



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

Ref: QSO-20-12-All

DATE: March 4, 2020
TO: State Survey Agency Directors
FROM: Director
Quality, Safety & Oversight Group
SUBJECT: Suspension of Survey Activities

Memorandum Summary

- *CMS is committed* to taking critical steps to ensure America's health care facilities are prepared to respond to the threat of the 2019 Novel Coronavirus (COVID-19).
- 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 COVID-19 and other respiratory illnesses.

Background

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 and other respiratory illness. Specifically, CMS is suspending non-emergency inspections across the country, allowing inspectors to turn their focus on the most serious health and safety threats like infectious diseases and abuse. This shift in approach will also allow inspectors to focus on addressing the spread of the coronavirus disease 2019 (COVID-19). CMS is issuing this memorandum to State Survey Agencies to provide important guidelines for the inspection process in situations in which a COVID-19 is suspected.

Discussion

Effective immediately, survey activity is limited to the following (in Priority Order):

- All immediate jeopardy complaints (cases that represents a situation in which entity noncompliance has placed the health and safety of recipients in its care at risk for serious injury, serious harm, serious impairment or death or harm) and allegations of abuse and neglect;
- Complaints alleging infection control concerns, including facilities with potential COVID-19 or other respiratory illnesses;

- Statutorily required recertification surveys (Nursing Home, Home Health, Hospice, and ICF/IID facilities);
- Any re-visits necessary to resolve current enforcement actions;
- Initial certifications;
- Surveys of facilities/hospitals that have a history of infection control deficiencies at the immediate jeopardy level in the last three years;
- Surveys of facilities/hospitals/dialysis centers that have a history of infection control deficiencies at lower levels than immediate jeopardy.

Due to the dynamic nature of this situation, we will be posting updated FAQs in real-time at the following website: <https://www.cms.gov/medicare/quality-safety-oversight-general-information/coronavirus>

For survey of facilities with Complaints alleging infection control concerns, including facilities with potential COVID-19 or other respiratory illness, please refer to the attached (Attachment A- Survey Planning in Facilities with Active or Suspected Cases of COVID-19 Cases; Attachment B- Infection Prevention, Control & Immunizations).

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

Attachment A- Survey Planning in Facilities with Active or Suspected Cases of COVID-19 Cases

Attachment B- Infection Prevention, Control & Immunizations

cc: Survey and Operations Group Management

Attachment A- Survey Planning in Facilities with Active or Suspected Cases of COVID-19 Cases

I. Protocols for Coordination and Investigation of Facilities with Actual or Suspected COVID-19 Cases

When a COVID-19 confirmed case or presumptive positive case (e.g., positive local test but pending confirmatory test), is identified in a Medicare/Medicaid certified provider or supplier, State Survey Agencies and Accrediting Organizations (AO) are requested to do the following:

- Notify the appropriate CMS Regional Office (if they are not already aware) of the facility and date of patient/resident COVID-19 or presumptive respiratory illness or confirmed status;
- Coordinate on initiating any Federal complaint or recertification survey of the impacted facility until CDC (and any other relevant Federal/State/Local response agencies) have cleared the facility for survey. The CMS Regional Office will then authorize a survey, if necessary;
- Ensure surveyors have all necessary Personal Protective Equipment (PPE) appropriate to allow a survey of the facility; Refer to CDC Infection Control resources for the most up to date guidance.
- Suspend any Federal enforcement action for any deficiencies identified until reviewed and approved by the CMS Regional Office to ensure consistent and appropriate action.

These protocols will be updated as circumstances warrant. We are asking Accrediting Organizations to copy their CMS AO liaison on any communications with the CMS Regional Office.

II. Focused Surveying – Prioritizing Threats

In all cases, concerns of **Immediate Jeopardy (IJ)** (cases that represents a situation in which entity noncompliance has placed the health and safety of recipients in its care at risk for serious injury, serious harm, serious impairment or death or harm) and cases of abuse and neglect allegations from complaints will continue to receive high priority for survey. Non-emergency surveys will be suspended.

III. Survey Planning in Facilities with Active or Suspected Cases of COVID-19 Infection

Introduction: Under What Circumstances Will CMS Authorize an On-site Survey/Investigation of a Facility With Persons who are Known or Suspected of Being COVID-19 Positive

When a COVID-19 confirmed case or presumptive positive case (e.g., positive local test but pending confirmatory test), is identified in a Medicare/Medicaid certified provider or supplier,

State Survey Agencies and Accrediting Organizations must notify the appropriate CMS Regional location (if they are not already aware) of the facility and date of patient/resident COVID-19 presumptive or confirmed status.

Before initiating any Federal complaint or recertification survey of the impacted facility, CMS will coordinate with the CDC (and any other relevant Federal/State/Local response agencies) to approve the facility for survey.

