e.g., contact precautions); [40]
- Use disposable or dedicated noncritical resident-care equipment (e.g., blood pressure cuff, bedside commode). If noncritical equipment is shared between residents, it will be cleaned and disinfected following manufacturer's instructions with an EPA-registered disinfectant after use; [40]
- Clean and disinfect objects and environmental surfaces that are touched frequently (e.g., bed rails, over-bed table, bedside commode, lavatory surfaces in resident bathrooms) with an EPA-registered disinfectant for healthcare use at least daily and when visibly soiled; [40] and
- Provide education to residents (to the degree possible/consistent with the resident's capacity) and their representatives or visitors on the use of transmission-based precautions.

NOTE: Refer to CDC guidelines for current recommendations on standard and transmission-based precautions. http://www.cdc.gov/hicpac/2007IP/2007isolationPrecautions.html

Contact Precautions

Contact precautions are intended to prevent transmission of infections that are spread by direct (e.g., person-to-person) or indirect contact with the resident or environment, and require the use of appropriatePPE, including a gown and gloves upon entering (i.e., before making contact with the resident or resident's environment) the room or cubicle. Prior to leaving the resident's room or cubicle, the PPE is removed and hand hygiene isperformed.

Droplet Precautions

The use of droplet precautions applies when respiratory droplets contain viruses or bacteria particles which may be spread to another susceptible individual. Respiratory viruses can enter thebody via the nasal mucosa, conjunctivae and less frequently the mouth.[59] Examples of droplet-borne organisms that may cause infections include, but are not limited to Mycoplasma pneumoniae, influenza, and other respiratory viruses.

59 Hall, C.B., Douglas, Jr., R.G., Schnabal, K.C., and Geiman, J.M. (1981, September). Infectivity of respiratory syncytial virus by various routes of inoculation. *Infection and Immunity. 33*(3), 779-783.

Respiratory droplets are generated when an infected person coughs, sneezes, talks, or during procedures such as suctioning, endotracheal intubation, cough induction by chest physiotherapy, and cardiopulmonary resuscitation.[40] The maximum distance for droplet transmission is currently unresolved, but the area of defined risk based on epidemiological findings is approximately 3-10 feet.[40] In contrast to airborne pathogens, droplet-borne pathogens are generally not transmitted through the air over long distances.

Facemasks are to be used upon entry (i.e., within three feet of a resident) into a resident's room or cubicle with respiratory droplet precautions.[40] If substantial spraying of respiratory secretions is anticipated, gloves and gown as well as goggles (or face shield in place of goggles) should be worn.[40] The preference for a resident on droplet precautions would be to place the resident in a private room.[40] If a private room is not available, the resident could be cohorted with a resident with the same infectious agent, or share a room with a roommate with limited risk factors.[40] Spatial separation of at least 3 feet and drawing the curtain between resident beds is especially important for residents in multi-bed rooms with infections transmitted by the droplet route.[40]

Airborne Precautions

Airborne transmission occurs when pathogens are so small that they can be easily dispersed in the air, and because of this, there is a risk of transmitting the disease through inhalation. These small particles containing infectious agents may be dispersed over long distances by air currents and may be inhaled by individuals who have not had face-to-face contact with (or been in the same room with) the infectious individual. Staff caring for residents on airborne precautions should wear a fit-tested N95 or higher level respirator that is donned prior to room entry.[40]

NOTE: According to the CDC, preventing the spread of pathogens that are transmitted by the airborne route requires the use of special air handling and ventilation systems such as an airborne infection isolation room (AIIR) to contain and then safely remove the infectious agent.[40] Residents with infections requiring an AIIR must be transported to an acute care setting unless the facility can place the resident in a private AIIR room with the door closed. In cases when AIIR is required, such as for a resident with TB, it is important for the facility to have a plan (e.g., public health notification and exposure workup) in place to effectively manage a situation involving a resident with suspected or active TB while awaiting the resident's transfer to an acute care setting.[40]

MEDICAL DEVICE SAFETY

Medical devices may be used for administration of medications, point-of-care testing, or for other medical uses.

Point-of-Care Testing

Point-of-care testing is diagnostic testing that is performed at or near the site of resident care. This may be accomplished through use of portable, handheld instruments such as blood glucose meters or prothrombin time meters. This testing may involve obtaining a blood specimen from the resident using a fingerstick device. The guidance regarding fingerstick devices and blood glucose meters is applicable to other point-of-care devices where a blood specimen is obtained (e.g., prothrombin time meters).

Fingerstick Devices

CDC recommends the use of single-use, auto-disabling fingerstick devices in settings where assisted blood glucose monitoring is performed. This practice prevents inadvertent reuse of fingerstick devices for more than one person. Additionally, the use of single-use, auto-disabling fingerstick devices protects healthcare staff from needlestick injuries. If reusable fingerstick devices are used for assisted monitoring of blood glucose, then they **must never be used for more than one resident**. Although the package instructions for some fingerstick devices may indicate or imply the potential for multiple resident use, CMS guidance, based upon nationally recognized standards of practice from the CDC and FDA, prohibits the use of fingerstick devices for more than one resident.

NOTE: If fingerstick devices are used on more than one resident, surveyors must cite at this tag and utilize the guidelines in Appendix Q for immediate jeopardy. Furthermore, the state survey agency (SA) must notify the appropriate state public health authority of the deficient practice.

NOTE: For information on fingerstick safety, please refer to:

- https://www.cdc.gov/injectionsafety/fingerstick-devicesbgm.html
- https://www.cdc.gov/injectionsafety/providers/blood-glucose-monitoring_faqs.html

Blood Glucose Meters

Blood glucose meters, can become contaminated with blood and, if used for multiple residents, must be cleaned and disinfected after each use according to manufacturer's instructions for multi-patient use. Additionally, staff must **not** carry blood glucose meters in pockets.
The FDA has released guidance for manufacturers regarding appropriate products and procedures for cleaning and disinfection of blood glucose meters. This guidance can be found at the FDA's website:
http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/InVitroDiagnostics/ucm227935.htm
An excerpt from this guidance reads:

> "The disinfection solvent you choose should be effective against HIV, Hepatitis C, and Hepatitis B virus. Outbreak episodes have been largely due to transmission of Hepatitis B and C viruses. However, of the two, Hepatitis B virus is the most difficult to kill. Please note that 70% ethanol solutions are not effective against viral bloodborne pathogens and the use of 10% bleach solutions may lead to physical degradation of your device." A list of Environmental Protection Agency (EPA) registered disinfectants can be found at the following website: https://www.epa.gov/pesticide-registration/selected-epa-registered-disinfectants.

Furthermore, "healthcare personnel should consult the manufacturers of blood glucose meters in use at their facilities to determine what products, meeting the criteria specified by the FDA, are compatible with their meter prior to using any EPA-registered disinfectant for disinfection

purposes. If manufacturers are unable to provide this information then the meter should not be used for multiple patients."[60]

Blood glucose meters dedicated for single-resident use should be stored in a manner that will protect against inadvertent use of the device for additional residents and also cross-contamination via contact with other meters or equipment.

NOTE: If the facility failed to clean and disinfect, per device manufacturer's instructions, and blood glucose meters are used for more than one resident, surveyors must cite this tag and utilize the guidelines in Appendix Q as it may constitute immediate jeopardy.

For more information on point-of-care testing, refer to CDC's website at: https://www.cdc.gov/injectionsafety/blood-glucose-monitoring.html

Safe Medication Administration

All injectable medications must be prepared and administered in accordance with safe injection practices, including but not limited to the following:

- Injections are prepared using aseptic technique in a clean area, free from potential sources of contamination (e.g., blood, body fluids, contaminated equipment);
- Needles and syringes are used for only one resident (this includes manufactured prefilled syringes and cartridge devices such as insulin pens).
  NOTE: If it is identified that needles or syringes are used for more than one resident, surveyors must cite noncompliance at this tag and utilize the guidelines in Appendix Q for immediate jeopardy. The SA must notify the appropriate state public health authority of the deficient practice;

- Medication containers are entered with a new needle and a new syringe, even when obtaining additional doses for the same resident. If noncompliance is found, further investigation is warranted.
  NOTE: If the medication container is used for more than one resident, a new needle and/or syringe was not used with each access, and the container was then used for another resident, surveyors must cite noncompliance at this tag and utilize the guidelines in Appendix Q for immediate jeopardy. The SA must notify the appropriate state public health authority of the deficient practice;

- Single dose (single-use) medication vials, ampules, and bags or bottles of intravenous solution are used for only one resident;

- Medication administration tubing and connectors are used for only one resident.

