



STATE OF TENNESSEE
DEPARTMENT OF HEALTH
DIVISION OF HEALTH LICENSURE & REGULATION
OFFICE OF HEALTH CARE FACILITIES
665 MAINSTREAM DRIVE, SECOND FLOOR
NASHVILLE, TENNESSEE 37243
TELEPHONE (615) 741-7221
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PM 82 AMENDED

Board for Licensing Health Care Facilities

Policy Memorandum

**SUBJECT: INTERPRETATION AND TEMPORARY WAIVER OF RULES
RELATED TO TREATMENT AND CONTAINMENT OF COVID-19**

DATE: MARCH 13, 2020

POLICY: 82 AMENDED

**EFFECTIVE: MARCH 13, 2020
* APRIL 1, 2020**

**APPROVED: MARCH 13, 2020
* APRIL 1, 2020**

The Board issues this policy to facilitate the treatment and containment of COVID-19. With this same aim, on March 12, 2020, Tennessee Governor, Bill Lee, issued Executive Order No. 14, which suspends certain statutes and rules. See Attachment A. In letters dated March 4, 2020, March 9, 2020, and March 10, 2020, the Centers for Medicare and Medicaid (CMS) suspended certain survey activities and issued guidance for the following federally certified facility types: hospitals, hospices, end stage renal dialysis (ESRD) treatment facilities, home health agencies, and nursing homes. See Attachments D through J.

The Board interprets its rules related to maintaining patient and resident safety as requiring that all licensed facility types appropriately screen and monitor patients, residents, staff, and visitors for any symptoms of COVID-19. The Centers for Disease Control and Prevention (CDC) guidance found at <https://www.cdc.gov/coronavirus/2019-ncov/healthcare-facilities/prevent-spread-in-long-term-care-facilities.html> shall be followed for patient/residents, staff, and visitors with known or suspected COVID 19. See Attachment C.

Licensed facilities with policies or plans in place regarding the restriction or limitation of visitation will be held to those policies or plans. The following rules are hereby suspended in order to allow these facilities types to restrict or limit visitation in order to protect residents from the spread of COVID-19:

Assisted Care Living Facilities (ACLF)	Tenn. Comp. R. & Reg. 1200-08-25-.14(1)(o)
Residential Homes for the Aged (RHA)	Tenn. Comp. R. & Reg. 1200-08-11-.11(15)
Traumatic Brain Injury Residential Homes	Tenn. Comp. R. & Reg. 1200-08-37-.15(o)
Adult Care Homes	Tenn. Comp. R. & Reg. 1200-08-36-.15(o)

All federally certified facility types are to follow CMS guidance.

COVID-19 is excluded from Tenn. Comp. R. & Reg. 1200-08-25-.06(5)(a) and Tenn. Comp. R. & Reg. 1200-08-11-.04(7) which allow ACLFs and RHAs, respectively, to allow employees with a reportable communicable disease to continue to work in the facility if there is a written protocol in place and approved by the Board's administrative office. Workers with known or suspected COVID-19 shall not report to work.

Finally, to allow for the construction of temporary structures related to the treatment and containment of COVID-19, the Board interprets its building standards to include the provisions in Attachment B – COVID-19 Facility Requirements – Temporary Structures.

This policy shall remain in effect until October 7, 2020 or at an earlier date as determined by the Board.

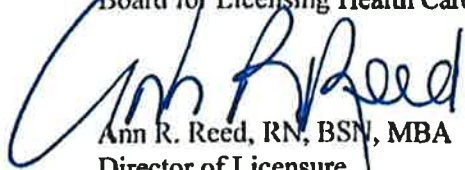
* Board Policy #82, as it relates to temporary hospital structures, includes (1) use by a hospital of its existing space to provide hospital services in a manner that temporarily varies from FGI guidelines, such as a hospital using single occupancy rooms for semi-private occupancy and (2) use by a hospital of space to provide hospital services temporarily at a location not previously approved for occupancy by the hospital, such as an inpatient rehabilitation facility, a nursing facility or a hotel.



Jim Shulman, Chairman Pro Tem
Board for Licensing Health Care Facilities



Rene Saunders, M.D., Chairman
Board for Licensing Health Care Facilities



Ann R. Reed, RN, BSN, MBA
Director of Licensure
Board for Licensing Health Care Facilities

Attachments:

Attachment A	Executive Order No. 14, Issues March 12, 2020
Attachment B	COVID-19 Facility Requirements – Temporary Structures
Attachment C	March 11, 2020 TDH Commissioner Memo to LTC Facilities
Attachment D-J	CMS Letters Providing Guidance to Federally Certified Facilities



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Residential Homes for the Aged (RIIA)	Tenn. Comp. R. & Reg. 1200-08-11-.11(15)
Traumatic Brain Injury Residential Homes	Tenn. Comp. R. & Reg. 1200-08-37-.15(o)
Adult Care Homes	Tenn. Comp. R. & Reg. 1200-08-36-.15(o)
HIV Supportive Living Centers	Tenn. Comp. R. & Reg. 1200-08-28-.12(e)

All federally certified facility types are to follow CMS guidance.


COVID-19 is excluded from Tenn. Comp. R. & Reg. 1200-08-25-.06(5)(a) and Tenn. Comp. R. & Reg. 1200-08-11-.04(7) which allow ACLFs and RHAs, respectively, to allow employees with a reportable communicable disease to continue to work in the facility if there is a written protocol in place and approved by the Board's administrative office. Workers with known or suspected COVID-19 shall not report to work.

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Jim Shulman, Chairman Pro Tem
Board for Licensing Health Care Facilities



Ann R. Reed, RN, BSN, MBA
Director of Licensure
Board for Licensing Health Care Facilities

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Attachment A	Executive Order No. 14, Issues March 12, 2020
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Attachment D-J	CMS Letters Providing Guidance to Federally Certified Facilities



STATE OF TENNESSEE
EXECUTIVE ORDER
BY THE GOVERNOR

No. 14

**AN ORDER SUSPENDING PROVISIONS OF CERTAIN STATUTES AND
RULES IN ORDER TO FACILITATE THE TREATMENT AND CONTAINMENT OF
COVID-19**

WHEREAS, Coronavirus Disease 2019 (COVID-19) is a respiratory disease caused by the SARS-CoV-2 virus that can result in mild or severe symptoms, including fever, cough, and shortness of breath, and can lead to serious illness or death, particularly in the case of older adults and persons with serious chronic medical conditions; and

WHEREAS, COVID-19 is frequently spread through close contact between persons and respiratory transmission; and

WHEREAS, in late 2019, a significant outbreak of COVID-19 was identified in China, and this disease has since spread to many other countries; and

WHEREAS, to date, according to the Centers for Disease Control and Prevention (CDC), there have been 938 cases of COVID-19 identified in the United States, which have resulted in 29 deaths; and

WHEREAS, on January 16, 2020, the Tennessee Department of Health activated the State Health Operations Center (SHOC), and on January 21, 2020, following CDC guidance, the Department designated COVID-19 as a reportable disease in Tennessee; and

WHEREAS, on March 4, 2020, I announced the formation of a Coronavirus Task Force to enhance Tennessee's coordinated efforts to prevent, identify, and treat potential cases of COVID-19, and that task force convened its first meeting a few days later; and

WHEREAS, on March 4, 2020, the first case of COVID-19 in the State of Tennessee was identified, and several additional confirmed or presumptively positive cases of COVID-19 have since been identified in Tennessee; and

WHEREAS, on March 11, 2020, the World Health Organization declared the outbreak a global pandemic; and

WHEREAS, on January 31, 2020, the U.S. Secretary of Health and Human Services declared a public health emergency to aid the nation's healthcare community in responding to COVID-19; and

WHEREAS, several states, including Kentucky, Florida, North Carolina, Colorado, Connecticut, New Jersey, New York, and others, have declared states of emergency to facilitate their responses to COVID-19; and

WHEREAS, the spread and identification of additional cases of COVID-19 in Tennessee is likely to continue, and therefore, taking proactive steps to prevent a substantial risk to public health and safety is paramount; and

WHEREAS, public and private health care, emergency, and other entities are engaged in efforts throughout the state to treat and prevent the additional spread of COVID-19, and the provisions of this Order are necessary to maximize those efforts to protect the health and safety of Tennesseans; and

WHEREAS, Tennessee Code Annotated, Section 58-2-107(e)(1), provides that during a state of emergency, the Governor is authorized to "[s]uspend any law, order, rule or regulation prescribing the procedures for conduct of state business or the orders or rules or regulations of any state agency, if strict compliance with any such law, order, rule, or regulation would in any way prevent, hinder, or delay necessary action in coping with the emergency;" and

WHEREAS, pursuant to this authority and the general emergency management powers of the Governor under law, the temporary suspension of selected state laws and rules is necessary to facilitate the response to the current public health situation.

NOW THEREFORE, I, Bill Lee, Governor of the State of Tennessee, by virtue of the power and authority vested in me by the Tennessee Constitution and other applicable law, do hereby declare a state of emergency exists to facilitate the response to COVID-19 and order the following:

1. The Commissioner of Health or her designee, in conjunction with the Director of the Tennessee Emergency Management Agency (TEMA) or his designee, shall implement the Tennessee Emergency Management Plan (TEMP) and all applicable annexes to coordinate the State's response to COVID-19.
2. The relevant provisions of Tennessee Code Annotated, Titles 63 and 68, and related rules are hereby suspended to the extent necessary to give the Commissioner of Health the discretion to allow a health care professional who is licensed in another state, and who would otherwise be subject to licensing requirements under Title 63 or Title 68, to engage in the practice of such individual's profession in Tennessee,

if such individual is a health care professional who is assisting in the medical response to COVID-19.

