DEPARTMENT OF HEALTH & HUMAN SERVICES

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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 <u>QSOG_EmergencyPrep@cms.hhs.gov</u>.

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. <u>Protocols for Coordination and Investigation of Facilities with Actual or Suspected COVID-</u> 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 <u>status</u>;
- 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: <u>Under What Circumstances Will CMS Authorize an On-site</u>
<u>Survey/Investigation of a Facility With Persons who are Known or Suspected of Being COVID-19 Positive</u>

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 on 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 fittested 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.