  NOTE: Surveyors must cite at this tag if noncompliance is identified and utilize the guidelines in Appendix Q for immediate jeopardy. The SA must notify the appropriate state

60 Centers for Disease Control and Prevention. (2016). Frequently asked questions (FAQs) regarding assisted blood glucose monitoring and insulin administration. Accessed on June 9, 2017 from https://www.cdc.gov/injectionsafety/providers/blood-glucose-monitoring_faqs.html

public health authority of the deficient practice; and

- Multi-dose vials to be used for more than one resident are kept in a centralized medication area (e.g., medication room or cart) and do not enter the immediate resident treatment area (e.g., resident room). If multi-dose vials enter the immediate resident treatment area, they should be discarded immediately after use.
  NOTE: For more information on multi-dose vials, please refer to: https://www.cdc.gov/injectionsafety/providers/provider_faqs_multivials.html

Insulin pens are pen-shaped injector devices that contain a reservoir for insulin or an insulin cartridge. These devices are designed to permit self-injection and are intended for single-person use, using a new needle for each injection. **Insulin pens are designed to be used multiple times by a single resident only and must never be shared.** Facility staff must follow manufacturer's instructions for administration. Regurgitation of blood into the insulin cartridge after injection will create a risk of bloodborne pathogen transmission if the pen is used for more than one resident, even when the needle is changed. The FDA makes the following recommendations to prevent transmission of bloodborne infections in residents who require insulin pens:

- Insulin pens containing multiple doses of insulin are meant for single-resident use only, and must never be used for more than one person, even when the needle is changed;
- Insulin pens must be clearly labeled with the resident's name and other identifiers to verify that the correct pen is used on the correct resident; and
- Facilities should review their policies and procedures and educate their staff regarding safe use of insulin pens.

NOTE: Sharing insulin pens, or similar devices, between residents is similar to reusing needles or syringes for more than one resident. If noncompliance is found, surveyors must cite at this tag and utilize the guidelines in Appendix Q for immediate jeopardy. The SA must notify the appropriate state public health authority of the finding.

For more information on insulin pens, please refer to: https://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProvid ers/DrugSafetyInformationforHeathcareProfessionals/ucm133352.htm

Accessing Vascular Devices

Vascular access devices, especially central venous catheters (CVC), increase the risk for local and systemic infections as well as additional complications such as septic thrombophlebitis. Intravascular access devices such as implanted ports may be accessed multiple times per day, for hemodynamic measurements or to obtain samples for laboratory analysis, thus increasing the risk of contamination and subsequent clinical infection. Limiting access to CVCs for only the primary purpose may help reduce the risk of infection. The following CDC guidelines are provided as a reference for current standards of practice for the care of CVCs:

- http://www.cdc.gov/HAI/settings/outpatient/basic-infection-control-prevention-plan-2011/central-venous-catheters.html
- http://www.cdc.gov/dialysis/PDFs/collaborative/Hemodialysis-Central-Venous-Catheter-STH-Protocol.pdf

- http://www.cdc.gov/dialysis/PDFs/collaborative/Catheter-Exit-Site-Care-Observations.pdf
- http://www.cdc.gov/hicpac/pdf/guidelines/bsi-guidelines-2011.pdf

SYSTEM OF RECORDING IPCP INCIDENTS

A facility must develop and implement a system for recording incidents identified under the facility's IPCP and the corrective actions taken by the facility based on the investigation of the incidents. A facility-identified incident (e.g., HAI) may include the spread of disease due to errors in infection prevention and control. The facility's system should include defining, identifying, analyzing, and reporting incidents related to failures in infection control practices to the director of nursing, medical director, and the QAA committee. These may include but are not limited to the following:

- Identification of methods by which the facility would obtain information on incidents from residents, family, and direct care/direct access staff;
- A description of how the facility addresses and investigates the incident(s);
- Measures to be implemented for the prevention of incidents or potential incidents as they relate to infection prevention and control;
- Development and implementation of corrective actions;
- Monitoring for the effectiveness of its implemented changes; and
- Methods for feedback to appropriate individuals involved in the failed practices.

LINENS

Laundry Services

The facility must develop and follow practices on handling, storing, processing, and transporting laundry. The facility must monitor to ensure that the laundry practices are implemented, any deviations from practices must be identified, and corrective actions are put in place.

Laundry includes resident's personal clothing, linens, (i.e., sheets, blankets, pillows), towels, washcloths, and items from departments such as nursing, dietary, rehabilitative services, beauty shops, and environmental services. Laundry services may be provided onsite or the facility may have a written agreement in place for offsite laundry services. Regardless of the location where the laundry is processed, the facility must ensure that all laundry is handled, stored, processed and transported in a safe and sanitary method.

Handling Laundry

The facility staff should handle all used laundry as potentially contaminated and use standard precautions (i.e., gloves). Alternatively, if not all used linens are handled as potentially contaminated, staff would provide separation with special identification of bags and containers for contaminated linens with labels, color coding, or other alternative means of separation of the laundry for appropriate handling and processing. The facility should use the following practices:

- Contaminated laundry is bagged or contained at the point of collection (i.e., location where it was used); [58]
- Leak-resistant containers or bags are used for linens or textiles contaminated with blood or body substances;[58]
- Sorting and rinsing of contaminated laundry at the point of use, hallways, or other open resident care spaces is prohibited; and [58]

- Staff should handle soiled textiles/linens with minimum agitation to avoid the contamination of air, surfaces, and persons. [58]

Transport of Laundry

The facility practices must include how staff will handle and transport the laundry with appropriate measures to prevent cross-contamination. This includes but is not limited to the following:

- Contaminated linen and laundry bags are not held close to the body or squeezed when transporting;[45]
- No special precautions (i.e., double bagging) or categorizing for linen originating in transmission-based precaution rooms is necessary;[58]
- Double bagging of linen is only recommended if the outside of the bag is visibly contaminated or is observed to be wet through to the outside of the bag;[45]
- Contaminated linen carts must be cleaned and disinfected whenever visibly soiled and according to a schedule developed by the facility;[41]
- Separate carts must be used for transporting clean and contaminated linen. 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; and [58]
- Clean linens must be transported by methods that ensure cleanliness and protect from dust and soil during intra or inter-facility loading, transport, and unloading. [58]

Linen Storage

Facility practices must address linen storage, and should include but are not limited to:

- Covers are not needed on contaminated textile hampers in resident care areas (unless state licensing rules require them); and [58]
- Clean linen must always be kept separate from contaminated linen. The use of separate rooms, closets, or other designated spaces with a closing door provides the most secure methods for reducing the risk of accidental contamination.[61]

Processing Laundry Including the Use of Laundry Equipment and Detergents in the Facility

The facility must have a process to clean laundry. Detergent and water physically remove many microorganisms from the linen through dilution during the wash cycle. Advances in laundry equipment technology allow modern-day detergents to be much more effective in removing soil and reducing the presence of microbes than those used in the past when much of the research on laundry processing was first conducted. Washing/drying processes includes the use of manufacturer's instructions for use (IFU) for laundry additives and equipment maintenance. The facility staff must prevent contamination of laundry in processing areas. The facility has laundry practices that includes but are not limited to the following:

- Availability and use of hand hygiene products, as well as appropriate PPE (i.e., gloves and gowns) while sorting and handling contaminated linens; [58]
- The receiving area for contaminated textiles is clearly separated from clean laundry areas. Workflow should prevent cross-contamination; [58]

61 Healthcare Laundry Accreditation Council. (2015). Checklist: Accreditation standards 2016 edition. Accessed on June 9, 2017 from http://media.wix.com/ugd/076879_24e999ab2b484cac8c3c30ee9af77cc0.pdf

- If using fans in laundry processing areas, prevent cross-contamination of clean linens from air blowing from soiled processing areas (i.e., the ventilation should not flow from soiled processing areas to clean laundry areas); [58]
- Laundry equipment (e.g., washing machines, dryers) is used and maintained according to the manufacturer's IFU to prevent microbial contamination of the system; [58]
- Damp laundry is not left in machines overnight; [58]
- Laundry detergents, rinse aids or other additives are used according to the manufacturer's IFU's; [58]

  NOTE: Facilities should communicate information regarding allergies that may impact how an individual resident's laundry is processed.

- Ozone cleaning systems are acceptable for processing laundry;
- If laundry chutes are used, they are designed and maintained so as to minimize dispersion of aerosols from contaminated laundry (e.g., no loose items in the chute and bags are closed before tossing into the chute); [58] and
- The facility should be using the fabric manufacturer's recommended laundry cycles, water temperatures and chemical detergent products:
  - Recommendations for laundry processed in hot water temperatures is 160ºF (71ºC) for 25 minutes;[58] and
  - For laundry that is not hot water compatible, low temperature washing at 71 to 77 ºF (22-25 ºC) plus a 125-part-per-million (ppm) chlorine bleach rinse has been found to be effective and comparable to high temperature wash cycles.[58]

  NOTE: The facility is not required to monitor water temperatures during laundry processing cycles, unless specified by state rules. A chlorine bleach rinse is not required for all laundry items processed in low temperature washing environments due to the availability of modern laundry detergents that are able to produce hygienically clean laundry without the presence of chlorine bleach. The facility should refer to the manufacturer's recommendations for the use of the detergent and items being laundered.

Offsite Professional Laundry Services

If linen is sent off-site to a professional laundry, the facility has practices that address how the service will be provided, including how linen is processed and handled to prevent contamination from dust and dirt during loading and transport. The facility should assure that this laundry service meets healthcare industry laundry standards.

Mattresses and Pillows

Standard permeable mattresses and pillows can become contaminated with body substances duringresident care if the integrity of the covers of these items is compromised. A mattress cover is generally a fitted, protective material, the purpose of which is to prevent the mattress from becoming contaminated with body fluids and substances. A linen sheet placed on the mattress is not considered a mattress cover. Patches for tears and holes in mattress covers do not provide an impermeable surface over the mattress. **NOTE**: Bed and bath linens must be maintained in good condition (Refer to §483.10(i) Safe environment, F584, for further information).