3. The provisions of Tennessee Code Annotated, Section 63-10-207(a) and (c), are hereby suspended to allow a pharmacist to dispense an extra 30-day supply of maintenance prescriptions without proper authorization to persons as is necessary to respond to and prevent the spread of COVID-19 in Tennessee, subject to all other provisions of Tennessee Code Annotated, Sections 63-10-207 and 63-1-164.
4. The provisions of Tennessee Code Annotated, Section 68-11-201(20), are hereby suspended to the extent necessary to allow health care professionals who would otherwise be subject to licensing requirements to provide localized treatment of patients in temporary residences.
5. The provisions of Tenn. Comp. R. & Regs. 1200-06-03-.16 are suspended to allow testing for COVID-19 at alternate testing sites without prior approval by the Medical Laboratory Board; provided, that laboratories shall notify the Medical Laboratory Board of any such alternate testing sites.
6. The provisions of Tennessee Code Annotated, Section 68-11-202(c)(1)-(8), are hereby suspended to allow for the construction of temporary structures, the plans for which would otherwise be subject to review for new construction, additions, or substantial alterations, as directed by the Commissioner of Health and the Director of TEMA in response to COVID-19; provided, that there shall be inspections of such structures to ensure safety, as necessary.
7. In accordance with Tennessee Code Annotated, Section 47-18-5103, it is hereby declared that in Tennessee an abnormal economic disruption exists, and therefore, persons are prohibited from charging any other person a price for medical supplies or emergency supplies, as listed in Tennessee Code Annotated, Section 47-18-5103(a)(1)(C) and (D), that is grossly in excess of the price generally charged for the same or similar goods or services in the usual course of business. Paragraph 7 of this Order shall remain in effect until 12:01 a.m., Central Daylight Time, on March 27, 2020.
8. The provisions of Tennessee Code Annotated, Section 55-4-401, through Tennessee Code Annotated, Section 55-4-413, Tennessee Code Annotated, Section 55-7-201, through Tennessee Code Annotated, Section 55-7-209, and Tenn. Comp. R. & Regs. 1680-07-01-.01 through Tenn. Comp. R. & Regs. 1680-07-01-.25 that set forth maximum height, length, and width limitations are hereby suspended in the case of vehicles participating in the response to COVID-19, subject to the following conditions:
 - a. A vehicle must be transporting emergency supplies, equipment, or mobile structures to affected areas.

- b. A vehicle shall be permitted only to travel on (1) Interstate Highways; (2) highways on the National Highway System; and (3) other state-maintained roads as may be required to obtain access to needed services off of the aforementioned highways, without any restrictions on their time of movement except as may otherwise be provided in this Order.
 - c. A vehicle may transport a divisible or non-divisible load up to a maximum gross vehicle weight of 95,000 pounds and a maximum axle weight of 20,000 pounds, except on any bridge or overpass with a lower posted weight limit.
 - d. The outer bridge span of any five-axle truck tractor/semi-trailer combination shall be no less than fifty-one feet (51').
 - e. The overall dimensions of a vehicle and load shall not exceed:
 - i. One hundred feet (100') in length;
 - ii. Fourteen feet, four inches (14' 4") in height on the Interstate Highway System, except on Interstate 55, and thirteen feet, six inches (13' 6") in height on Interstate 55 and any other highway on the National Highway System; or
 - iii. Fourteen feet, six inches (14' 6") in width.
 - f. Vehicles that do not exceed ten feet (10') in width may travel seven (7) days per week during daylight or nighttime hours without any time restrictions.
 - g. Any person, firm, company, corporation, or other entity that undertakes the movement of any overweight and/or overdimensional article and/or commodity on the highways of Tennessee shall hold Tennessee and its officers and employees harmless from any claims for damages resulting from the exercise of any of the privileges granted under this Order and, to this end, shall carry liability insurance with an insurer, acceptable to the Tennessee Department of Transportation's Oversize and Overweight Permit Office, in the amount of not less than three hundred thousand dollars (\$300,000) for each claimant and one million dollars (\$1,000,000) per occurrence. The transporter shall carry the certificate of insurance in the vehicle at all times.
 - h. Paragraph 8(c) of this Order shall take effect only upon the issuance of and in accordance with an appropriate declaration by the President of the United States.
9. In accordance with 49 C.F.R. § 390.23, as adopted by Tenn. Comp. R. & Regs. 1340-06-01-.08, there is hereby provided a temporary exception from the federal rules and regulations in 49 C.F.R. Part 395 limiting the hours of service for the

operator of a commercial motor vehicle providing supplies, equipment, personnel, and other provisions to assist persons affected by COVID-19, subject to the following conditions:

- a. Nothing in this Order shall be construed as an exemption from the Commercial Driver's License requirements in 49 C.F.R. § 383, the financial requirements in 49 C.F.R. § 387, or applicable federal size and weight limitations.
 - b. No motor carrier operating under the terms of this Order shall require or allow an ill or fatigued driver to operate a motor vehicle. A driver who notifies a motor carrier that he or she needs immediate rest shall be given at least ten (10) consecutive hours off-duty before the driver is required to return to service.
10. The relevant provisions of Tennessee Code Annotated, Title 71, Chapter 3, Part 5, and related rules are hereby suspended to the extent necessary to give the Commissioner of Human Services the discretion to waive the child care licensure requirements, including requirements concerning capacity, care categories, grouping, license transfers, and drop-in centers, if necessary to respond to the effects of COVID-19.
 11. The Division of TennCare is hereby authorized to create policies or modify existing policies as is necessary to ensure that members of the TennCare and CoverKids programs continue to receive medically necessary services without disruption during this state of emergency.
 12. Pursuant to Tennessee Code Annotated, Section 58-2-107(e)(2), I hereby direct the Tennessee Department of Health and the Tennessee Department of Commerce and Insurance to continue working with health insurance plans operating in the state to identify and remove any burdens to responding to COVID-19 and improve access to treatment options and medically necessary screening and testing for COVID-19.
 13. This Order shall remain in effect until 12:01 a.m., Central Daylight Time, on May 11, 2020, at which time the suspension of any state laws and rules shall cease and be of no further force or effect.

IN WITNESS WHEREOF, I have subscribed my signature and caused the Great Seal of the State of Tennessee to be affixed this 12th day of March, 2020.


GOVERNOR

ATTEST

SECRETARY OF STATE



COVID-19 FACILITY REQUIREMENTS Temporary Structures

Fire Department Access

1. Fire department access roads must maintain a width of at least 20 feet wide and a vertical clearance that is unobstructed for a height that is at least 13'-6", for the whole distance of the access road. [NFPA 101: 18.2.3.4.1.1 & 18.2.3.4.1.2]

Tents

1. Tents shall be erected and located in accordance with NFPA 101: Section 11.11.
2. Tents shall meet the flame propagation performance criteria contained within NFPA 701, *Standard Methods of Fire Tests for Flame Propagation of Textiles and Films*. [NFPA 101: 11.11.2.1]
3. All required means of egress routes must be constantly maintained throughout from any point of origin within any tent, to include the exit discharge to the public way. [NFPA 101: 20.2.5, 38.2.5, 7.5.1.1, 7.1.10.1]
4. Means of egress shall be illuminated and provided with emergency lighting in compliance with NFPA 101:, Section 20.2.9
5. A minimum spacing of not less than 10 feet must be provided between adjacent tents and/or buildings. [NFPA 101: 11.11.3.2 & 11.11.3.5]
6. Tents shall be cleared of all flammable or combustible material or vegetation that is not used for necessary support equipment. [NFPA 101: 11.11.4.1]
7. Only listed and labeled fuel fired heating devices and/or electric heating devices shall be used. [NFPA 101: 11.11.6.1.1 & 11.11.6.2.1]
8. Heaters shall be connected to electricity by an electric cable that is suitable for outside use and is of sufficient use and is of sufficient size to handle the electrical load. [NFPA 101: 11.11.6.2.3]
9. A 2A10BC Portable fire extinguishing equipment shall be furnished, maintained, and placed not more than 75 feet travel distance to reach an extinguisher at any one point within a tent. [NFPA 101: 11.11.5 & NFPA 10] If a fuel fired heater is used, a 2A10BC fire extinguisher must be located not exceeding a 50 Ft. travel distance to reach an extinguisher at any one point within a tent. [NFPA 101: 11.11.6.1.2]
10. The maximum number of people allowed to occupy a room, space, or building (Occupant Load). Occupant load for exterior outside tents used for triage must not be less than 100 Ft² per person. [NFPA 101: Table 7.3.1.2]
11. Occupant load for exterior outside tents used to render services to patients for a time duration equaling or exceeding 24 hours.

Healthcare Use	Ft ² per person
Inpatient treatment departments	240
Sleeping Departments	120

12. Smoking shall be prohibited within and in the near vicinity of any tent that is erected and have plainly visible signs posted that read as follows: "NO SMOKING". [NFPA 101: 11.11.4.2.1 & 11.11.4.2.2]

COVID-19 FACILITY REQUIREMENTS Temporary Structures

3/12/2020

13. Staff shall have the means to contacting first responders (fire department, police department) in the event of a disaster. [NFPA 101: 21.7.2.2]
14. Nonflammable medical gas associated with patient care shall not exceed a quantity of 12, size E cylinders (300 Cu. Ft.) and the floor area shall not exceed 22,500 Ft². The container shall be properly secured, such as a rack to prevent them from tipping over or being damaged. In this case the medical gas is considered an "operational supply" and not storage. Storage of medical gas cylinders or containers shall be stored outside the tent [NFPA 99: 11.3]

Mobile Units (Trailer)

1. The maximum number of people allowed to occupy a room, space, or building (Occupant Load). Occupant load for any mobile unit used for triage must not be less than 100 Ft² per person. [NFPA 101: Table 7.3.1.2]
2. Mobile units shall be located not less than 10 feet from any building and/or tent, in compliance with [NFPA 101: 4.6.1.2]
3. Means of egress shall be illuminated and provided with emergency lighting in compliance with NFPA 101., Section 20.2.9
4. All required means of egress routes must be constantly maintained throughout from any point of origin within the mobile unit, to include the exit discharge to the public way. [NFPA 101: 20.2.5, 38.2.5, 7.5.1.1, 7.1.10.1]
5. A 2A10BC Portable fire extinguishing equipment shall be furnished, maintained, and placed not more than 75 feet travel distance to reach an extinguisher at any one point within a mobile unit. [NFPA 101: 11.11.5 & NFPA 10]
6. Nonflammable medical gas associated with patient care shall not exceed a quantity of 12, size E cylinders (300 Cu. Ft.) and the floor area shall not exceed 22,500 Ft². The container shall be properly secured, such as a rack to prevent them from tipping over or being damaged. In this case the medical gas is considered an "operational supply" and not storage. Storage of medical gas cylinders or containers shall be stored outside the mobile unit [NFPA 99: 11.3]
7. Staff shall have the means to contacting first responders (fire department, police department) in the event of a disaster. [NFPA 101: 21.7.2.2]

Hospital Facilities

Means of Egress

1. All required means of egress routes must be constantly maintained throughout from any point of origin within the facility, to include the exit discharge to the public way. [NFPA 101: 19.2.5.1, 19.2.1, 1, 7.5.1.1, 7.1.10.1]
2. Corridor widths must not be reduced to less than a minimum clear width of 8 feet (96 inches). [NFPA 101: 18.2.3.4]

Occupant Load

1. The maximum number of people allowed to occupy a room, space, or building (Occupant Load). Occupant load shall be in accordance with NFPA 101: Table 7.3.1.2

Healthcare Use	Ft ² per person
Inpatient treatment departments	240
Sleeping Departments	120



MEMORANDUM

DATE: March 11, 2020
TO: Long-Term Care Facilities
FROM: Lisa Piercey, MD, MBA, FAAP, Commissioner
SUBJECT: COVID-19 (Novel Coronavirus) Guidance for Long-Term Care Facilities

As you know, older persons or people with underlying medical conditions are at increased risk of severe complications from COVID-19 infection. The Centers for Disease Control and Prevention (CDC) and Centers for Medicare and Medicaid Services (CMS) have recently issued guidance recommending that nursing facilities screen visitors and staff for symptoms of respiratory infection, international travel to restricted countries, and contact with anyone who has or is suspected to have COVID-19.