The CMS Regional locations will authorize an on-site survey if reported conditions at the facility are triaged at immediate jeopardy. Immediate jeopardy means there are conditions at the facility that are causing or are likely to cause one or more recipients of care to suffer serious injury, harm, impairment or death. CMS Regional locations will also authorize on-site surveys where the complaint or facility reported incident involves infection control concerns in the facility.

If conditions at such facilities do not rise to the immediate jeopardy level, then desk audits will be performed, and on-site investigations may be authorized once all active or suspected cases of COVID-19 have been cleared from the facility.

I. Before Survey Entry

Determine survey team composition for minimal but optimal number of surveyors required to efficiently and effectively conduct the onsite observations required. Generally, one to two surveyors for an abbreviated complaint survey focusing on the COVID-19 infection control and/or quality of care issues would be sufficient. Do not include any surveyors who are currently ill or have underlying health conditions that may make them particularly vulnerable to COVID-19.

A. Personal Protective Equipment Considerations

Ensure survey team members have needed personal protective equipment (PPE) that may be required onsite to observe resident care in close quarters. If the facility has gowns, gloves, face shields or other eye protection that may be used by surveyors, such PPE may be used onsite by surveyors. However, if observation of care provided to symptomatic patients/residents who are confirmed or presumed to be COVID-19 positive is anticipated, then survey agencies and accrediting organizations should refer to the CDC Interim Infection Prevention and Control Recommendations for Patients with Confirmed Coronavirus Disease 2019 (COVID-19) or Persons Under Investigation for COVID-19 in Healthcare

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

This guidance indicates, “Respirator use must be in the context of a complete respiratory protection program in accordance with Occupational Safety and Health Administration (OSHA) Respiratory Protection standard 29 CFR 1910.134). Staff should be medically cleared and fit-tested if using respirators with tight-fitting face-pieces (e.g., a NIOSH-certified disposable N95) and trained in the proper use of respirators, safe removal and disposal, and medical contraindications to respirator use...” More information on the use of respirators may be found here: https://www.osha.gov/SLTC/etools/respiratory/respirator_basics.html

B. Offsite Planning Considerations

Conduct offsite planning based on available information from: (1) facility-reported information; (2) CDC information and guidance from its onsite visit before the SA/CMS investigation; (3) available hospital information regarding patients transferred to the hospital; and/or (4) complaint allegations. Determine and prioritize key observations that should be conducted. Compile a preliminary list of the likely interviews with various facility staff and the types of records, policies or other documents that may be needed. This may be revised after onsite observations and interviews, which may lead to additional areas of investigation.

II. Onsite Survey Activities

Upon entry, notify the facility administrator of the limited nature of the planned survey. Coordinate with the facility staff a plan and timeline for conducting the needed observations. Plan to conduct as many observations on the entry day. If by the end of the first day, the surveyors were not able to completed necessary observations, coordinate with the facility when the observations may be completed by the next day. Unless there are extenuating circumstances, plan to complete all onsite observations and corresponding interviews within two days. When possible during observations, if symptomatic patients/residents are able to tolerate wearing face masks, this will reduce the need for surveyors to wear respirator masks.

Coordinate with the facility on how to gather medical record information, with the goal to conduct as much record review offsite as possible. 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.

Adhere to Standard, Contact and Airborne Precautions and refer to the CDC Interim Infection Prevention and Control Recommendations for Patients with Confirmed Coronavirus Disease 2019 (COVID-19) or Persons Under Investigation for COVID-19 in Healthcare Settings.

During onsite observation and investigation, focus on concerns with:

- Improper transmission precautions procedures
- Lack of staff knowledge of transmission precautions
- Improper staff use of PPE and/or inadequate hand hygiene
- High-risk, significant environmental cleaning issues
- Ineffective and/or improper laundering of linens
- Possible IC surveillance program issues - also consider how influenza & pneumococcal programs are managed

Conduct concurrent interviews of staff with observations during or directly after observations as appropriate. Conduct needed interviews with patients/residents onsite, as these may be difficult to obtain offsite. Patients may be discharged. Residents may have a difficult time responding to questions by telephone. While onsite, if there are periods of time when no observations can be made, attempt to conduct other needed interviews and review medical records.

For nursing home investigations, use the LTC investigative protocols for infection control (IC) and the environment:

III. Complete Survey Offsite

Except for interviews that should be conducted concurrently with observations, conduct other interviews offsite with staff by telephone. If any patient/resident interviews could not be conducted while onsite, then attempt to conduct those by telephone.

After coordinating with the facility and determining what medical record review may be conducted offsite, complete as much of the record review offsite as possible. Request facility policies and procedures for review offsite.