The facility must have practices that address the methods for cleaning and disinfecting items that are to be used for another resident after an individual resident's use such as but not limited to the following:[58]

- Mattress covers with tears or holes are replaced;
- Moisture resistant mattress covers are cleaned and disinfected between use for different residents with an EPA-approved germicidal detergent to help prevent the spread of infections;
- Fabric mattress covers are laundered between use for different residents;
- Pillow covers and washable pillows are laundered in a hot water laundry cycle between use for different residents or when they become contaminated with body substances; and
- Mattresses are discarded if bodily fluids have penetrated into the mattress fabric.

ANNUAL REVIEW OF IPCP

The facility's IPCP and its standards, policies and procedures must be reviewed at least annually to ensure effectiveness and that they are in accordance with current standards of practice for preventing and controlling infections; the IPCP must be updated as necessary. In addition, the facility population and characteristics may change over time, and the facility assessment may identify components of the IPCP that must be changed accordingly.

INVESTIGATIVE SUMMARY

Surveyors would use the Infection Control Facility Task to determine compliance with the infection control part of the survey. One surveyor should coordinate the review of the facility's overall infection prevention and control program **(**IPCP), however, each member of the survey team should assess for compliance throughout the entire survey when observing his/her assigned areas and tasks. The IPCP must be facility-wide and include all departments and contracted services. The surveyor should corroborate any concerns observed through interviews and record and/or document review.

Observations

Specific observations for the provision of infection prevention and control practices such as following standard precautions (e.g., hand hygiene and the appropriate use of PPE) should be made by all team members throughout the survey. Observe care of a resident on transmission-based precautions, if any, to determine if implemented appropriately based on precaution type (i.e., contact, droplet, airborne). If concerns are identified, expand the sample to include more residents with transmission-based precautions.

Observe laundry services throughout the survey (e.g., resident and laundry rooms) to determine whether staff handle, store, and transport linens appropriately.

Interviews

Surveyors should interview appropriate facility staff regarding the IPCP. In addition, any potential concerns should be followed up with interviews and record reviews as needed.

KEY ELEMENTS OF NONCOMPLIANCE

To cite deficient practice at F880, the surveyor's investigation will generally show that the facility failed to do **any one** or more of the following:

- Establish and maintain an IPCP designed to provide a safe, sanitary, and comfortable environment and to help prevent development and transmission of disease and infection;
- The IPCP must be reviewed at least annually and updated as necessary;
- Implement a system for preventing, identifying, reporting, investigating, and controlling infections and communicable diseases for all residents, staff, volunteers, visitors, and other individuals providing services under a contractual arrangement, based on the facility assessment (see §483.70(e)) and follows accepted national standards;
- Develop and implement written IPCP standards, policies, and procedures that are current and based on national standards. These must include:
  - When and to whom possible incidents of communicable diseases should be reported;
  - Developing and implementing a system of surveillance to identify infections or communicable diseases;
  - How to use standard precautions (to include appropriate hand hygiene) and how and when to use transmission-based precautions (i.e., "isolation precautions"); and/or
  - Prohibiting staff with a communicable disease or infected skin lesions from direct contact with residents or their food, if direct contact will transmit disease.
- Assure that staff handle, store, process and transport laundry to prevent the spread of infection; and/or
- Maintain a system for recording identified incidents, and taking appropriate corrective actions.

DEFICIENCY CATEGORIZATION

Examples of Severity Level 4 Non-Compliance: Immediate Jeopardy to Resident Health or Safety include but are not limited to:

- The facility failed to follow standard precautions during the performance of routine testing of blood glucose. The facility reused fingerstick devices for more than one resident. This practice of reusing fingerstick devices for more than one resident created an immediate jeopardy to resident health by potentially exposing residents who required blood glucose testing to the spread of bloodborne infections in the facility.
- The facility failed to investigate, document surveillance of, and implement preventative measures to address an outbreak of gastrointestinal illness among residents in one unit of the facility. As a result, several residents in an adjoining unit became seriously ill with diarrheal illnesses resulting in dehydration.
- Facility staff failed to handle soiled linens using safe and sanitary techniques. A resident was observed to have an acute onset of vomiting and diarrhea resulting in soiled clothing and linens. The nursing staff removed the soiled/contaminated clothing and linens, rinsed them out in the bathroom sink, and placed the wet/soiled linen onto the floor. The bathroom was shared with a roommate who utilized the sink for oral hygiene purposes and stored his/her toothbrush and glass on the sink. The roommate, subsequently developed vomiting and diarrhea, with the development of severe dehydration, resulting in hospitalization.

An Example of Severity Level 3 Non-Compliance: Actual Harm that is not Immediate Jeopardy includes but is not limited to:

- The facility failed to identify and prevent the spread of infestation when a case of scabies (i.e., a highly contagious skin condition caused by the itch mite Sarcoptes scabiei) was not diagnosed or adequately treated, and the resident was not placed on transmission-based precautions. Resident A was admitted with an undiagnosed, reddened, itchy pin-point rash which spread, became infected, and disrupted the resident's sleep. A month later, multiple residents developed a red, pin-point rash with severe itching, which was not present prior to resident A being admitted. The facility failed to identify through assessment and therefore, implement control measures to prevent the transmission of scabies among multiple residents in the facility, causing the residents physical harm. In addition to the physical harm, the residents experienced psychosocial harm due to anxiety and loss of sleep from severe itching and lack of timely diagnosis.
- The facility failed to ensure that linens were handled and processed in a manner to prevent the spread of pediculosis (i.e., head lice) after a resident (resident A) in a semi private room was diagnosed with pediculosis. Staff were aware of the presence of pediculosis, but did not handle the resident's linens or clothing appropriately, removing bed linens and placing them on the roommate's chairs and other furnishings. The resident's roommate (resident B) became infested with pediculosis. The resident's roommate was non-verbal and unable to express that he had intense itching and began to scratch himself.

An Example of Severity Level 2 Non-Compliance: No Actual Harm with Potential for more than Minimal Harm that is not Immediate Jeopardy includes but is not limited to:

- The facility failed to ensure that its staff demonstrates proper use of gloves with hand hygiene between residents to prevent the spread of infections. The nurse administered medications to a resident via a gastric tube and while wearing the same gloves proceeded to administer oral medications to another resident. The nurse did not remove the used gloves nor perform hand hygiene between the two residents.
- The facility failed to implement appropriate measures for the transport of contaminated linens. As a result, the potential exists for transmission of organisms from contaminated uniforms to residents during the delivery of care. A nursing assistant was observed removing bed linens contaminated with urine and fecal material without the use of gloves, and carrying the contaminated linens against his/her uniform down the hall to the laundry bin. The nursing assistant proceeded to assist the resident's roommate with transferring to his/her chair, and his/her uniform made contact with the resident's skin and clothing.
- The facility failed to ensure that a staff member implemented appropriate processes related to handling and storing wound care supplies. As a result, the potential existed for transmission of organisms between residents who received dressing changes. A staff member who was providing wound care, was observed to place dressing supplies on one resident's bedding and after completing the dressing change, placed the supplies, which are used for other residents, in the unit's dressing cart.

An Example of Severity Level 1 Non-Compliance: No actual harm with potential for minimal harm includes but is not limited to:

- The facility failed to ensure that the IPCP program was reviewed annually. The survey was conducted and it was determined that the facility last reviewed the IPCP at 14 months instead of annually (i.e., 12 months). There were no infection control findings outside of annual review and documentation.

POTENTIAL TAGS FOR ADDITIONAL INVESTIGATION

For staff competency concerns, refer to the following F tags:

- F725 or 726, §483.35(a),(c) for Nursing Services;
- F741, §483.40 for any Behavioral Health staff caring for residents with dementia or a history of trauma and/or post-traumatic stress disorder;
- F801, §483.60(a) for Food and Nutrition staff; and
- F839, §483.70(f), Administration for any other staff not referenced above.

If the surveyor has concerns about 1) the overuse of transmission-based ("isolation") precautions, 2) the inappropriate transferring of rooms unnecessarily; or 3) the inappropriate use of PPE such as gloves when used unnecessarily, where residents indicate they are "untouchable," dirty or unclean, review under §483.10(a)(1), F550, Resident Rights (Dignity) or §483.24, F675, Quality of Life.

For concerns related to possible involuntary seclusion, refer to §483.12 (a)(1), F603.

Data from injectable, scheduled drug tracking should be regularly reviewed and discrepancies or unusual access patterns are investigated including whether residents should be screened for exposure to bloodborne pathogens (refer to 483.45, F755, Pharmacy Services for further information on reconciliation concerns).

For concerns related to the QAA committee's responsibility to identify or correct quality deficiencies, which may include systemic infection control concerns, refer to 483.75(g)(2)(ii), F867, QAA Activities.

For concerns related to the medical director's role in responsibility for care, refer to §483.70(h), F841, Medical Director.

COVID-19 Long-Term Care Facility Guidance
April 2, 2020

The Centers for Medicare & Medicaid Services (CMS) and the Centers for Disease Control and Prevention (CDC) are issuing new recommendations to State and local governments and long-term care facilities (also known as nursing homes) to help mitigate the spread of the 2019 Novel Coronavirus (COVID-19). Long-term care facilities are a critical component of America's healthcare system. They are unique, as they serve as both healthcare providers and as full-time homes for some of the most vulnerable Americans.

In recent weeks, CMS and CDC, at President Trump's direction, have worked together to swiftly issue unprecedented targeted direction to the long-term care facility industry, including a general prohibition of visitors implemented on March 13, 2020, as well as strict infection control and other screening recommendations. However, recent observations made by CDC and CMS experts onsite in facilities have emphasized that even more must be done to universally implement this key guidance.