Links to these guidance documents are available on-line:

CMS Guidance: <https://www.cms.gov/medicareprovider-enrollment-and-certificationsurvey/certificationgeninfopolicy-and/qso-20-14-nh.pdf>

CDC Guidance: <https://www.cdc.gov/coronavirus/2019-ncov/healthcare-facilities/prevent-spread-in-long-term-care-facilities.html>

These guidelines contain extensive details and recommendations for long-term care facilities (LTCF). Examples of such recommendations include:

- Visitation should be limited to only those who are essential for the resident’s emotional well-being and care (e.g. families of person receiving end-of-life care).
- Restrict non-essential personnel including volunteers and non-essential consultant personnel from entering the building.
- Send letters or emails to families advising them of limitations to visitation, and facilitate use of alternative methods for visitation (e.g., video conferencing) during the next several months.
- Post signs at the entrances to the facility instructing visitors to not enter if they have fever or symptoms of a respiratory infection.
- Screen all healthcare personnel at the beginning of their shift for fever and respiratory symptoms.
- Actively monitor all residents (at least daily) for fever and respiratory symptoms (shortness of breath, new or change in cough, and sore throat).

An extensive amount of information regarding COVID-19, including advice for medical providers, patients, and the general public is available on the websites of the Tennessee Departments of Health (<https://www.tn.gov/health/cedep/ncov.html>) and CDC (<https://www.cdc.gov/coronavirus/2019-ncov/>). In addition, for general questions the public can contact our hotline between 10am and 10pm (877-857-2945). Questions from medical institutions and medical providers can be directed to (615) 741-7247.

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-20-12-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.bhs.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/e-tools/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 complete 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;

Infection Prevention, Control & Immunizations

- 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**

Infection Prevention, Control & Immunizations

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:

Infection Prevention, Control & Immunizations

- 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**

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
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Baltimore, Maryland 21244-1850



EXHIBIT
tabbies
Attachment E

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

Ref: QSO-20-13-Hospitals

DATE: March 4, 2020
TO: State Survey Agency Directors
FROM: Director
Quality, Safety & Oversight Group
SUBJECT: Guidance for Infection Control and Prevention Concerning Coronavirus Disease (COVID-19): FAQs and Considerations for Patient Triage, Placement and Hospital Discharge

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.
- **Coordination with the Centers for Disease Control (CDC) and local public health departments** - We encourage all hospitals 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>).
- **Hospital Guidance and Actions** - CMS regulations and guidance support hospitals taking appropriate action to address potential and confirmed COVID cases and mitigate transmission including screening, discharge and transfers from the hospital, and visitation.

Background

The Centers for Medicare & Medicaid Services (CMS) is committed to the protection of patients and residents of healthcare facilities from the spread of infectious disease. This memorandum responds to questions we have received and provides important guidance for hospitals and critical access hospitals (CAH's) in addressing the COVID-19 outbreak and minimizing transmission to other individuals. Specifically, we address FAQs related to optimizing patient placement, with the goal of addressing the needs of the individual patient while protecting other patients and healthcare workers.

Guidance

Hospitals should monitor the CDC website (<https://www.cdc.gov/coronavirus/2019-nCoV/index.html>) for up to date information and resources. They should contact their local health department if they have questions or suspect a patient or healthcare provider has COVID-19. Hospitals should have plans for monitoring healthcare personnel with exposure to patients with known or suspected COVID-19. Additional information about monitoring healthcare personnel

is available here: <https://www.cdc.gov/coronavirus/2019-ncov/hcp/guidance-risk-assessment-hcp.html>

Guidance for Addressing Patient Triage and Placement of Patients with known or suspected COVID-19

Which patients are at risk for severe disease for COVID-19?

Based upon CDC data, older adults and those with underlying chronic medical conditions or immunocompromised state may be most at risk for severe outcomes. This should be considered in the decision to monitor the patient as an outpatient or inpatient.

How should facilities screen visitors and patients for COVID-19?

Hospitals should identify visitors and patients at risk for having COVID-19 infection before or immediately upon arrival to the healthcare facility. They should ask patients about the following:

1. Fever or symptoms of a respiratory infection, such as a cough and sore throat.
2. International travel within the last 14 days to restricted countries. For updated information on restricted countries visit: <https://www.cdc.gov/coronavirus/2019-ncov/travelers/index.html>
3. Contact with someone with known or suspected COVID-19.

For patients, implement respiratory hygiene and cough etiquette (i.e., placing a facemask over the patient's nose and mouth if that has not already been done) and isolate the patient in an examination room with the door closed. If the patient cannot be immediately moved to an examination room, ensure they are not allowed to wait among other patients seeking care. Identify a separate, well-ventilated space that allows waiting patients to be separated by 6 or more feet, with easy access to respiratory hygiene supplies. In some settings, medically-stable patients might opt to wait in a personal vehicle or outside the healthcare facility where they can be contacted by mobile phone when it is their turn to be evaluated.

Inform infection prevention and control services, local and state public health authorities, and other healthcare facility staff as appropriate about the presence of a person under investigation for COVID-19. Additional guidance for evaluating patients in U.S. for COVID-19 infection can be found on the CDC [COVID-19 website](#).

Provide supplies for respiratory hygiene and cough etiquette, including 60%-95% alcohol-based hand sanitizer (ABHS), tissues, no touch receptacles for disposal, facemasks, and tissues at healthcare facility entrances, waiting rooms, patient check-ins, etc.

How should facilities monitor or restrict health care facility staff?

The same screening performed for visitors should be performed for hospital staff.

- Health care providers (HCP) who have signs and symptoms of a respiratory infection should not report to work.
- Any staff that develop signs and symptoms of a respiratory infection while on-the-job, should:

- Immediately stop work, put on a facemask, and self-isolate at home;
- Inform the hospital's infection preventionist, and include information on individuals, equipment, and locations the person came in contact with; and
- Contact and follow the local health department recommendations for next steps (e.g., testing, locations for treatment).
- Refer to the CDC guidance for exposures that might warrant restricting asymptomatic healthcare personnel from reporting to work (<https://www.cdc.gov/coronavirus/2019-ncov/hcp/guidance-risk-assessment-hcp.html>).

Hospitals 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>).

What are recommended infection prevention and control practices, including considerations for patient placement, when evaluating and care for a patients with known or suspected COVID-19?

Recommendations for patient placement and other detailed infection prevention and control recommendations regarding hand hygiene, Transmission-Based Precautions, environmental cleaning and disinfection, managing visitors, and monitoring and managing healthcare personnel are available in 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.

Do all patients with known or suspected COVID-19 infection require hospitalization?

Patients may not require hospitalization and can be managed at home if they are able to comply with monitoring requests. More information is available here: <https://www.cdc.gov/coronavirus/2019-ncov/hcp/guidance-home-care.html>

Are there specific considerations for patients requiring diagnostic or therapeutic interventions?

Patients with known or suspected COVID-19 should continue to receive the intervention appropriate for the severity of their illness and overall clinical condition. Because some procedures create high risks for transmission (e.g., intubation) additional precautions include: 1) HCP should wear all recommended PPE, 2) the number of HCP present should be limited to essential personnel, and 3) the room should be cleaned and disinfected in accordance with environmental infection control guidelines.

Additional information about performing aerosol-generating procedures is available here: <https://www.cdc.gov/coronavirus/2019-ncov/infection-control/control-recommendations.html>

When is it safe to discontinue Transmission-based Precautions for hospitalized patients with COVID-19?

The decision to discontinue Transmission-Based Precautions for hospitalized patients with COVID-19 should be made on a case-by-case basis in consultation with clinicians, infection prevention and control specialists, and public health officials. This decision should consider disease severity, illness signs and symptoms, and results of laboratory testing for COVID-19 in respiratory specimens

More detailed information about criteria to discontinue Transmission-Based Precautions are available here: <https://www.cdc.gov/coronavirus/2019-ncov/hcp/disposition-hospitalized-patients.html>

Can hospitals restrict visitation of patients?

Medicare regulations require a hospital to have written policies and procedures regarding the visitation rights of patients, including those setting forth any clinically necessary or reasonable restriction or limitation that the hospital may need to place on such rights and the reasons for the clinical restriction or limitation. CMS sub-regulatory guidance identifies infection control concern as an example of when clinical restrictions may be warranted. Patients must be informed of his/her visitation rights and the clinical restrictions or limitations on visitation.

The development of such policies and procedures require hospitals to focus efforts on preventing and controlling infections, not just between patients and personnel, but also between individuals across the entire hospital setting (for example, among patients, staff, and visitors) as well as between the hospital and other healthcare institutions and settings and between patients and the healthcare environment. Hospitals should work with their local, State, and Federal public health agencies to develop appropriate preparedness and response strategies for communicable disease threats.

What are the considerations for discharge to a subsequent care location for patients with COVID-19?

The decision to discharge a patient from the hospital should be made based on the clinical condition of the patient. If Transmission-Based Precautions must be continued in the subsequent setting, the receiving facility must be able to implement all recommended infection prevention and control recommendations.

Although COVID-19 patients with mild symptoms may be managed at home, the decision to discharge to home should consider the patient's ability to adhere to isolation recommendations, as well as the potential risk of secondary transmission to household members with immunocompromising conditions. More information is available here: <https://www.cdc.gov/coronavirus/2019-ncov/hcp/guidance-home-care.html>

What are the implications of the Medicare Hospital Discharge Planning Regulations for Patients with COVID-19?

Medicare's Discharge Planning Regulations (which were updated in November 2019) requires that hospital assess the patient's needs for post-hospital services, and the availability of such services. When a patient is discharged, all necessary medical information (including communicable diseases) must be provided to any post-acute service provider. For COVID-19 patients, this must be communicated to the receiving service provider prior to the discharge/transfer and to the healthcare transport personnel.

Can hospitals restrict visitation of patients?

Medicare regulations require a hospital to have written policies and procedures regarding the visitation rights of patients, including those setting forth any clinically necessary or reasonable restriction or limitation that the hospital may need to place on such rights and the reasons for the clinical restriction or limitation. CMS sub-regulatory guidance identifies infection control

concern as an example of when clinical restrictions may be warranted. Patients must be informed of his/her visitation rights and the clinical restrictions or limitations on visitation.