In addition, consider investigating Governing Body and Quality Assurance Performance Improvement requirements that may relate to infection control or care issues offsite through telephone interviews and additional record review.

After completing all investigative procedures, determine compliance status and conduct any survey exit discussion with the facility by telephone. Draft the CMS-2567 offsite.

III: Enforcement Activities

Surveys resulting in deficiencies will have the imposition of some type of enforcement action ranging from request for corrective action plans to termination depending on the circumstances surrounding deficiencies.

Infection Prevention, Control & Immunizations

Infection Control: *This facility task must be used to investigate compliance at F880, F881, and F883. For the purpose of this task, "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) program must be facility-wide and include all departments and contracted services. If a specific care area concern is identified, it should be evaluated under the specific care area, such as for pressure ulcers, respiratory care, catheter care, and medication pass observations which include central lines, peripheral IVs, and oral/IM/respiratory medications.*

Coordination:

- One surveyor coordinates the facility task to review for:
 - The overall Infection Prevention and Control Program (IPCP);
 - The annual review of the IPCP policies and practices;
 - The review of the surveillance and antibiotic stewardship programs; and
 - Tracking influenza/pneumococcal immunization of residents.
- Team assignments must be made to include the review of:
 - Laundry services;
 - A resident on transmission-based precautions, if any;
 - Five sampled residents for influenza/pneumococcal immunizations; and
 - Other care-specific observations if concerns are identified.
- Every surveyor assesses IPCP compliance throughout the survey and communicates any concerns to the team.

Hand Hygiene:

- Staff implement standard precautions (e.g., hand hygiene and the appropriate use of personal protective equipment (PPE)).
- Appropriate hand hygiene practices are followed.
- Alcohol-based hand rub (ABHR) is readily accessible and placed in appropriate locations. These may include:
 - Entrances to resident rooms;
 - At the bedside (as appropriate for resident population);
 - In individual pocket-sized containers by healthcare personnel;
 - Staff work stations; and
 - Other convenient locations.
- Staff wash hands with soap and water when their hands are visibly soiled (e.g., blood, body fluids), or after caring for a resident with known or suspected *C. difficile* infection (CDI) or norovirus during an outbreak, or if endemic rates of CDI are high. ABHR is not appropriate to use under these circumstances.
- Staff perform hand hygiene (even if gloves are used) in the following situations:
 - Before and after contact with the resident;

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- After contact with blood, body fluids, or visibly contaminated surfaces or other 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, resident hand hygiene is performed after toileting and before meals.
- Interview appropriate staff to determine if hand hygiene supplies are readily available and who they contact for replacement supplies.
- Soap, water, and a sink are readily accessible in appropriate locations including, but not limited to, resident care areas, food and medication preparation areas.

1. Did staff implement appropriate hand hygiene? Yes No F880

Personal Protective Equipment (PPE):

- Determine if staff appropriately use and discard PPE including, but not limited to, the following:
- Gloves are worn if potential contact with blood or body fluid, mucous membranes, or non-intact skin;
 - 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;
 - A gown is worn for direct resident contact if the resident has uncontained secretions or excretions;
 - A facemask is worn if contact (i.e., within 3 feet) with a resident with new acute cough or symptoms of a respiratory infection (e.g., influenza-like illness);
 - 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;
 - PPE is 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).
- Interview appropriate staff to determine if PPE supplies are readily available and who they contact for replacement supplies.

2. Did staff implement appropriate use of PPE? Yes No F880

Transmission-Based Precautions:

- Determine if appropriate transmission-based precautions are implemented, including but not limited to:
- PPE use by staff (i.e., don gloves and gowns before contact with the resident and/or his/her environment while on contact precautions; don facemask within three feet of a resident on droplet precautions; don a fit-tested N95 or higher level respirator prior to room entry of a resident on airborne precautions;

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- 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 prior to use on another resident;
 - The least restrictive TBP possible under the circumstances;
 - 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 use at least daily and when visibly soiled.
- 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 with transmission-based precautions.

3. Did the staff implement appropriate transmission-based precautions? Yes No **F880** NA

Laundry Services:

- Determine whether staff handle, store, and transport linens appropriately including, but not limited to:
- Using standard precautions (i.e., gloves) and minimal agitation for contaminated linen;
 - Holding contaminated linen and laundry bags away from his/her clothing/body during transport;
 - Bagging/containing contaminated linen where collected, and sorted/rinsed only in the contaminated laundry area (double bagging of linen is only recommended if outside of the bag is visibly contaminated or is observed to be wet on the outside of the bag);
 - Transporting contaminated and clean linens in separate carts; if this is not possible, the contaminated linen cart should be thoroughly cleaned and disinfected per facility protocol before being used to move clean linens. Clean linens are transported by methods that ensure cleanliness, e.g., protect from dust and soil;
 - Ensuring mattresses, pillows, bedding, and linens are maintained in good condition and are clean (Refer to F584); and
 - If a laundry chute is in use, laundry bags are closed with no loose items.
- Laundry Rooms – Determine whether staff:
- Maintain/use washing machines/dryers according to the manufacturer's instructions for use;
 - If concerns, request evidence of maintenance log/record; and
 - Use detergents, rinse aids/additives, and follow laundering directions according to the manufacturer's instructions for use.