To provide critical, needed leadership for the Nation's long-term care facilities to prevent further spread of COVID-19, CMS and CDC are now recommending the following immediate actions to keep patients and residents safe:

1. **Nursing Homes should immediately ensure that they are complying with all CMS and CDC guidance related to infection control.**
    - In particular, facilities should focus on adherence to appropriate hand hygiene as set forth by CDC.
    - CMS has also recently issued extensive infection control guidance, including a self-assessment checklist that long-term care facilities can use to determine their compliance with these crucial infection control actions.
    - Facilities should also refer to CDC's **guidance** to long-term care facilities on COVID-19 and also use guidance on conservation of personal protective equipment (PPE) when unable to follow the long-term care facility guidance.

2. **As long-term care facilities are a critical part of the healthcare system, and because of the ease of spread in long-term care facilities and the severity of illness that occurs in residents with COVID-19, CMS urges State and local leaders to consider the needs of long-term care facilities with respect to supplies of PPE and COVID-19 tests.**
    - State and local health departments should work together with long-term care facilities in their communities to determine and help address long-term care facility needs for PPE and/or COVID-19 tests.

- **Medicare is now covering COVID-19 testing when furnished to eligible beneficiaries by certified laboratories. These laboratories may also choose to enter facilities to conduct COVID-19 testing.**

3. **Long-term care facilities should immediately implement symptom screening for all.**
   - In accordance with previous CMS guidance, *every* individual regardless of reason entering a long-term care facility (including residents, staff, visitors, outside healthcare workers, vendors, etc.) should be asked about COVID-19 symptoms and they must also have their temperature checked. An exception to this is Emergency Medical Service (EMS) workers responding to an urgent medical need. They do not have to be screened, as they are typically screened separately.
   - Facilities should limit access points and ensure that all accessible entrances have a screening station.
   - In accordance with previous CDC guidance, *every* resident should be assessed for symptoms and have their temperature checked every day.
   - Patients and residents who enter facilities should be screened for COVID-19 through testing, if available.

4. **Long-term care facilities should ensure all staff are using appropriate PPE when they are interacting with patients and residents, to the extent PPE is available and per CDC guidance on conservation of PPE.**
   - For the duration of the state of emergency in their State, all long-term care facility personnel should wear a facemask while they are in the facility.
   - Full PPE should be worn per CDC guidelines for the care of any resident with known or suspected COVID-19 per CDC guidance on conservation of PPE.
   - If COVID-19 transmission occurs in the facility, healthcare personnel should wear full PPE for the care of all residents irrespective of COVID-19 diagnosis or symptoms.
   - Patients and residents who must regularly leave the facility for care (e.g., hemodialysis patients) should wear facemasks when outside of their rooms.
   - When possible, all long-term care facility residents, whether they have COVID-19 symptoms or not, should cover their noses and mouths when staff are in their room. Residents can use tissues for this. They could also use cloth, non-medical masks when those are available. Residents should not use medical facemasks unless they are COVID-19-positive or assumed to be COVID-19-positive.

5. **To avoid transmission within long-term care facilities, facilities should use separate staffing teams for COVID-19-positive residents to the best of their ability, and work with State and local leaders to designate separate facilities or units within a facility to separate COVID-19 negative residents from COVID-19 positive residents and individuals with unknown COVID-19 status.**
   - Long-term care facilities should exercise as best as possible consistent assignment (meaning the assignment of staff to certain patients and residents) for all patients and residents regardless of symptoms or COVID-19 status. This practice can enhance staff's familiarity with their assigned patients and residents, helping them detect emerging condition changes that unfamiliar staff may not notice. The goal is to decrease the number of different staff interacting with each patient and resident as well as the number of times those staff interact

with the patient and resident. Also, staff as much as possible should not work across units or floors.

i. Long-term care facilities should redeploy existing training related to consistent assignment, and ensure staff are familiar with the signs and symptoms of COVID-19.

- Long-term care facilities should separate patients and residents who have COVID-19 from patients and residents who do not, or have an unknown status.
    i. To this end, long-term care facilities should work with State and local community leaders to identify and designate facilities dedicated to patients and residents with known COVID-19-positive and those with suspected COVID-19, ensuring they are separate from patients and residents who are COVID-19-negative;
    ii. COVID-19-positive units and facilities must be capable of maintaining strict infection control practices and testing protocols, as required by regulation;
        1. When possible, facilities should exercise consistent assignment, or have separate staffing teams for COVID-19-positive and COVID-19-negative patients.
    iii. There may be a need for some of these COVID-19-positive long-term care facilities to have the capacity, staffing, and infrastructure to manage higher intensity patients, including ventilator management;
    iv. State agencies including health departments, hospitals, and nursing home associations will have to ensure coordination among facilities to determine which facilities will have a designation and to provide adequate staff supplies and PPE; and, if possible, isolate all admitted residents (including readmissions) in their room in the COVID-19-positive facility for 14 days if their COVID-19 status is unknown; and
    v. Long-term care facilities should, to the fullest extent possible, inform residents and their families of limitations of their access to and ability to leave and re-enter the facility, as well as any requirements and procedures for placement in alternative facilities for COVID-19-positive or unknown status.

COVID-19 Long-term Care Facility - Frequently Asked Questions (FAQs)
Source: QSO Letter 20-28, April 24, 2020

Surveys and Infection Control Self-Assessment

15. Q: On March 23, 2020, CMS released a memorandum on "Prioritization of Survey Activities" (QSO memorandum 20-20-All). Can you summarize the intent of this memorandum?

A: During the COVID-19 pandemic, CMS is prioritizing the types of surveys that state and federal surveyors will conduct. Specifically, we are focusing our oversight to protect nursing home residents from the most serious types of noncompliance, called "Immediate Jeopardy." These are situations where residents are at risk for imminent danger for serious injury or death. This includes situations regarding resident abuse, or a nursing home's failure to provide the appropriate clinical care that is likely to cause serious harm to residents. We are also focusing on protecting residents from COVID-19 through a new survey that assesses a facility's infection control preparedness using the latest guidance from the CDC and CMS. This survey allows surveyors to focus on the critical items needed to prevent the spread of COVID-19. Surveyors are instructed to spend as little time onsite as possible, and review as much as possible offsite, such as a facility's infection control or emergency preparedness policies. If surveyors identify potential situations that may constitute immediate jeopardy during these focused surveys, they will investigate them. Otherwise, surveyors should not be spending time onsite investigating noncritical or routine issues. This survey prioritization, including the suspension of standard surveys, will continue until CMS provides notification of any changes or the PHE ends.

16. Q: The CMS memorandum on the Prioritization of Survey Activities (QSO memorandum 20-20-All), including a new focused infection control survey process that facilities can use as a self-assessment form. What is CMS' expectation for the voluntary COVID-19 infection prevention and control self-assessment?

A: If an onsite survey is conducted, surveyors may ask facilities for their self-assessment, but they will still conduct their own assessment using the **focused survey process** noted in the memorandum. Since several types of surveys have been currently suspended, the number of facilities that would normally be surveyed is limited. In light of this, we urge nursing homes to complete the self-assessment to help ensure they are prepared to prevent the transmission of COVID-19. State agencies may call facilities to ask if they've completed the self-assessment. CMS has also encouraged residents and families to ask the nursing home if they've completed the self-assessment, and what the results are.

17. **Q: Does the self-assessment count as an official survey?**
    A: No. The self-assessment is a way for nursing homes to prepare themselves to prevent the spread of COVID-19. Surveyors may call facilities to remind them to conduct the self-assessment, or ask for their results. While these results are not entered into the CMS system as an official survey, we urge nursing homes to conduct the self-assessment, and remind them that they are responsible for complying with essential health and safety standards to keep residents safe. CMS has also encouraged residents and families to ask the nursing home if they've completed the self-assessment, and what the results are.

18. **Q: Should nursing homes screen surveyors as they enter the building?**
    A: Nursing homes may screen state or federal surveyors prior to entering nursing homes, but as stated in the **QSO-20-14-NH (REVISED)** memo, "*CMS and state survey agencies are constantly evaluating their surveyors to ensure they don't pose a transmission risk when entering a facility. For example, surveyors may have been in a facility with COVID-19 cases in the previous 14 days, but because they were wearing PPE effectively per CDC guidelines, they pose a low risk to transmission in the next facility, and must be allowed to enter. However, there are circumstances under which surveyors should still not enter, such as if they have a fever.*"

19. **Q: Section four of the COVID-19 Focused Survey for Nursing Homes tool includes a probe under Infection Surveillance of: *"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, vital signs are taken per shift), respiratory illness, and/or other signs/symptoms of COVID-19 and immediately isolate anyone who is symptomatic?"* Does this mean that blood pressure must be checked every shift on every resident?**
    A: Section four, infection surveillance, of the COVID-19 Focused Survey for Nursing Homes tool is referring to the surveillance required to identify cases of COVID-19 and does not necessarily require blood pressure monitoring of each resident in the facility on every shift. Individual resident assessments should be resident-centered, focused on the individual resident's current health status, and balanced on the need for assessment data with risk of disease transmission. Practitioners have the discretion regarding which residents require their blood pressure to be taken every shift. Facilities should designate vital sign equipment (including blood pressure cuff) to either individual residents or to specific wings or units, and clean and disinfect appropriately according to the equipment and disinfectant manufacturers' instructions, using an Environmental Protection Agency (EPA)-registered hospital-grade disinfectant.