The development of such policies and procedures require hospitals to focus efforts on preventing and controlling infections, not just between patients and personnel, but also between individuals across the entire hospital setting (for example, among patients, staff, and visitors) as well as between the hospital and other healthcare institutions and settings and between patients and the healthcare environment. Hospitals should work with their local, State, and Federal public health agencies to develop appropriate preparedness and response strategies for communicable disease threats.

Important CDC Resources:

- 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 Interim Infection Prevention and Control Recommendations for Patients with Confirmed Coronavirus Disease 2019 (COVID19) or Persons Under Investigation for COVID-19 in Healthcare Settings.: https://www.cdc.gov/coronavirus/2019-ncov/infection-control/control/recommendations.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fcoronavirus%2F2019-ncov%2Fhosp%2Finfection-control.html

CDC Updates:

<https://www.cdc.gov/coronavirus/2019-ncov/whats-new-all.html>

CMS Resources

CMS has additional guidance which may be beneficial to hospitals related to EMTALA requirements and other topics surrounding the health and safety standards during emergencies. The document Provider Survey and Certification Frequently Asked Questions (FAQs), Declared Public Health Emergency All-Hazards are located at <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertEmergPrep/Downloads/All-Hazards-FAQs.pdf>. These FAQs are not limited to situations involving 1135 Waivers, but are all encompassing FAQs related to public health emergencies and survey activities and functions.

Contact: Questions about this memorandum should be addressed to QSOG_EmergencyPrep@cms.hhs.gov. Questions about COVID-19 guidance/screening criteria should be addressed to the State Epidemiologist or other responsible state or local public health officials in your state.

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

Ref: QSO-20-14-NH

DATE: March 4, 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

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.
- **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

CMS is responsible for ensuring the health and safety of nursing homes 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're providing additional guidance to nursing homes to help control and prevent the spread of the virus.

Guidance

Facilities should 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 patients are essential to prevent unnecessary exposures among patients, 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 patients, patient 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 (Frequently Asked Questions) about some specific areas related to COVID-19:

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

How should facilities monitor or limit visitors?

Facilities should screen visitors for the following:

1. International travel within the last 14 days to restricted countries. For updated information on restricted countries visit: <https://www.cdc.gov/coronavirus/2019-ncov/travelers/index.html>
2. Signs or symptoms of a respiratory infection, such as a fever, cough, and sore throat.
3. Has had contact with someone with or under investigation for COVID-19.

If visitors meet the above criteria, facilities may restrict their entry to the facility. Regulations and guidance related to restricting a resident's right to visitors can be found at 42 CFR §483.10(f)(4), and at F-tag 563 of Appendix PP of the State Operations Manual. Specifically, a facility may need to restrict or limit visitation rights for reasonable clinical and safety reasons. This includes, "restrictions placed to prevent community-associated infection or communicable disease transmission to the resident. A resident's risk factors for infection (e.g., immunocompromised condition) or current health state (e.g., end-of-life care) should be considered when restricting visitors. In general, visitors with signs and symptoms of a transmissible infection (e.g., a visitor is febrile and exhibiting signs and symptoms of an influenza-like illness) should defer visitation until he or she is no longer potentially infectious (e.g., 24 hours after resolution of fever without antipyretic medication)."

How should facilities monitor or restrict health care facility staff?

The same screening performed for visitors should be performed for facility staff (numbers 1, 2, and 3 above).

- Health care providers (HCP) who have signs and symptoms of a respiratory infection should not report to work.
- Any staff that develop signs and symptoms of a respiratory infection while on-the-job, should:
 - Immediately stop work, put on a facemask, and self-isolate at home;
 - Inform the facility's infection preventionist, and include information on individuals, equipment, and locations the person came in contact with; and
 - Contact and follow the local health department recommendations for next steps (e.g., testing, locations for treatment).
- Refer to the CDC guidance for exposures that might warrant restricting asymptomatic healthcare personnel from reporting to work (<https://www.cdc.gov/coronavirus/2019-ncov/hcp/guidance-risk-assesment-hcp.html>).

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>).

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 patient assuming: 1) the patient 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.

(<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 patient 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 patient 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 patient diagnosed with COVID-19 and still under Transmission-based Precautions for COVID-19 as long as it 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.

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 sanitizer (ABHS), tissues, no touch receptacles for disposal, and facemasks at healthcare facility entrances, waiting rooms, patient check-ins, etc.

- Ensure ABHS 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.).

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>

CMS Resources:

- Long term care facility – Infection control self-assessment worksheet: https://qsep.cms.gov/data/252/A_NursingHome_InfectionControl_Worksheet_11-8-19508.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

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

Ref: QSO-20-16-Hospice

DATE: March 9, 2020
TO: State Survey Agency Directors
FROM: Director
Quality, Safety & Oversight Group
SUBJECT: Guidance for Infection Control and Prevention Concerning Coronavirus Disease 2019 (COVID-19) by Hospice Agencies

Memorandum Summary

CMS is committed to protecting American patients by ensuring health care facilities have up-to-date information to adequately respond to COVID-19 concerns.

- **Coordination with the Centers for Disease Control and Prevention (CDC) and local public health departments** - We encourage all Hospice Agencies to monitor the CDC website for updated 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>).
- **Hospice Guidance and Actions** - CMS regulations and guidance support Hospice Agencies taking appropriate action to address potential and confirmed COVID cases and mitigate transmission including screening, treatment, and transfer to higher level care (when appropriate). This guidance applies to both Medicare and Medicaid providers.

Background

The Centers for Medicare & Medicaid Services (CMS) is committed to the protection of patients and residents of healthcare facilities or homecare settings from the spread of infectious disease. This memorandum responds to questions we have received and provides important guidance for Hospice Agencies in addressing the COVID-19 outbreak and minimizing transmission to other individuals.

Guidance

Hospice Agencies should regularly monitor the CDC website (see links below) for information and contact their local health department when needed (<https://www.cdc.gov/coronavirus/2019-ncov/whats-new-all.html>). Also, hospice agencies should be monitoring the health status of patients, residents, visitors, volunteers, and staff under their care setting for signs or symptoms of

COVID-19. Per CDC, prompt detection, triage and isolation of potentially infectious patients are essential to prevent unnecessary exposures among patients, healthcare personnel, and visitors at the facility. For exposed staff, hospice agencies should consider frequent monitoring for potential symptoms of COVID-19 as needed throughout the day.

In addition to the overarching regulations and guidance, we have provided the following information (Frequently Asked Questions) about some specific areas related to COVID-19:

Guidance for Addressing COVID-19 in Hospices (In-patient units, nursing facilities, assisted living, hospitals and home settings)

Which patients are at risk for severe disease from COVID-19?

Based upon CDC data, older adults, those with underlying chronic or life-limiting medical conditions such as hospice patients are presumed to be at greater risk of poor outcomes when infected with novel coronavirus.

Refer to the CDC guidance for people at higher risk: <https://www.cdc.gov/coronavirus/2019-ncov/specific-groups/high-risk-complications.html>

How should providers screen visitors and patients for COVID-19 in a Hospice that provides short-term inpatient care directly or in an inpatient unit of another facility?

Hospices should identify volunteers, visitors and patients at risk for having COVID-19 infection before or immediately upon arrival to the inpatient unit. They should be asked about the following:

1. International travel within the last 14 days to countries with sustained community transmission. For updated information on affected countries visit: <https://www.cdc.gov/coronavirus/2019-ncov/travelers/index.html>
2. Signs or symptoms of a respiratory infection, such as a fever, cough, and sore throat.
3. In the last 14 days, has had contact with someone with or under investigation for COVID-19, or are ill with respiratory illness.
4. Residing in a community where community-based spread of COVID-19 is occurring.

For patients with respiratory symptoms, implement respiratory hygiene and cough etiquette (i.e., placing a facemask over the patient's nose and mouth) and isolate the patient in a private room with the door closed. If the patient cannot be immediately moved to a private location, ensure they are not allowed to wait among other patients who reside in the inpatient unit. Identify a separate, well-ventilated space that allows patients to be separated by 6 or more feet, with easy access to respiratory hygiene supplies.

Medicare requires Hospice Agencies to provide appropriate medical supplies for respiratory hygiene and cough etiquette, including 60%-95% alcohol-based hand sanitizer (ABHS), tissues, no touch receptacles for disposal, facemasks, and tissues at healthcare facility entrances.

Inform infection prevention and control services, local and state public health authorities, and other healthcare facility staff as appropriate about the presence of a person under investigation

(PUI) for COVID-19. For hospice patients with symptoms, determination about whether or not to conduct diagnostic testing versus presuming a positive COVID-19 diagnosis (based on his/her symptoms and exposure) should be a decision among the patient, patient representative, hospice agency and state and local public health authority. Additional guidance for evaluating patients in U.S. for COVID-19 infection can be found on the CDC [COVID-19 website](#).

How should hospice programs monitor or restrict health care staff or hospice volunteers?

The same screening performed for patients and visitors should be performed for hospice staff and volunteers.

- Health care providers (HCP) and volunteers who have signs and symptoms of a respiratory infection should not report to work.
- Anyone that develop signs and symptoms of a respiratory infection while on-the-job, should:
 - Immediately stop work, put on a facemask, and self-isolate at home;
 - Inform the hospice's infection control manager/team to include information on individuals, equipment, and locations the person came in contact with; and
 - Contact and follow the local health department recommendations for next steps (e.g., testing, locations for treatment).
- Refer to the CDC guidance for exposures that might warrant restricting asymptomatic healthcare personnel or volunteers from reporting to work (<https://www.cdc.gov/coronavirus/2019-ncov/hcp/guidance-risk-assesment-hcp.html>).

Hospices 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>).

When a hospice patient is in an inpatient unit, what are recommended infection prevention and control practices, including considerations for patient placement, when evaluating and care for a patient with known or suspected COVID-19?

Recommendations for patient placement and other detailed infection prevention and control recommendations are available in the <https://www.cdc.gov/coronavirus/2019-ncov/infection-control/control-recommendations.html>.

Consider, where appropriate allowing certain types of volunteer activities to be performed via phone or other electronic devices to minimize risk of exposure in the event of a suspected or positive COVID-19 case.

Do hospice patients with known or suspected COVID-19 infection require hospitalization?

Hospice patients and/or their families should carefully discuss care options with the hospice team to ensure the goals and wishes of hospice patient are respected consistent with patient rights requirements. Patients can be managed at home if the patient is stable, the environmental exposure to COVID-19 to others in the household can be minimized, and if there are appropriate infection control precautions made and PPE available.