4. Did the facility store, handle, transport, and process linens properly? Yes No **F880**

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Policy and Procedure:

- The facility established a facility-wide IPCP including written IPCP standards, policies, and procedures that are current and based on national standards.
- The policies and procedures are reviewed at least annually.
- Concerns must be corroborated as applicable including the review of pertinent policies/procedures as necessary.

5. Did the facility develop and implement an overall IPCP including policies and procedures that are reviewed annually?

- Yes No F880

Infection Surveillance:

- The facility has established/implemented a surveillance plan, based on a facility assessment, for identifying, tracking, monitoring and/or reporting of infections.
- The plan includes early detection, management of a potentially infectious, symptomatic resident and the implementation of appropriate transmission-based precautions.
- The plan uses evidence-based surveillance criteria (e.g., CDC NHSN Long-Term Care or revised McGeer Criteria) to define infections and the use of a data collection tool.
- The plan includes ongoing analysis of surveillance data and review of data and documentation of follow-up activity in response.
- The facility has a process for communicating the diagnosis, antibiotic use, if any, 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.
- The facility has a current list of reportable communicable diseases.
- Staff can identify to whom and when communicable diseases, healthcare-associated infections (as appropriate), and potential outbreaks must be reported.
- Prohibiting employees with a communicable disease or infected skin lesions from direct contact with residents or their food, if direct contact will transmit disease.
- Interview appropriate staff to determine if infection control concerns are identified, reported, and acted upon.

6. Did the facility provide appropriate infection surveillance? Yes No F880

Antibiotic Stewardship Program:

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

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- Written antibiotic use protocols on antibiotic prescribing, including the documentation of the indication, dosage, and duration of use of antibiotics;
- Protocols to review clinical signs and symptoms and laboratory reports to determine if the antibiotic is indicated or if adjustments to therapy should be made and identify what infection assessment tools or management algorithms are used for one or more infections (e.g., SBAR tool for urinary tract infection (UTI) assessment, Loeb minimum criteria for initiation of antibiotics);
- A process for a periodic review of antibiotic use by prescribing practitioners: for example, review of laboratory and medication orders, progress notes and medication administration records to determine whether or not an infection or communicable disease has been documented and whether an appropriate antibiotic has been prescribed for the recommended length of time. Determine whether the antibiotic use monitoring system is reviewed when the resident is new to the facility, when a prior resident returns or is transferred from a hospital or other facility, during each monthly drug regimen review when the resident has been prescribed or is taking an antibiotic, or any antibiotic drug regimen review as requested by the QAA committee;
- Protocols to optimize the treatment of infections by ensuring that residents who require antibiotics are prescribed the appropriate antibiotic;
- A system for the provision of feedback reports on antibiotic use, antibiotic resistance patterns based on laboratory data, and prescribing practices for the prescribing practitioner.

7. Did the facility conduct ongoing review for antibiotic stewardship? Yes No **F881**

Influenza and Pneumococcal Immunizations:

- Select five residents in the sample to review for the provision of influenza/pneumococcal immunizations.
- Document the names of residents selected for review.
- Give precedence in selection to those residents whom the survey team has selected as sampled residents.
- Review the records of the five residents sampled for documentation of:
 - Screening and eligibility to receive the vaccine;
 - The provision of education related to the influenza or pneumococcal immunizations (such as the benefits and potential side effects);
 - The administration of pneumococcal and influenza vaccine, in accordance with national recommendations. Facilities must follow the CDC and ACIP recommendations for vaccines; and
 - Allowing a resident or representative to refuse either the influenza and/or pneumococcal vaccine. If not provided, documentation as to why the vaccine was not provided.
- For surveys occurring during influenza season, unavailability of the influenza vaccine can be a valid reason why a facility has not implemented the influenza vaccine program, especially during the early weeks of the influenza season. Ask the facility to demonstrate that:
 - The vaccine has been ordered and the facility received a confirmation of the order indicating that the vaccine has been shipped or that the product is not available but will be shipped when the supply is available; and
 - Plans are developed on how and when the vaccines are to be administered.

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As necessary, determine if the facility developed influenza and pneumococcal vaccine policies and procedures, including the identification and tracking/monitoring of all facility residents' vaccination status.

8. Did the facility provide influenza and/or pneumococcal immunizations as required or appropriate? Yes No **F883**