Infection Control

F880

The LTC Facility Self-Assessment Worksheet

This 2019 Nursing Home Infection Control Worksheet (ICWS) is a collaborative effort by CMS and CDC and meant to be used by facilities as a self-assessment tool. It comprises both regulatory requirements and best practices in infection prevention and control. A facility that uses this ICWS will identify gaps in practice and have a "roadmap" that can lead to an improved infection prevention and control program. *(Source: QSO Letter 20-03, November 22, 2019)*

Table of Contents

The LTC Facility Self-Assessment Worksheet

Section A	Infection Prevention and Control Program (IPCP) Infrastructure	Assessments	Comments
A.1.	The facility has written infection prevention and control policies and procedures which are based on current nationally recognized evidence-based guidelines (e.g., CDC/HICPAC), regulations or standards for its Infection Prevention and Control Program (IPCP).	□ Yes □ No	
A.2.	The facility has evidence of mandatory personnel infection prevention and control training which includes the IPCP written standards, policies, and procedures.	□ Yes □ No	
A.3.	The facility has documentation of a facility infection control risk assessment conducted according to infection control professional organizations (e.g., APIC, SHEA) guidelines.	□ Yes □ No	
A.4.	Facility has documentation of an **annual** review of the IPCP using a risk assessment of both facility and community risks and updates the program as necessary.	□ Yes □ No	
Section B	**Infection Preventionist**	**Assessments**	**Comments**
B.1.	The facility has designated one or more individuals with initial and maintain ongoing specialized training in infection prevention and control as the Infection Preventionist (IP). This individual works at least part-time in the facility. ***Examples*** *of specialized training may include: Participation in infection control courses organized by the state or recognized professional societies (e.g., APIC, SHEA, state/local health department, CDC).* A free online and on- demand infection prevention and control training titled "Nursing Home Infection Preventionist Training Course" is available on CDC's TRAIN website (https://www.train.org/cdctrain/training_plan/3814).	□ Yes □ No	
B.2.	There is written evidence that the IP is a member of the facility's quality assessment and assurance committee and reports to the committee on a regular basis.	□ Yes □ No	
Section C	**Quality Assessment and Assurance (QAA) Committee**	**Assessment**	**Comments**
C.1.	The IP has provided documentation of incidents of communicable disease and infections identified under the facility's IPCP to the QAA Committee.	□ Yes □ No	
C.2.	The facility's written QAA Committee plan includes monitoring and evaluation of the activities of the IPCP.	□ Yes □ No	
C.3.	There is evidence that the QAA Committee develops plans of action to address incidents of communicable disease identified during review of infection surveillance, staff adherence to infection prevention practices, and antibiotic stewardship data provided by the IP.	□ Yes □ No	
C.4.	Adverse events related to breaches in infection prevention practices are analyzed using root cause analysis (RCA) in order to promote sustainable practice improvements throughout the facility.	□ Yes □ No	

Section D	Infection Surveillance http://www.cdc.gov/nhsn/ltc/	Assessment	Comments
D.1.	The facility has a written surveillance plan, based on the risk assessment, outlining activities for monitoring/tracking infections occurring in residents of the facility.	□ Yes □ No	
D.2.	The facility has system in place for early detection and management of potentially infectious symptomatic residents at the time of admission, including implementation of precautions as appropriate ***Examples:*** *Documenting recent antibiotic use, and history of infections or colonization with C. difficile or antibiotic-resistant organisms.*	□ Yes □ No	
D.3.	The facility has a system in place (e.g., notification of IP by clinical laboratory) for early detection and management of potentially infectious symptomatic residents, including implementation of precautions as appropriate.	□ Yes □ No	
D.4.	The facility surveillance practices include: a. Use of published surveillance criteria (e.g., CDC National Healthcare Safety Network (NHSN) Long Term Care Criteria) to define infections. b. Use of a data collection tool. c. Report to QAA (e.g., quarterly). d. Follow-up activity in response to surveillance data (e.g., outbreaks). e. Report summarizing surveillance data annually.	□ Yes □ No □ Yes □ No □ Yes □ No □ Yes □ No □ Yes □ No	
D.5.	The facility has a current list of communicable diseases which are reportable to local/state public health authorities.	□ Yes □ No	
D.6.	The facility staff can demonstrate knowledge of when and to whom to report communicable diseases, healthcare associated infections (as appropriate), and potential outbreaks.	□ Yes □ No	
Section E	**Antibiotic Stewardship Programs** http://www.cdc.gov/longtermcare/prevention/antibiotic-stewardship.html	**Assessments**	**Comments**
E.1.	The facility has an antibiotic stewardship program that has been approved by the governing body (e.g., facility administrator and facility leadership) to improve antibiotic use.	□ Yes □ No	
E.2.	The facility IP is responsible for ensuring the antibiotic stewardship program is implemented, and the facility has identified one or more clinical leaders accountable for antibiotic stewardship-related duties as per their position description (e.g., nursing director, medical director, or consultant pharmacist).	□ Yes □ No	
E.3.	The facility has written protocols on antibiotic prescribing. ***Note:*** *The intent is to verify appropriateness based on clinical indications and laboratory findings, duration of use, and national standards.*	□ Yes □ No	

Section E	Antibiotic Stewardship Programs http://www.cdc.gov/longtermcare/prevention/antibiotic-stewardship.html	Assessments	Comments
E.4.	The facility uses infection assessment tools or management algorithms for antibiotic use for one or more infections. *Examples: Use of an SBAR tool for UTI assessment, application of the Loeb minimum criteria for initiation of antibiotics.*	□ Yes □ No	
E.5.	The facility has a report summarizing antibiotic use from pharmacy data created within last 3 months. *Note: Report could include number of new starts, types of drugs prescribed, or number of days of antibiotic treatment per 1,000 resident days.*	□ Yes □ No	
E.6.	The facility has a report summarizing antibiotic resistance (i.e. antibiogram) based on laboratory data created within the past 18 months.	□ Yes □ No	
E.7.	The facility clinical leadership (e.g., medical director, director of nursing, infection preventionist, or consulting pharmacist) provides clinical prescribers with feedback about their antibiotic prescribing practices.	□ Yes □ No	
E.8.	The facility clinical leadership (e.g., medical director, director of nursing, infection preventionist, or consulting pharmacist) has provided training on antibiotic use (stewardship) to all nursing staff and clinical providers with prescribing privileges within the last 12 months.	□ Yes □ No	
E.9.	The facility has educational materials on antibiotic stewardship for residents and families.	□ Yes □ No	
Section F	**Hand Hygiene**	**Assessments**	**Comments**
F.1.	*The facility hand hygiene policies promote preferential use of alcohol-based hand rub (ABHR) over soap and water in most clinical situations.* ***Note**: Soap and water should be used when hands are visibly soiled (e.g., blood, body fluids) and is also preferred after caring fora patient with known or suspected C. difficile or norovirus during an outbreak, or if rates of C. difficile infection in the facility are persistently high.*	□ Yes □ No	
F.2.	All personnel receive training **and competency** validation on HH at the time of employment.	□ Yes □ No	
F.3.	All personnel receive training and **competency validation** on HH at least every 12 months.	□ Yes □ No	

Section F	Hand Hygiene	Assessments	Comments
F.4.	The facility audits (monitors and documents) HH adherence and provides feedback among the following: a. Nursing staff including RNs, LPN, and CNAs b. Therapy staff (e.g., PT, OT, speech) c. Clinical staff including physicians, NPs, PAs d. Dietary and nutrition including food-preparers e. Environmental services personnel f. Contract staff (e.g., dialysis staff, physical therapy, respiratory therapy, phlebotomy, wound care physician, podiatrist)	□ Yes □ No □ Yes □ No □ Yes □ No □ Yes □ No □ Yes □ No □ Yes □ No	
F.5.	Facility has written and implemented a resident HH policy (e.g., HH performed immediately before meals).	□ Yes □ No	
	Hand Hygiene Tracer Hand hygiene is performed in a manner consistent with the LTC facility infection control practices, policies, and procedures to maximize the prevention of infection and communicable disease including the following: ***Note:*** *Observations for compliance with hand hygiene elements should be assessed throughout the facility.*		
F.6.	Soap, water, and a sink are readily accessible inappropriate locations including, but not limited to, resident care areas, food and medication preparation areas. ***Note:*** *Resident care supplies should be protected from splashing water if located close to sinks.*	□ Yes □ No	
F.7.	Alcohol-based hand rub is readily accessible and placed inappropriate locations. Some examples may include: • Entrance to the facility • Entrances to resident rooms • At the bedside (as appropriate for resident population) • In individual pocket-sized containers carried by healthcare personnel • Staff workstation, and/or • Other convenient locations	□ Yes □ No	
F.8.	Personnel perform hand hygiene (even if gloves are used): a. Before contact with the resident b. Before performing antiseptic task (e.g., insertion of an invasive device (e.g., urinary catheter)	□ Yes □ No □ Yes □ No	
F.9.	Personnel perform hand hygiene: a. After contact with the resident b. After contact with blood, body fluids, or visibly contaminated surfaces c. After contact with objects and surfaces in the resident's environment d. After removing personal protective equipment (e.g., gloves, gown, facemask)	□ Yes □ No □ Yes □ No □ Yes □ No □ Yes □ No	