Patients whose symptoms are exacerbated by COVID-19 and cannot be adequately managed in the home setting, should be transferred to a hospice inpatient unit. More information is available here: <https://www.cdc.gov/coronavirus/2019-ncov/hcp/guidance-home-care.html>.

When is it safe to discontinue Transmission-based Precautions inpatient hospice patients with COVID-19?

The decision to discontinue Transmission-Based Precautions for hospitalized patients with COVID-19 should be made on a case-by-case basis in consultation with clinicians, infection prevention and control specialists, and public health officials. This decision should consider disease severity, illness signs and symptoms, and results of laboratory testing for COVID-19 in respiratory specimens.

Currently, negative RT-PCR results from at least 2 consecutive sets of nasopharyngeal and throat swabs collected at least 24 hours apart are needed before discontinuing Transmission-Based Precautions. A total of four negative specimens are needed to meet this requirement.

More detailed information about criteria to discontinue Transmission-Based Precautions are available here: <https://www.cdc.gov/coronavirus/2019-ncov/hcp/disposition-hospitalized-patients.html>.

When is it safe to discontinue in-home isolation for in home hospice patients with COVID-19?

The decision should be made on a case-by-case basis in consultation with clinicians and public health officials. This decision should consider disease severity, illness signs and symptoms, and results of laboratory testing for COVID-19 in respiratory specimens

Guidance for discontinuation of in-home isolation precautions is the same as that to discontinue Transmission-Based Precautions for hospitalized patients with COVID-19. **For more information, see:** <https://www.cdc.gov/coronavirus/2019-ncov/hcp/disposition-in-home-patients.html>

Considerations to discontinue in-home isolation include all of the following:

- Resolution of fever, without use of antipyretic medication
- Improvement in illness signs and symptoms
- Negative results of an FDA Emergency Use Authorized molecular assay for COVID-19 from at least two consecutive sets of paired nasopharyngeal and throat swabs specimens collected ≥ 24 hours apart (total of four negative specimens—two nasopharyngeal and two throat). See Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens from Patients Under Investigation (PUIs) for 2019 Novel Coronavirus (2019-nCoV) for specimen collection guidance.

Can hospices restrict visitation of patients (in-patient unit provided directly by the hospice)?

Medicare regulations require a hospice to focus on preventing and controlling infections. Hospices may have policies regarding the visitation rights of patients and may wish to set clinical restrictions on visitation subject to patient's rights. If the inpatient hospice is not provided by the hospice itself (such as a hospital), that provider may have established additional visitation restrictions associated with that setting to address COVID-19 transmission concerns.

What are the considerations when caring for a hospice patient in their home?

For hospice patients with known or suspected COVID-19 who remain in their homes, there are a number of infection prevention and control practices that should be followed. The CDC advises the patient to stay home except to get medical care, separate yourself from other people and animals in the home as much as possible (in a separate room with the door closed), call ahead before visiting your doctor, and wear a facemask in the presence of others when out of the patient room.

For everyone in the home, CDC advises covering coughs and sneezes followed by washing your hands or using an alcohol-based hand rub, not sharing personal items (dishes, eating utensils, bedding) with individuals with known or suspected COVID-19, cleaning all “high-touch” surfaces everyday, and monitoring your symptoms. Please see:
<https://www.cdc.gov/coronavirus/2019-ncov/hcp/guidance-prevent-spread.html>

CMS regulations also require that hospice agencies provide the types of necessary supplies and equipment required by the individualized plan of care. For a patient with COVID-19, this would include supplies for respiratory hygiene and cough etiquette, including 60%-95% alcohol-based hand sanitizer (ABHS). However, given supply shortages, State and Federal surveyors should not cite hospice agencies for not providing certain supplies (e.g., personal protective equipment (PPE) such as gowns, N95 respirators, surgical masks and alcohol-based hand rubs (ABHR)) if they are having difficulty obtaining these supplies for reasons outside of their control. However, we do expect providers/suppliers 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.

What Personal Protective Equipment should hospice staff routinely use when visiting the home of a patient suspected of COVID-19 exposure or confirmed exposure?

If care provided to symptomatic patients who are confirmed or presumed to be COVID-19 positive is anticipated, then Hospice Agencies 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>

Health care professionals who enter the room of a patient with known or suspected COVID-19 should adhere to Standard Precautions and use a facemask or respirator, gown, gloves, and eye protection. When available, respirators (instead of facemasks) are preferred; they should be prioritized for situations where respiratory protection is most important and the care of patients with pathogens requiring Airborne Precautions (e.g., tuberculosis, measles, varicella).

What are the considerations for discharge to a subsequent care location for hospice patients with COVID-19?

The decision should be made based on the clinical condition of the patient including careful consultation with the patient, patient representatives and/or their family, and understanding their individual needs and goals of care. If Transmission-Based Precautions must be continued in the subsequent setting, the receiving facility must be able to implement all recommended infection prevention and control recommendations. Be sure the transportation team is aware that the patient has confirmed COVID-19.

Although COVID-19 patients with mild symptoms may be managed at home, the decision to discharge to home should consider the patient's ability to adhere to isolation recommendations, as well as the potential risk of secondary transmission to household members with immunocompromising conditions. More information is available here:

<https://www.cdc.gov/coronavirus/2019-ncov/hcp/guidance-home-care.html>.

If hospice care is provided in a nursing home, we have advised nursing homes that hospice workers should be allowed entry provided that hospice staff is following the appropriate CDC guidelines for Transmission-Based Precautions, and using PPE properly.

Important CDC Resources:

CDC Resources for Health Care Facilities:

- 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>
- 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 Updates:

<https://www.cdc.gov/coronavirus/2019-ncov/whats-new-all.html>

[Sign up for the newsletter](#) to receive weekly emails about the coronavirus disease 2019 (COVID-19) outbreak.

FDA Resources:

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

CMS Resources:

Hospice Infection Control and Prevention regulations and guidance: 42 CFR 418.60, Infection Control, Appendix M of the State Operations Manual, Infection Prevention and Control.

https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_m_hospice.pdf.

Contact: Questions about this memorandum should be addressed to QSOG_EmergencyPrep@cms.hhs.gov. Questions about COVID-19 guidance/screening criteria should be addressed to the State Epidemiologist or other responsible state or local public health officials in your state.

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

Ref: QSO-20-15 Hospital/CAH/EMTALA

DATE: March 9, 2020
TO: State Survey Agency Directors
FROM: Director
Quality Safety and Oversight Group
SUBJECT: Emergency Medical Treatment and Labor Act (EMTALA) Requirements and Implications Related to Coronavirus Disease 2019 (COVID-19)

Memorandum Summary

COVID-19 and EMTALA Requirements: This Memorandum conveys information in response to inquiries from hospitals and critical access hospitals (CAHs) concerning implications of COVID-19 for their compliance with EMTALA. This guidance applies to both Medicare and Medicaid providers.

- **EMTALA Screening Obligation:** Every hospital or CAH with a dedicated emergency department (ED) is required to conduct an appropriate medical screening examination (MSE) of all individuals who come to the ED, including individuals who are suspected of having COVID-19, and regardless of whether they arrive by ambulance or are walk-ins. Every ED is expected to have the capability to apply appropriate COVID-19 screening criteria when applicable, to immediately identify and isolate individuals who meet the screening criteria to be a potential COVID-19, to contact their state or local public health officials to determine next steps.
- **EMTALA Stabilization, Transfer & Recipient Hospital Obligations:** In the case of individuals with suspected or confirmed COVID-19, hospitals and CAHs are expected to consider current guidance of CDC and public health officials in determining whether they have the capability to provide appropriate isolation required for stabilizing treatment and/or to accept appropriate transfers. In the event of any EMTALA complaints alleging inappropriate transfers or refusal to accept appropriate transfers, CMS will take into consideration the public health guidance in effect at the time.

Background

Due to increasing public concerns with COVID-19, CMS is receiving inquiries from the hospital industry concerning implications for their compliance with EMTALA. Concerns center around

the ability of hospitals and CAHs to fulfill their EMTALA screening obligations while minimizing the risk of exposure from COVID-19 infected individuals to others in the ED, including healthcare workers, and the isolation requirements for COVID-19. In addition, we have also received questions about the applicability of EMTALA stabilization, transfer and recipient hospital obligations in the case of individuals who are found to have met the screening criteria for possible COVID-19 infection or who have been determined to have COVID-19.

Please note this memorandum applies to both hospital and critical access hospital (CAH) wherever "hospital" is referenced.

EMTALA requires Medicare-participating hospitals and CAHs that have a dedicated emergency department to, at a minimum:

- Provide a medical screening exam (MSE) to every individual who comes to the ED for examination or treatment for a medical condition to determine if they have an emergency medical condition (EMC). An emergency medical condition is present when there are acute symptoms of sufficient severity such that the absence of immediate medical attention could reasonably be expected to result in serious impairment or dysfunction.
- Provide necessary stabilizing treatment for individuals with an emergency medical condition EMC within the hospital's capability and capacity; and
- Provide for transfers of individuals with EMCs, when appropriate.

Please see *Attachment 1* for a discussion of alternate screening locations and increased surges in numbers of patients presenting to the ED.

Are hospitals required to accept transfers of patients with suspected or confirmed COVID-19 from small or rural hospitals that don't have appropriate or sufficient isolation facilities or equipment to meet current state or local public health or CDC recommendations?

Hospitals with capacity and the specialized capabilities needed for stabilizing treatment are required to accept appropriate transfers from hospitals without the necessary capabilities. Hospitals should coordinate with their State/local public health officials regarding appropriate placement of individuals who meet specified COVID-19 assessment criteria, and the most current standards of practice for treating individuals with confirmed COVID-19 infection status.

As in any case concerning a hospital's EMTALA obligations with respect to transfers of individuals, CMS would evaluate the capabilities and capacity of both the referring and recipient hospitals in order to determine whether a violation has occurred. Among other things, we would take into account the CDC's recommendations at the time of the event in question in assessing whether a hospital had the requisite capabilities and capacity. We note that the CDC's recommendations focus on factors such as the individual's recent travel or exposure history and presenting signs and symptoms in differentiating the types of capabilities hospitals should have to screen and treat that individual. The presence or absence of negative pressure rooms (Airborne Infection Isolation Room (AIIR)) would not be the sole determining factor related to transferring patients from one setting to another when in some cases all that would be required would be a private room. See the CDC website for the most current infection prevention and

control recommendations for hospital patients with suspected or known COVID-19:
<https://www.cdc.gov/coronavirus/2019-ncov/hcp/clinical-guidance-management-patients.html>

In addition, all Medicare-participating hospitals with specialized capabilities are required to accept appropriate transfers of individuals with EMCs if the hospital has the specialized capabilities an individual requires for stabilization as well as the capacity to treat these individuals. This recipient hospital obligation applies regardless of whether the hospital has a dedicated emergency department.