Section F	Hand Hygiene Tracer	Assessments	Comments
F.10.	When being assisted by healthcare personnel, resident hand hygiene is performed: a. Prior to resident leaving room if on transmission-based precautions b. After toileting c. Before meals	□ Yes □ No □ Yes □ No □ Yes □ No	
F.11.	The facility does not add soap to a partially empty soap dispenser (topping off). **Note:** Topping off can lead to bacterial contamination of the soap.	□ Yes □ No	
Section G	**Standard Precautions Tracer**	**Assessments**	**Comments**
G.1.	Supplies necessary for adherence to proper personal protective equipment (PPE) use (e.g., gloves, gowns, masks) are readily accessible in resident care areas (i.e., nursing units, therapy rooms, and resident rooms).	□ Yes □ No	
G.2.	Gloves are worn if there is contact with blood or body fluid, mucous membranes, or non-intact skin.	□ Yes □ No	
G.3.	Gloves are removed after contact with blood or body fluids, mucous membranes, or non-intact skin.	□ Yes □ No	
G.4.	Gloves are changed and hand hygiene performed before moving from a contaminated-body site to a clean-body site during resident care.	□ Yes □ No	
G.5.	Gown is worn for direct resident contact if the resident has uncontained secretions or excretions.	□ Yes □ No	
G.6.	Facemask is worn if contact with resident with new acute cough or respiratory symptoms (e.g., influenza-like illness).	□ Yes □ No	
G.7.	Appropriate mouth, nose and eye protection (e.g., facemasks, face shield) is worn for performing aerosol-generating and/or procedures that are likely to generate splashes or sprays of blood or body fluids.	□ Yes □ No	
G.8.	PPE is appropriately discarded after resident care prior to leaving room, followed by hand hygiene.	□ Yes □ No	
Section H	**Transmission-Based Precautions**	**Assessments**	**Comments**
H.1.	The facility has policies and procedures for transmission-based precautions (TBP) (i.e., Contact Precautions, Droplet Precautions, Airborne Isolation Precautions) to be followed to prevent spread of infections; which includes selection and use of PPE (e.g., indications, donning/doffing procedures) and specifies the clinical conditions for which specific PPE should be used (e.g., *C. difficile,* influenza).	□ Yes □ No	

Section H	Transmission-Based Precautions	Assessments	Comments
H.2.	Residents with known or suspected infections, or with evidence of symptoms that represent an increased risk for transmission, are placed on the appropriate TBP. Note: Resident placement (e.g., single/private room or cohorted) is made on an individual case basis based on presence of risk factors for increased likelihood of transmission (e.g., uncontained drainage, stool incontinence). **Note**: Facility should have a process to manage residents on TBP when no single/private room is available.	□ Yes □ No	
H.3.	The facility limits the movement of residents (in accordance with policies) on TBP with active symptoms [diarrhea, nausea and vomiting, draining wounds that cannot be contained for highly infectious diseases (e.g., norovirus, C. difficile, MDRO)] outside of their room for medically necessary purposes only.	□ Yes □ No	
H.4.	Facility has written policies and procedures to ensure that after resident discharge, all visibly or potentially contaminated surfaces are thoroughly cleaned and disinfected, and all linens and towels (e.g., textiles) are replaced. **Note**: Privacy curtains should be changed or cleaned with an EPA-registered disinfectant after discharge.	□ Yes □ No	
	Transmission-Based Precautions Tracer	**Assessments**	**Comments**
H.5.	Signs indicating a resident is on TBP and required PPE are clear and visible on the door or next to the door.	□ Yes □ No	
H.6.	Staff are able to successfully verbalize the PPE required before entering a resident's room.	□ Yes □ No	
H.7.	Hand hygiene is performed before entering resident care environment.	□ Yes □ No	
H.8.	Gloves and gowns are donned upon entry into the environment (e.g., room or cubicle) of resident on Contact Precautions.	□ Yes □ No	
H.9.	Dedicated or disposable noncritical resident-care equipment (e.g., blood pressure cuffs) is used, or if not available, then equipment is cleaned and disinfected according to manufacturers' instructions prior to use on another resident.	□ Yes □ No	
H.10.	Gloves and gowns are removed and properly discarded, and hand hygiene is performed before leaving the resident care environment. ***Note:*** *Although preferred for most clinical circumstances, ABHR is not appropriate when hands are visibly soiled (e.g., blood, body fluids) or after caring for a resident with known or suspected C. difficile or norovirus during an outbreak or if endemicrates of C. difficile infection (CDI) are high. In these circumstances, soap and water should be used.*	□ Yes □ No	

Section H	Transmission-Based Precautions Tracer	Assessments	Comments
H.11.	In rooms with residents on Contact Precaution, objects and environmental surfaces that are touched frequently (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 use at least daily and when visibly soiled.	□ Yes □ No	
Section I	**Injection Practices and Sharps Safety (Medications and Infusates) Tracer**	**Assessments**	**Comments**
I.1.	Appropriate personnel receive training **and competency validation** on injection safety procedures at time of employment.	□ *Yes* □ *No*	
I.2.	Appropriate personnel receive training **and competency validation** on injection safety procedures at least every 12 months.	□ *Yes* □ *No*	
I.3.	The facility audits (monitors and documents) and provides feedback to personnel regarding their adherence to injection safety practices ***Note**: If yes, facility should provide documentation of audits.*	□ *Yes* □ *No*	
I.4.	The facility has policies and procedures to monitor and track personnel with access to injectable controlled substances to prevent potential transmission of infections secondary to contamination of syringes and medication vials. Note: this question highlights the relationship between narcotics theft/drug diversion and contaminated syringes and medication vials.	□ Yes □ No	
I.5.	Injections are prepared using clean (aseptic) technique in an area that has been cleaned and is free of contamination (e.g., visible blood or body fluids). ***Note:** Clean technique includes performing hand hygiene before injection or medication preparation.*	□ Yes □ No	
I.6.	Needles are used for only one resident.	□ Yes □ No	
I.7.	Syringes are used for only one resident (this includes manufactured prefilled syringes).	□ Yes □ No	
I.8.	Insulin pens are used for only one resident.	□ Yes □ No	
I.9.	The rubber septum on any mediation vial, whether unopened or previously accessed, are disinfected with alcohol prior to piercing.	□ Yes □ No	
I.10.	Medication vials are entered with a new needle. ***Note:** Reuse of syringes and/or needles to enter a medication vial contaminates the contents of the vial, making the vial unsafe for use on additional residents.*	□ Yes □ No	
I.11.	Medication vials are entered with a new syringe. ***Note:** Reuse of syringes and/or needles to enter a medication vial contaminates the contents of the vial, making the vial unsafe for use on additional residents.*	□ Yes □ No	

Section I	Injection Practices and Sharps Safety (Medications and Infusates) Tracer	Assessments	Comments
I.12.	Medication vial labeled for single dose is only used only once and for only one resident.	□ Yes □ No	
I.13.	Bags of IV solutions are used for only one resident (and not as a source of flush solution for multiple residents).	□ Yes □ No	
I.14.	Medication administration tubing and connectors are used for only one resident.	□ Yes □ No	
I.15.	Multi-dose medication vials are dated when they are first opened and discarded within 28 days unless the manufacturer specifies a different (shorter or longer) date for that opened vial. ***Note:*** *The beyond-use date is different from the expiration date for the vial. The multi-dose vial can be dated with either the date opened or the discard date as per facility policy, as long as it is clear what the date represents and the same policy is used consistently throughout the facility.*	□ Yes □ No	
I.16.	Multi-dose medication vials used for more than one resident are stored appropriately and do not enter the immediate resident care area (e.g. procedure rooms, resident room). ***NOTE****: If multi-dose vials enter the immediate resident care area, they must be dedicated for single resident use and discarded immediately after use*.	□ Yes □ No	
I.17.	All sharps are disposed of in puncture-resistant sharps containers.	□ Yes □ No	
I.18.	Sharps containers are replaced when the fill line is reached.	□ Yes □ No	
I.19.	Sharps containers are disposed of appropriately as medical waste.	□ Yes □ No	
Section J	**Point-of-Care Devices (e.g., Blood Glucose Meter, INR Monitor) Tracer**	**Assessment**	**Comments**
J.1	Appropriate personnel receive training **and competency validation** on point of care testing procedures (e.g., during assisted blood glucose monitoring) at time of employment.	□ Yes □ No	
J.2.	Appropriate personnel receive training **and competency validation** on point of care testing procedures (e.g., during assisted blood glucose monitoring) at least every 12 months.	□ Yes □ No	
J.3.	Supplies necessary for adherence to safe point-of-care testing (e.g., single- use, auto-disabling lancets, sharps containers) are readily accessible in resident care areas.	□ Yes □ No	
J.4.	Hand hygiene is performed before and after the procedure for each resident.	□ Yes □ No	
J.5.	Gloves are worn by healthcare personnel when performing the fingerstick procedure to obtain the sample of blood and are removed after the procedure (followed by hand hygiene).	□ Yes □ No	

Section J	Point-of-Care Devices (e.g., Blood Glucose Meter, INR Monitor) Tracer	Assessment	Comments
J.6.	Fingerstick devices are not used for more than one resident. ***Note**: This includes both the lancet and the lancet holding device.*	□ Yes □ No	
J.7.	If used for more than one resident, the point-of-care testing device (e.g., blood glucose meter, INR monitor) is cleaned and disinfected after every use according to device and disinfectant manufacturer's instructions. ***Note:** If manufacturer does not provide instructions for cleaning and disinfection, then the device should not be used for >1 resident.*	□ Yes □ No	
J.8.	The facility has protocols for performing fingersticks and point-of-care testing (e.g., assisted blood glucose monitoring).	□ Yes □ No	
J.9.	The facility audits (monitors and documents) and provides feedback to personnel regarding their adherence to point-of-care testing practices.	□ Yes □ No	
Section K	**Central Venous Line/Catheters: Accessing and Maintenance Tracer**	**Assessment**	**Comments**
K.1.	Only properly trained personnel who demonstrate competence for access and maintenance of central venous catheters are given this responsibility.	□ Yes □ No	
K.2.	Central venous line/catheter insertion date and indication are documented.	□ Yes □ No	
K.3.	Hand hygiene is performed before and after manipulating catheter.	□ Yes □ No	
K.4.	Central line dressings are observed to be clean, dry, and intact.	□ Yes □ No	
K.5.	Dressing is changed with clean (aseptic)technique using clean gloves or sterile gloves.	□ Yes □ No	
K.6.	Access port is scrubbed with an appropriate antiseptic (chlorhexidine, povidoneiodine, iodophor, or 70% alcohol) prior to accessing.	□ Yes □ No	
K.7.	Catheter is accessed only with sterile devices.	□ Yes □ No	
K.8.	Residents with central venous catheters are assessed regularly to determine continued need for the catheter and this assessment is documented in the medical record. (The central line is promptly removed when no longer needed.)	□ Yes □ No	

Section L	Indwelling Urinary Catheter Tracer	Assessment	Comments
L.1.	The attending physician/practitioner has provided a written rationale for the use of a urinary catheter consistent with evidence-based guidelines (e.g., acute urinary retention, bladder outlet obstruction, neurogenic bladder or terminally ill for comfort measures).	□ Yes □ No	
L.2.	Only trained personnel who have demonstrated competency are given the responsibility of inserting urinary catheters.	□ Yes □ No	
L.3.	Catheter is secured properly.	□ Yes □ No	
L.4.	Catheter insertion date and indication are documented.	□ Yes □ No	
Section M	**Urinary Catheter Access and Maintenance Tracer**	**Assessment**	**Comments**
M.1.	Only trained personnel who have demonstrated competency are given the responsibility of maintaining and removing urinary catheters.	□ Yes □ No	
M.2.	Hand hygiene is performed before and after manipulating the urinary catheter and gloves are worn.	□ Yes □ No	
M.3.	Urine collection bag is kept below the level of the bladder and off the floor at all times.	□ Yes □ No	
M.4.	Urinary catheter tubing is unobstructed and free of kinking.	□ Yes □ No	
M.5.	Urine bag is emptied using a separate, clean collection container for each resident; drainage spigot does not touch collecting container.	□ Yes □ No	
M.6.	Urine samples are obtained via needleless port and not obtained from the collection bag.	□ Yes □ No	
M.7.	Residents with indwelling urinary catheters are assessed regularly for continued need for the catheter, and the need is documented. The attending physician/practitioner has documented a valid clinical indication for the use of the catheter and ongoing assessment and orders for the removal when the clinical condition demonstrates that catheterization is no longer necessary. The written rationale for the use of a urinary catheter is consistent with evidence-based guidelines (e.g. acute urinary retention, bladder outlet obstruction, neurogenic bladder or terminally ill for comfort measures).	□ Yes □ No Yes □ No	

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Section N	Respiratory Therapy Tracer	Assessment	Comments
N.1.	Hand hygiene is performed before and after contact with a resident or any respiratory equipment used on the resident.	□ Yes □ No	
N.2.	Gloves are worn when in contact with respiratory secretions and changed before contact with another resident, object, or environmental surface.	□ Yes □ No	
N.3.	Only sterile solutions (e.g. water or saline) are used for nebulization.	□ Yes □ No	
N.4.	Single-dose vials for aerosolized medications are not used for more than one resident.	□ Yes □ No	
N.5.	If multi-dose vials for aerosolized medications are used, manufacturers' instructions for handling, storing, and dispensing the medications are followed.	□ Yes □ No	
N.6.	If multi-dose vials for aerosolized medications are used for more than one resident, they are stored appropriately and do not enter the immediate resident treatment area.	□ Yes □ No	
N.7.	Jet nebulizers are for single resident use and are cleaned and stored as per facility policy, rinsed with sterile water, and air-dried between treatments on the same resident. ***Note:*** *Mesh nebulizers which remain in the ventilator circuit and are not cleaned or disinfected are changed at an interval recommended by manufacturer's instructions. Nebulizers/drug combination systems are cleaned and disinfected according to the manufacturer's instructions.*	□ Yes □ No	
N.8.	The head of the bed is elevated at an angle of 30-45°, in the absence of medical contraindications, for residents at high risk for aspiration (e.g. resident with an enteral tube in place).	□ Yes □ No	

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Section O	Wound Management Tracer	Assessment	Comments
O.1.	Hand hygiene is performed before a wound procedure.	□ Yes □ No	
O.2.	Gloves are worn during the wound dressing procedure.	□ Yes □ No	
O.3.	Face protection (e.g., goggles and facemask, or a face shield) is worn during wound care procedures that may generate splashes or aerosols such as irrigation, pulse lavage, and handling of equipment such as vacuum-assisted closure devices.	□ Yes □ No	
O.4.	A gown is worn if healthcare personnel contamination is anticipated during the dressing procedure (e.g. large or excessively draining wounds).	□ Yes □ No	
O.5.	Reusable dressing care equipment (e.g., bandage scissors) must be cleaned and reprocessed (i.e., disinfected or sterilized according to manufacturer's instructions) if shared between residents. Refer to current CDC guidelines. CDC Guideline for Disinfection and Sterilization in Healthcare Facilities,2008 https://www.cdc.gov/hicpac/Disinfection_Sterilization/6_0disinfection.html	□ Yes □ No	
O.6.	Clean wound dressing supplies (e.g. gauze, measure tape) are handled in a way to prevent cross contamination between residents (e.g., wound care supply cart which remains outside of resident care areas; unused supplies are not returned to the clean supply cart but either discarded or remain dedicated to resident; supplies on the cart should only be handled by individuals with clean hands).	□ Yes □ No	
O.7.	The dressing change is conducted per physician/practitioner orders.	□ Yes □ No	
O.8.	Multi-dose wound care medications (e.g., ointments, creams) should be dedicated to one resident whenever possible. Dedicated containers should be properly labeled and stored. ***NOTE**: If multi-dose wound care medications (e.g., ointments, creams) are used for more than one resident, then the medications should be stored in a central medication area and should not enter the resident treatment area. For example, a small aliquot of medication should be dispensed into a clean container for single-resident use. Any medication container entering a resident's care area should be dedicated for that single-resident use.*	□ Yes □ No	
O.9.	Gloves are removed and hand hygiene is performed immediately after the procedure.	□ Yes □ No	
O.10.	Wound care documentation in resident's medical record reflects the condition of the wound and includes the following: a. Type of dressing b. Frequency of dressing change c. Wound description (e.g., measurement, characteristics)	□ Yes □ No □ Yes □ No □ Yes □ No	

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Section P	Cleaning and Disinfection of Environmental Surfaces and Reusable Equipment	Assessment	Comments
P.1.	The facility has cleaning/disinfection policies which include routine and terminal cleaning and disinfection of resident rooms, and high-touch surfaces in common areas. ***Note:*** *Privacy curtains should be changed when visibly soiled.*	□ Yes □ No	
P.2.	The facility cleaning/disinfection policies include handling of equipment shared among residents (e.g., blood pressure cuffs, rehab therapy equipment, etc.) **Note**: Personnel can verbalize who is responsible for cleaning and disinfection of sharedequipment	□ Yes □ No	
P.3.	Facility has policies and procedures to ensure that reusable medical devices (e.g., wound care equipment, podiatry equipment, and dental equipment) are cleaned and reprocessed appropriately prior to use on another resident. ***Note:*** *If external consultants (e.g., wound care nurses, dentists or podiatrists) provide services, verify these providers have adequate supplies and space to follow appropriate cleaning/disinfection (reprocessing) procedures to prevent transmission of infectious agents.*	□ Yes □ No	
P.4.	Appropriate personnel receive job-specific training and competency validation on cleaning and disinfection procedures at the time of employment and within the past 12 months. ***Note:*** *If environmental services are performed by contract personnel, verify that training is provided by contracting company.*	□ Yes □ No	
P.5.	The facility audits (monitors and documents) and provides feedback to personnel regarding the quality of cleaning and disinfection procedures.	□ Yes □ No	
P.6.	Supplies necessary for appropriate cleaning and disinfection procedures (e.g., EPA-registered for use in healthcare facilities, including products labelled as effective against *C. difficile* and norovirus) are available and used according to manufacturer instructions for use. ***Note:*** *If environmental services are performed by contract personnel, verify that appropriate EPA-registered products are provided by contracting company.*	□ Yes □ No	