What are the screening sites that may be set up?

Hospitals may set up alternative screening sites on campus

- The MSE does not have to take place in the ED. A hospital may set up alternative sites on its campus to perform MSEs.
 - Individuals may be redirected to these sites after being logged in. The redirection and logging can even take place outside the entrance to the ED.
 - The person doing the directing should be qualified (e.g., an RN) to recognize individuals who are obviously in need of immediate treatment in the ED.
- The content of the MSE varies according to the individual's presenting signs and symptoms. It can be as simple or as complex, as needed, to determine if an EMC exists.
- MSEs must be conducted by qualified personnel, which may include physicians, nurse practitioners, physician's assistants, or RNs trained to perform MSEs and acting within the scope of their State Practice Act.
- The hospital must provide stabilizing treatment (or appropriate transfer) to individuals found to have an EMC, including moving them as needed from the alternative site to another on-campus department.

B. Hospitals may set up screening at off-campus, hospital-controlled sites.

- Hospitals and community officials may encourage the public to go to these sites instead of the hospital for screening for influenza-like illness (ILI). *However, a hospital may not tell individuals who have already come to its ED to go to the off-site location for the MSE.*
- Unless the off-campus site is already a dedicated ED (DED) of the hospital, as defined under EMTALA regulations, EMTALA requirements do not apply.
- The hospital should not hold the site out to the public as a place that provides care for EMCs in general on an urgent, unscheduled basis. They can hold it out as an ILI screening center.
- The off-campus site should be staffed with medical personnel trained to evaluate individuals with ILIs.
- If an individual needs additional medical attention on an emergent basis, the hospital is required, under the Medicare Conditions of Participation, to arrange

referral/transfer. Prior coordination with local emergency medical services (EMS) is advised to develop transport arrangements.

C. Communities may set up screening clinics at sites not under the control of a hospital

- There is no EMTALA obligation at these sites.
- Hospitals and community officials may encourage the public to go to these sites instead of the hospital for screening for ILI. *However, a hospital may not tell individuals who have already come to its ED to go to the off-site location for the MSE.*
- Communities are encouraged to staff the sites with medical personnel trained to evaluate individuals with ILIs.
- In preparation for a pandemic, the community, its local hospitals and EMS are encouraged to plan for referral and transport of individuals needing additional medical attention on an emergent basis.

EMTALA Obligations when Screening Suggests Possible COVID-19

If an individual comes to an ED of a hospital, as the term “comes to the emergency department” is defined in the regulation at §489.24(b), either by ambulance or as a walk-in, the hospital must provide the individual with an appropriate MSE. We emphasize that it is a violation of EMTALA for hospitals and CAHs with EDs to use signage that presents barriers to individuals who are suspected of having COVID-19 from coming to the ED, or to otherwise refuse to provide an appropriate MSE to anyone who has come to the ED for examination or treatment of a medical condition. However, use of signage designed to help direct individuals to various locations on the hospital property, as that term is defined in the regulation at §489.24(b), for their MSE would be acceptable. If the hospital is intending to use another location to conduct the MSE, please see *Attachment 1* for additional information.

If during the MSE the hospital concludes that an individual who has come to its ED may be a possible COVID-19 case, consistent with accepted standards of practice for COVID-19 screening, the hospital is expected to isolate the patient immediately. Although levels of services provided by EDs vary greatly across the country, it is CMS’ expectation that all hospitals are able to, within their capability, provide MSEs and initiate stabilizing treatment, while maintaining the isolation requirements for COVID-19 and coordinating with their State or local public health officials, who will in turn arrange coordination, as necessary, with the CDC.

Stabilizing treatment means, with respect to an “emergency medical condition”, to provide such medical treatment of the condition necessary to assure, within reasonable medical probability, that no material deterioration of the condition is likely to occur. Once an individual is admitted or the emergency medical condition ends, the obligations under EMTALA end.

At the time of this memo’s publication, CDC’s screening guidance (<https://www.cdc.gov/coronavirus/2019-ncov/hcp/clinical-criteria.html>) called for hospitals to contact their State or local public health officials when they have a case of suspected COVID-19. Officials will advise of next steps, in accordance with CDC recommendations on testing.

Other Enforcement Considerations

Should CMS receive complaints alleging either inappropriate transfers by a sending hospital or refusal of a recipient hospital to accept an appropriate transfer, it will take into consideration CDC guidance and State or local public health direction at the time of the alleged noncompliance. It will also take into consideration any clinical considerations specific to the individual case(s).

Consistent with their obligations under the hospital and CAH Conditions of Participation (CoPs) §482.42 and §485.640, hospitals and CAHs are expected to adhere to accepted standards of infection control practice to prevent the spread of infectious disease and illness, including COVID-19. Standard, contact, and airborne precautions with eye protection should be used when caring for the patient as noted in CDC's [Interim Health Care Infection Prevention and Control Recommendations for Patients Under Investigation for Coronavirus Disease 2019 \(COVID-19\)](#). The CDC has issued extensive guidance on applicable isolation precautions and CMS strongly urges hospitals to follow this guidance. CMS recognizes the difficulties securing the recommended personal protective equipment (PPE) required for training and patient care that may be present in some circumstances at the time of this memorandum.

Hospitals and CAHs are expected under their respective CoPs at §482.11(a) and §485.608(a) to comply with Occupational Safety and Health Administration (OSHA) requirements, but CMS and state surveyors acting on its behalf do not assess compliance with requirements of other Federal agencies.

Latest CDC Guidance

The most up-to-date guidance regarding screening, testing, treatment, isolation, and other COVID-19 topics can be found on the CDC website at <https://emergency.cdc.gov/han/11AN00427.asp>. Hospitals and CAHs are strongly urged to monitor this site as well as their State public health website and follow recommended guidelines and acceptable standards of practice. State Survey Agencies are also encouraged to monitor the CDC and their state public health websites for up-to-date information.

CMS Resources

CMS has released a memo regarding triage, assessment and discharge for hospitals which will provide additional information about responding to COVID-19 cases. <https://www.cms.gov/files/document/qso-20-13-hospitalspdf.pdf-2>

CMS has additional guidance which may be beneficial related to EMTALA, and other topics surrounding health standards and quality. The document Provider Survey and Certification Frequently Asked Questions (FAQs), Declared Public Health Emergency All-Hazards are located at <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertEmergPrep/Downloads/All-Hazards-FAQs.pdf>. These FAQs are not limited to situations involving 1135 Waivers, but are all encompassing FAQs related to public health emergencies and survey activities and functions.

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Questions about this memo should be addressed to QSOG_EmergencyPrep@cms.hhs.gov.

FDA Resources:

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

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 Wright

cc: Survey & Certifications Group Management

Attachment (2)

FACT SHEET



**Emergency Medical Treatment and Labor Act (EMTALA) &
Surges in Demand for Emergency Department (ED) Services**

I. What is EMTALA?

- EMTALA is a Federal law that requires all Medicare-participating hospitals (**including critical access hospitals (CAHs)**) with dedicated EDs to perform the following for **all** individuals who come to their EDs, regardless of their ability to pay:
 - An *appropriate* medical screening exam (MSE) to determine if the individual has an Emergency Medical Condition (EMC). If there is no EMC, the hospital's EMTALA obligations end.
 - If there is an EMC, the hospital must:
 - + Treat and stabilize the EMC within its capability (including inpatient admission when necessary); **OR**
 - + Transfer the individual to a hospital that has the capability and capacity to stabilize the EMC.
- Hospitals with specialized capabilities (with or without an ED) may not refuse an appropriate transfer under EMTALA if they have the capacity to treat the transferred individual.
- EMTALA ensures access to hospital emergency services; it need not be a barrier to providing care in a disaster.

II. Options for Managing Extraordinary ED Surges Under Existing EMTALA Requirements (No Waiver Required)

A. Hospitals may set up alternative screening sites on campus

- The MSE does not have to take place in the ED. A hospital may set up alternative sites on its campus to perform MSEs.
 - Individuals may be redirected to these sites after being logged in. The redirection and logging can even take place outside the entrance to the ED.
 - The person doing the directing should be qualified (e.g., an RN) to recognize individuals who are obviously in need of immediate treatment in the ED.
- The content of the MSE varies according to the individual's presenting signs and symptoms. It can be as simple or as complex, as needed, to determine if an EMC exists.

- MSEs must be conducted by qualified personnel, which may include physicians, nurse practitioners, physician's assistants, or RNs trained to perform MSEs and acting within the scope of their State Practice Act.
- The hospital must provide stabilizing treatment (or appropriate transfer) to individuals found to have an EMC, including moving them as needed from the alternative site to another on-campus department.

B. Hospitals may set up screening at off-campus, hospital-controlled sites.

- Hospitals and community officials may encourage the public to go to these sites instead of the hospital for screening for influenza-like illness (ILI). *However, a hospital may not tell individuals who have already come to its ED to go to the off-site location for the MSE.*
- Unless the off-campus site is already a dedicated ED (DED) of the hospital, as defined under EMTALA regulations at 42 CFR § 489.24(b), EMTALA requirements do not apply.
- The hospital should not hold the site out to the public as a place that provides care for EMCs in general on an urgent, unscheduled basis. They can hold it out as an ILI screening center.
- The off-campus site should be staffed with medical personnel trained to evaluate individuals with ILIs.
- If an individual needs additional medical attention on an emergent basis, the hospital is required, under the Medicare Conditions of Participation, to arrange referral/transfer. Prior coordination with local emergency medical services (EMS) is advised to develop transport arrangements.

C. Communities may set up screening clinics at sites not under the control of a hospital

- There is no EMTALA obligation at these sites.
- Hospitals and community officials may encourage the public to go to these sites instead of the hospital for screening for ILI. *However, a hospital may not tell individuals who have already come to its ED to go to the off-site location for the MSE.*
- Communities are encouraged to staff the sites with medical personnel trained to evaluate individuals with ILIs.
- In preparation for a pandemic, the community, its local hospitals and EMS are encouraged to plan for referral and transport of individuals needing additional medical attention on an emergent basis.

III. EMTALA Waivers

- An EMTALA waiver allows hospitals to:
 - Direct or relocate individuals who come to the ED to an alternative off-campus site, in accordance with a State emergency or pandemic preparedness plan, for the MSE.