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Section Q	Healthcare Personnel Safety	Assessment	Comments
Q.1.	The facility has policies prohibiting contact with residents or their food when personnel have potentially communicable diseases or infected skin lesions.	□ Yes □ No	
Q.2.	The employee health policies address the following: a. Work-exclusion policies that encourage reporting of illnesses. b. Education of personnel on prompt reporting of illness to supervisor and/or employee health.	□ Yes □ No □ Yes □ No	
Q.3.	The facility based on federal guidelines and applicable state law, has a written policy to provide personnel TB screening.	□ Yes □ No	
Q.4.	The facility has a protocol for monitoring and evaluating clusters or outbreaks of illness among healthcare personnel.	□ Yes □ No	
Q.5.	The facility has an exposure control plan which address potential hazards posed by specific services provided by the facility (i.e., OSHA requirement for bloodborne pathogens).	□ Yes □ No	
Q.6.	All personnel receive training and competency validation on managing a bloodborne pathogen exposure at the time of employment and at least every 12 months.	□ Yes □ No	
Section R	**Respiratory Disease Prevention [(e.g. Pneumococcal, Influenza and Tuberculosis (TB)]**	**Assessment**	**Comments**
R.1.	The facility has a written policy to assess risk for TB (based on local health department data) and provide screening to residents on admission.	□ Yes □ No	
R.2.	The resident's medical record includes documentation of TB screening on admission.	□ Yes □ No	
R.3.	The facility has a written policy that requires family and visitors take appropriate precautions if they are having symptoms of respiratory infection during their visit.	□ Yes □ No	
R.4.	Signs are posted at the entrances with instructions to individuals with symptoms of respiratory infection to: cover their mouth/nose when coughing or sneezing, use and dispose of tissues, and perform hand hygiene after contact with respiratory secretions. ***Note:*** *See CDC website for examples of signage.*	□ Yes □ No	
R.5	The facility provides resources for performing hand hygiene (i.e., alcohol-based hand rub) near the entrance and in common areas.	□ Yes □ No	
R.6	The facility has policy to provide facemasks to residents with a new cough and other symptomatic persons upon entry to the facility.	□ Yes □ No	

Section R	Respiratory Disease Prevention [(e.g. Pneumococcal, Influenza and Tuberculosis (TB)]	Assessment	Comments
R.7.	All personnel receive education the at the time of employment and at least every 12 months on the importance of infection prevention measures to contain respiratory secretions to prevent the spread of respiratory pathogens.	□ Yes □ No	
R.8.	The facility documents resident immunization status for pneumococcal and influenza vaccination at time of admission (or as required by per state law). ***Note:*** *The process by which a facility determines resident immunization status may include information provided by the resident/or family member healthcare designated power of attorney.*	□ Yes □ No	
R.9.	The resident's medical record includes documentation that indicates (at a minimum) either the resident received the pneumococcal immunizations, or the resident refused or had a contraindication to one or both pneumococcal vaccinations.	□ Yes □ No	
R.10.	The resident's medical record includes documentation that an influenza immunization is offered annually. ***Note:*** *The resident or the resident's representative has the opportunity to refuse influenza immunization.*	□ Yes □ No	
R.11	Facility has policy and procedures to ensure the resident or resident's representative receives education regarding benefits and potential side effects of each immunization.	□ Yes □ No	
Section S	**Linen Management**	**Assessment**	**Comments**
S.1.	Personnel handle soiled linens with minimum agitation to avoid contamination of the environment.	□ Yes □ No	
S.2.	Soiled linens are bagged or otherwise contained at the point of collection in leak-proof containers or bags and are not sorted or rinsed in the location of use. ***Note:*** *Covers are not needed on contaminated textile hampers in resident care areas.*	□ Yes □ No	
S.3.	The receiving area for contaminated/soiled linen is clearly separated from clean laundry areas. ***Note:*** *Workflow should prevent cross contamination (i.e., If fans are used the ventilation should not flow from dirty to clean laundry areas).*	□ Yes □ No	
S.4.	If facility laundry services are contracted out and performed offsite, the contractor must show evidence that the laundry service meets healthcare industry laundry standards.	□ Yes □ No	
S.5.	Clean linen are packaged, transported, and stored in a manner that ensures cleanliness and protection from contamination (e.g., dust and soil).	□ Yes □ No	

Section S	Linen Management	Assessment	Comments
S.6.	The facility should be using the fabric manufacturer's recommended laundry cycles, water temperatures, and chemical/detergent products.	□ Yes □ No	
S.7.	The facility has handwashing stations and PPE (e.g., gloves, gowns, and aprons) in areas where non-bagged, soiled linen is handled.	□ Yes □ No	
S.8.	The facility has a policy for cleaning and disinfecting linen carts on the premises or for cart exchange off the premises.	□ Yes □ No	
Section T	**Infection Prevention, Antibiotic Stewardship, and Responsibility of Care During Care Transitions**	**Assessment**	**Comments**
T.1.	When transferring a resident to another facility, the LTC facility has a process that resident documentation is sent to the receiving facility providers includes direct contact information [name, phone number, email] for the resident's treating clinician (MD, APN, PA), transferring nursing unit and case manager(if applicable) before or at the time of transfer . **CDC sample transfer forms:** https://www.cdc.gov/hai/prevent/prevention_tools.html	□ Yes □ No	
T.2.	The LTC facility has a process and ensures that documentation of resident infection, colonization or known history of positive culture with multidrug-resistant organism, *C. difficile,* or other epidemiologically important organism (e.g. scabies)is sent to receiving provider (e.g., hospital)before or at the time of transfer.	□ Yes □ No	
T.3.	The LTC facility has a process and ensures that documentation of the presence of clinical signs or symptoms of potentially communicable diseases (e.g., vomiting, diarrhea, cough) is sent to receiving provider before or at the time of transfer.	□ Yes □ No	
T.4.	The LTC facility has a process and ensures that communication of critical information regarding central lines and urinary catheters (i.e., insertion date, rationale), or other medical devices, is sent to receiving provider before or at the time of transfer.	□ Yes □ No	
T.5.	The LTC facility has a process and ensures that communication of the rationale and use of transmission-based precautions/PPE is sent to receiving provider before or at the time of transfer (e.g., C. difficile with diarrhea).	□ Yes □ No	
T.6.	The LTC facility has a process and ensures that communication of current or recent (i.e., within past 7 days) antibiotic use, which includes dose, route, indication, start date/stop date, and date and time of last antibiotic administered is sent to receiving provider before or at the time of transfer.	□ Yes □ No	

Section T	Infection Prevention, Antibiotic Stewardship, and Responsibility of Care During Care Transitions	Assessment	Comments
T.7.	The LTC facility verifies that critical medications and equipment are available at the receiving facility (e.g., critical access hospital) at the time of transfer to prevent disruptions in the continuity of care (e.g., IV antibiotics and administration equipment).	□ Yes □ No	
T.8.	The LTC facility has a process to send additional information about potentially transmissible infections, resistant organisms, and antibiotic use if missing or unavailable at the time of resident transfer to the hospital.	□ Yes □ No	
T.9.	The LTC facility ensures that essential resident information about potentially transmissible infections, resistant organisms, and antibiotic use is reviewed and addressed (e.g., TBP) at the time of arrival from a hospital.	□ Yes □ No	
Section U	**Water Management Program**	**Assessment**	**Comments**
U.1.	The facility has a water management program based on national guidelines and toolkits [e.g., The American Society of Heating, Refrigerating and Air-Conditioning Engineers (ASHRAE), The Centers for Disease Control and Prevention (CDC), and United States Environmental Protection Agency (EPA)] including control measures such as physical controls, temperature management, disinfectant level control, and visual inspections for biofilm, slime, scale, and sediment.	□ Yes □ No	
U.2.	The facility conducts, as a part of the water management program, a risk assessment to identify where Legionella and other opportunistic waterborne pathogens could grow and spread in the facility water system.	□ Yes □ No	
U.3.	The facility's water management program specifies testing protocols and acceptable ranges for control measures and documents the results of testing and corrective actions taken when control limits are not maintained.	□ Yes □ No	

F884 – COVID-19 Reporting Requirements

Effective May 8, 2020

§483.80 Infection control.

§483.80(g) *COVID-19 reporting*. The facility must--

(1) Electronically report information about COVID-19 in a standardized format specified by the Secretary. This report must include but is not limited to—

(i) Suspected and confirmed COVID-19 infections among residents and staff, including residents previously treated for COVID-19;

(ii) Total deaths and COVID-19 deaths among residents and staff;

(iii) Personal protective equipment and hand hygiene supplies in the facility;

(iv) Ventilator capacity and supplies in the facility;

(v) Resident beds and census;

(vi) Access to COVID-19 testing while the resident is in the facility;

(vii) Staffing shortages; and

(viii) Other information specified by the Secretary.

(2) Provide the information specified in paragraph (g)(1) of this section at a frequency specified by the Secretary, but no less than weekly to the Centers for Disease Control and Prevention's National Healthcare Safety Network. This information will be posted publicly by CMS to support protecting the health and safety of residents, personnel, and the general public.

F885 – Notifying Residents, Representatives, and Family of COVID-19 Cases

Effective May 8, 2020

§483.80(g)(3) - Inform residents, their representatives, and families of those residing in facilities by 5 p.m. the next calendar day following the occurrence of either a single confirmed infection of COVID-19, or three or more residents or staff with new-onset of respiratory symptoms occurring within 72 hours of each other. This information must—

(i) Not include personally identifiable information;

(ii) Include information on mitigating actions implemented to prevent or reduce the risk of transmission, including if normal operations of the facility will be altered; and

(iii) Include any cumulative updates for residents, their representatives, and families at least weekly or by 5 p.m. the next calendar day following the subsequent occurrence of either: each time a confirmed infection of COVID-19 is identified, or whenever three or more residents or staff with new onset of respiratory symptoms occur within 72 hours of each other.