- Effect transfers normally prohibited under EMTALA of individuals with unstable EMCs, so long as the transfer is necessitated by the circumstances of the declared emergency.
- By law, the EMTALA MSE and stabilization requirements can be waived for a hospital **only if**:
 - The President has declared an emergency or disaster under the Stafford Act or the National Emergencies Act ; *and*
 - The Secretary of HHS has declared a Public Health Emergency; *and*
 - The Secretary invokes her/his waiver authority (which may be retroactive), including notifying Congress at least 48 hours in advance; *and*
 - The waiver includes waiver of EMTALA requirements and the hospital is covered by the waiver.
- CMS will provide notice of an EMTALA waiver to covered hospitals through its Regional Offices and/or State Survey Agencies.
- Duration of an EMTALA waiver:
 - In the case of a public health emergency involving pandemic infectious disease, until the termination of the declaration of the public health emergency; *otherwise*
 - In all other cases, 72 hours after the hospital has activated its disaster plan.
 - In no case does an EMTALA waiver start before the waiver's effective date, which is usually the effective date of the public health emergency declaration.

EMTALA Obligations & 2019-Novel Coronavirus (COVID-19) Question and Answer Document

Note: For the purpose of this document, the term "hospital" includes all types of Medicare-participating hospitals, critical access hospitals (CAHs).

A. Patient Insurance/Payor Status

A.1. Is a Medicare-participating hospital required to provide EMTALA-mandated screening and stabilizing treatment for non-Medicare beneficiaries with likely or confirmed COVID-19?

EMTALA applies to all individuals who come to the dedicated emergency department (ED) of a Medicare-participating hospital or CAH, regardless of type or presence of insurance coverage or ability to pay. Further, Medicare-participating hospitals with specialized capabilities are required within the limits of their capability and capacity to accept appropriate transfers of individuals protected under EMTALA from other hospitals, without regard to insurance or ability to pay.

B. Specialized Capabilities

B.1. EMTALA requires that hospitals with specialized capabilities to treat COVID-19 accept appropriate transfers of individuals who require those services, if they have capacity to provide them. In the event of an EMTALA complaint related to an inappropriate transfer and/or a refusal of a recipient hospital to accept an appropriate transfer, how will CMS determine whether a hospital had the "specialized capabilities" with respect to COVID-19 required by the individual?

At the time of this FAQ document, no formally designated COVID-19 treatment centers are established. Some of the early COVID-19 cases were sent to hospitals previously designated as Ebola treatment centers however, no determination has been made that specialized centers would be developed for COVID-19 cases and therefore all hospitals are required at a minimum to screen, isolate, and begin stabilizing treatment as appropriate for any individual with suspected COVID-19 symptoms.

B.2: Are hospitals required to accept transfers of patients with suspected or confirmed COVID-19 from small or rural hospitals that don't have appropriate or sufficient isolation facilities or equipment to meet current state or local public health or CDC recommendations?

Hospitals with capacity and the specialized capabilities needed for stabilizing treatment are required to accept appropriate transfers from hospitals without the necessary capabilities. Hospitals should coordinate with their State/local public health officials regarding appropriate placement of individuals who meet specified COVID-19 assessment criteria, and the most current standards of practice for treating individuals with confirmed COVID-19 infection status.

As in any case concerning a hospital's EMTALA obligations with respect to transfers of individuals, CMS would evaluate the capabilities and capacity of both the referring and recipient hospitals in order to determine whether a violation has occurred. Among other things, we would take into account the CDC's recommendations at the time of the event in question in assessing

whether a hospital had the requisite capabilities and capacity. We note that the CDC's recommendations focus on factors such as the individual's recent travel or exposure history and presenting signs and symptoms in differentiating the types of capabilities hospitals should have to screen and treat that individual. The presence or absence of negative pressure rooms (Airborne Infection Isolation Room (AIIR)) would not be the sole determining factor related to transferring patients from one setting to another when in some cases all that would be required would be a private room. See the CDC website for the most current infection prevention and control recommendations for hospital patients with suspected or known COVID-19: <https://www.cdc.gov/coronavirus/2019-nCoV/hcp/clinical-guidance-management-patients.html>

C. Screening Examinations and Stabilizing Treatment Requirements

C.1: What are the EMTALA requirements for hospitals in regard to screening and treating individuals with possible COVID-19?

The EMTALA requirements for hospitals and CAHs are the same for individuals with possible COVID-19 symptoms as all other possible emergency medical conditions (EMCs). Hospitals and CAHs must:

- Provide an appropriate Medical Screening Exam (MSE) to every individual who comes to the Emergency Department (ED) for examination or treatment of a medical condition, to determine if they have an emergency medical condition (EMC); Provide necessary stabilizing treatment for individuals with an EMC within the hospital's capability and capacity; and
- Provide for appropriate transfers of individuals with EMCs if the hospital lacks the capability to stabilize them.

Specific to COVID-19, hospitals are encouraged to follow the CDC guidance for appropriate isolation procedures to minimize the risk of cross-contamination to other patients, visitors, and healthcare workers. For example, the CDC publishes and updates guidance related to COVID-19. Hospitals should consult the latest CDC guidance and coordinate with State/local public health authorities for guidance related to ongoing care and treatment of patients with COVID-19.

C.2: Are all hospitals expected to screen and treat individuals with possible COVID-19 symptoms?

Yes, all hospitals are expected, at a minimum to screen, isolate, and begin stabilizing treatment, as appropriate, for any individual with possible COVID-19 symptoms. Hospitals should coordinate with their State/local public health authorities regarding ongoing care and treatment.

C.3: Can hospitals ask patients to wait in their car or outside the hospital as CDC suggests in their COVID-19 guidance or is that violating EMTALA?

The MSE requirement of EMTALA requires that it be timely depending on the presenting signs and symptoms of the individual. Hospitals must perform an appropriate examination by a Qualified Medical Practitioner to determine if the patient has an emergency medical condition. If the individual, after an appropriate medical screening exam, meets the CDC criteria for potential COVID-19 and is determined to have no signs or symptoms that require immediate medical attention, then this would not present a direct EMTALA violation. In cases where a request is

made for medical care that is unlikely to involve an EMC, the individual's statement that s/he is not seeking emergency care, together with brief questioning by the QMP would be sufficient to establish that there is no EMC and the hospital's EMTALA obligation would be satisfied. However, the hospital should have a system in place to monitor those patients that opt to wait in their own vehicle to ensure that their condition has not deteriorated while awaiting further evaluation. Failure to do so could expose the hospital to a potential MSE violation because the MSE was not done timely. In that case, it could also be a violation of the Condition of Participation: Emergency Services. As noted during previous public health emergency situations such as EBOLA and H1N1, CMS will take into consideration any clinical considerations specific to the individual case(s).

C.4: If a hospital does not have Intensive Care Unit (ICU) capabilities is it required to screen and, when appropriate, initiate stabilizing treatment for individuals with suspected or confirmed COVID-19?

Yes. The lack of ICU capabilities does not exempt a hospital from performing an MSE and initiating stabilizing treatment for individuals with known or suspected COVID-19 who come to the hospital's ED seeking examination or treatment. Qualified medical personnel in hospitals that conduct the screening examination should be aware of the criteria for initial COVID-19 screening and should apply such screening when appropriate. Note that the CDC guidance for COVID-19, indicates that they should do the following:

- Promptly identify and triage patients with relevant exposure history AND signs or symptoms compatible with COVID-19 <https://www.cdc.gov/coronavirus/2019-ncov/infection-control/control-recommendations.html>.
- Immediately isolate any patient with relevant exposure history and signs or symptoms compatible with COVID-19 and take appropriate steps to adequately protect staff caring for the patient, including appropriate use of personal protective equipment (PPE).
- Immediately notify the hospital/facility infection control program, other appropriate facility staff, and the state and local public health agencies that a patient has been identified who has relevant exposure AND signs or symptoms compatible with COVID-19.

C.5: May hospitals refuse to allow individuals with suspected cases of COVID-19 into their ED?

No. For every individual who "comes to the emergency department," as that term is defined in §489.24(b) of the EMTALA regulations, for evaluation or treatment of a medical condition, whether by ambulance or by walking-in, hospitals are required to provide an appropriate medical screening examination. Qualified medical personnel in hospitals that conduct the screening examination should be aware of the criteria for initial COVID-19 screening and should apply such screening when appropriate. Hospitals that refuse to screen an individual who comes to their emergency department would likely be found to have violated EMTALA, regardless of presenting signs, symptoms, and possible diagnoses.

C.6: If a hospital remains open during COVID-19 or any other infectious outbreak, and is operating at or in excess of its normal operating capacity and cannot get sufficient staff, may the hospital shut down its emergency department (ED) without violating EMTALA?

Under these circumstances, EMTALA would not prohibit the hospital from closing its ED to new patients if it no longer had the capacity to screen and treat individuals (in effect, going on diversion). The hospital should follow any applicable State and local notice requirements and its own previously established plan for public notification when it goes on diversionary status. The hospital would continue to have an EMTALA obligation to individuals undergoing examination or treatment in its ED at the time it stops accepting new emergency patients. In addition, in spite of the “closure” if an individual comes to such a hospital and requests examination or treatment for an emergency medical condition, the hospital would be obligated by EMTALA to act within its capabilities to provide screening and, if necessary, stabilization.

C.7: Are all hospitals expected to have Personal Protective Equipment (PPE) and other equipment/facilities to screen and take care of suspected or confirmed COVID-19 patients?

There are no requirements established under EMTALA for hospitals to have specific PPE or equipment/facilities. Consistent with their obligations under the hospital and CAH Conditions of Participation (CoPs) at §482.42 and §485.640, hospitals and CAHs are expected to adhere to accepted standards of infection control practice to prevent the spread of COVID-19. However, the Emergency Preparedness Final Rule requires an all-hazards approach to the emergency preparedness planning and program. In February 2019, CMS updated subregulatory guidance in Appendix Z of the State Operations Manual (SOM), for facilities to plan for using an all-hazards approach, to include emerging infectious disease (EID) threats. Examples of EIDs include Influenza, Ebola, Zika Virus and others. Under this guidance, CMS specifically stated that these EIDs may require modifications to facility protocols to protect the health and safety of patients, such as isolation and personal protective equipment (PPE) measures.

The CDC has issued extensive guidance on applicable isolation precautions and CMS strongly urges hospitals to follow this guidance.

C.8: May hospitals decline to perform an MSE on an individual who comes to their ED with potential or suspected COVID-19 due to a lack of PPE or specialized equipment/facilities?

No. For every individual who “comes to the emergency department,” as that term is defined in §489.24(b) of the EMTALA regulations, for evaluation or treatment of a medical condition, whether by ambulance or by walking-in, hospitals are required to provide an appropriate medical screening examination. Qualified medical personnel in hospitals that conduct the screening examination must be aware of the criteria for initial COVID-19 screening and apply such screening when appropriate. Hospitals that refuse to screen an individual who comes to their emergency department would likely be found to have violated EMTALA, regardless of presenting signs, symptoms, and possible diagnoses.

C.9: Will CMS issue EMTALA waivers for hospitals related to COVID-19?

The statute governing EMTALA waivers sets a high threshold for issuing such waivers and also limits the nature and duration of an EMTALA waiver. At this time the requirements for CMS to issue EMTALA waivers have not been met (i.e., issuance of a Presidential disaster declaration and a Secretary's declaration of a public health emergency). For additional information, please visit <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertEmergPrep/1135-Waivers>.

C.10: What about ambulances operating under emergency medical services (EMS) systems – are they subject to EMTALA?

Public health officials, EMS systems and hospitals are free to develop protocols governing where EMS should transport individuals for emergency care. This includes developing protocols specific to individuals who meet criteria to be considered suspected cases of COVID-19. A hospital owned and operated ambulance operating under communitywide protocols that direct transport of individuals to a hospital other than the hospital that owns the ambulance, for example, to the closest appropriate hospital, the individual is considered to have come to the ED of the hospital to which the individual is transported, at the time the individual is brought onto hospital property and the hospital becomes subject to EMTALA.

Even in the case of ambulances that are owned and operated by a hospital, it is permissible to transport an individual to a different hospital for screening and treatment, so long as they are operating in accordance with a communitywide EMS protocol, or they are operating under the direction of a physician who is not employed or otherwise affiliated with the hospital that owns the ambulance.

C.11: May hospitals set up alternative screening sites within the hospital to screen possible COVID-19 patients, even if they don't have an EMTALA waiver?

Yes, hospitals have flexibilities to set up alternative screening sites at other parts of the hospital, both on- and off-campus. See *Attachment 1* for additional guidance regarding surges in emergency department services.

Additionally, per the Medicare Conditions of Participation, hospitals must have policies and procedures based on the facility's emergency preparedness plan and its role under a waiver declared by the HHS Secretary, in accordance with section 1135 of the Act, in the provision of care and treatment at an alternate care site identified by public health and emergency management officials. While we recognize at the time of these FAQs, an 1135 Waiver cannot be invoked as only the HHS Secretary has declared a public health emergency, we do expect facilities to have policies and procedures on alternate care sites.

However, absent an EMTALA waiver issued by CMS pursuant to a declaration of a public health emergency, hospitals may not direct an individual who has already come to their on-site emergency department to any off-campus location for screening.

C.11(a): What constitutes an alternative hospital location? For instance, can this include a tarped-off area of another room, a room constructed in the ambulance bay, or the room previously used as the decontamination room?

Hospitals have flexibilities under EMTALA to determine alternative locations outside the ED but within the hospital or on the hospital's property for screening examinations of individuals potentially exposed to or infected with COVID-19. Please see the Attachment 1: Fact Sheet for Addressing Hospital Surges

C.11(b): Do the Life Safety Code (LSC) requirements under the hospital or critical access hospital Conditions of Participation apply to alternative care sites?

Since alternative care sites are expected to be within the hospital or on the hospital's property (operating as part of the hospital/under the hospital's CMS Certification Number, they would be expected to meet LSC requirements. However, there may be situations where temporary examination areas are set up (please refer to above on alternate care sites).

Additionally, if compliance issues come up in such localized situations where no applicable section 1135 waiver [for declared public health emergencies] is available, CMS focuses on fundamentals, such as assuring medical and nursing staff have proper credentials and, in the case of medical staff, have privileges; assuring that care is safe, that patients' rights are protected and that medical records with sufficient information to promote safe care are maintained. Additionally, for facilities subject to the Life Safety Code (LSC), past experience has demonstrated that many facilities, even when functioning in a degraded status, or in the case of the establishment of alternative care sites, may continue to meet the LSC by implementing reasonable and prudent measures. For example, there were several hospitals that were damaged by Hurricane Katrina which continued to comply with the LSC by implementing reasonable and prudent measures, and therefore were able to continue operations in a degraded but safe environment for weeks or months until repairs could be completed.

Archived information on H1N1 which discussed alternate care sites can be located at:
<https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertEmergPrep/Downloads/SCLetter-10-06-Influenza.pdf>

We would also encourage facilities to review resources provided by the Assistant Secretary of Preparedness and Response (ASPR) Technical Resources Assistance Center and Information Exchange (TRACIE) located here: <https://asprtracie.hhs.gov/technical-resources/48/alternate-care-sites-including-shelter-medical-care/47>

C.11(c): Can alternative sites include outbuildings on the campus or use of tents in the parking lot?

Alternative screening sites may be located in other buildings on the campus of a hospital or in tents in the parking lot, as long as they are determined to be an appropriate setting for medical screening activities and meet the clinical requirements of the individuals referred to that setting. We also defer to screening guidance provided by the CDC.

C.11(d): What would be an acceptable alternative location on campus? Must the location currently exist as a part of the certified facility?

The location must be part of the certified hospital. If it is not currently part of the certified hospital, then the hospital must take steps to add the location as a new practice location of the hospital.

C.11(e): What type of approval process needs to be in place for a hospital to use an alternative location?

CMS does not require any approval process to use an alternative screening location that is already part of the certified hospital. If the hospital is adding a practice location, it must file a Form 855A with its Medicare Administrative Contractor to advise it of this action. The hospital is not required to obtain prior approval from CMS in order to bill Medicare for services at the added location. There is also no requirement for all added locations to be surveyed for compliance with the Medicare Hospital Conditions of Participation, but CMS retains the discretion to require a survey in individual cases.

States may have licensure requirements for prior approval of any additional practice locations, so hospitals are encouraged to consult with their State licensure authority on any applicable State requirements.

C.11(f): In the past when there have been disasters that resulted in ED surges alternative locations needed to be submitted and approved by State licensure authorities and also by CMS. Does this hold true for alternative locations for screening of potential COVID-19 patients?

See answer to the prior question. As stated, CMS does not require prior approval for hospitals that are adding a practice location. Hospitals should consult with their State licensure authority on any applicable State requirements.

D. Patient Rights

D.1: What action should the hospital take if an individual who meets the screening criteria for suspected COVID-19 wants to leave the hospital against medical advice?

Hospitals do not have authority to prevent the individual from leaving against medical advice. However, State or local public health authorities may have such authority under State or local law, and hospitals should coordinate with their local authorities on the appropriate way to handle an individual suspected of having COVID-19 who wants to leave the hospital environment.

Note that there is an EMTALA requirement at §489.24(d)(3) for a hospital to take all reasonable steps to secure the individual's written informed refusal (or that of the individual's representative) of further medical examination or treatment that the hospital has offered.

E. Enforcement

E.1: What will CMS do when a survey reveals that a hospital is not following nationally recognized guidelines regarding COVID-19 infection control processes?

EMTALA does not establish requirements for infection control practices. However, consistent with their obligations under the hospital and CAH Medicare CoPs at §482.42 and §485.640, hospitals and CAHs are expected to adhere to accepted standards of infection control practice and Medicare conditions.

The CDC has issued extensive guidance on applicable isolation precautions and CMS strongly urges hospitals to follow this guidance. Hospitals may be cited for deficiencies under the CoPs related to failure to follow accepted infection prevention and control standards of practice.

Hospitals should regularly check the official [CDC COVID-19 website](https://www.cdc.gov/coronavirus/2019-ncov/index.html)

(<https://www.cdc.gov/coronavirus/2019-ncov/index.html>) and consider signing up for [Sign up for the newsletter](#) to receive weekly emails about the coronavirus disease 2019 (COVID-19)

https://tools.cdc.gov/campaignproxyservice/subscriptions.aspx?topic_id=USCDC_2067.

E.2: How will CMS handle complaints about violations of EMTALA related to transfers/attempts to transfer individuals suspected or confirmed as having COVID-19?

If CMS receives complaints alleging either inappropriate transfers by a referring hospital or refusal of a recipient hospital to accept an appropriate transfer, the agency will consider the following (along with other factors) when making a determination of whether violations of EMTALA have occurred:

- The individual's clinical condition at the time of presentation to the referring hospital and at the time of the transfer request;
- The capabilities of the referring hospital,
- The screening and treatment activities performed by the referring hospital for the individual;
- Whether the request for transfer was consistent with any nationally recognized guidelines in effect at the time of the transfer request for COVID-19 screening, assessment, including guidance about transfer for further assessment or treatment of suspected or confirmed COVID-19; and,
- The capabilities of the recipient hospital and the recipient hospital's capacity at the time of the transfer request.

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-20-19-ESRD

DATE: March 10, 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 dialysis facilities

Memorandum Summary

- **CMS is dedicated** to the continued health and safety of patients obtaining care within dialysis facilities to ensure facilities are prepared to respond to the threat of COVID-19.
- **Dialysis Guidance and Actions** - CMS is providing additional guidance to dialysis facilities to help them focus their infection control and prevention practices to prevent the transmission of COVID-19.
- **Coordination with the Centers for Disease Control (CDC) and local public health departments** - We encourage all dialysis facilities to monitor the CDC website for updated 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

CMS is responsible for ensuring the health and safety within dialysis facilities by enforcing health and safety standards required to help facilities provide safe, quality care to dialysis patients. Due to the recent spread of COVID-19, we are providing additional guidance to dialysis facilities to help control and prevent the spread of the virus.

Guidance

Facilities should monitor the CDC website for information and resources (links below), and contact their local health department when needed. Also, facilities should be monitoring the health status of everyone (in-center and home dialysis patients/visitors/staff/etc.) in their facility for signs or symptoms of respiratory infection, including COVID-19. Per CDC, prompt detection, triage and isolation of potentially infectious patients are essential to prevent unnecessary exposures among patients, healthcare personnel, and visitors at the facility. Therefore, facilities should continue to be vigilant in identifying any possible exposed or

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 open lines of communication with patients, patient representatives and/or family and other care providers to respond to the individualized needs of each patient.

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

In addition to the requirements in the Conditions for Coverage (CFC) and associated guidance, we're providing the following information (Frequently Asked Questions) about some specific areas related to COVID-19:

Guidance for Limiting the Transmission of COVID-19 for Dialysis Facilities

What actions should dialysis facilities implement to promote early recognition and management of patients, staff and visitors?

Facilities should screen patients, staff and visitors and contact home dialysis patients for the following:

1. Signs or symptoms of a respiratory infection, such as a fever, cough, shortness of breath or sore throat.
2. Contact with someone with or under investigation for COVID-19.
3. International travel within the last 14 days to countries with widespread or ongoing community spread. For updated information on countries visit: <https://www.cdc.gov/coronavirus/2019-ncov/travelers/after-travel-precautions.html>
4. Residing in a community where community-based spread of COVID-19 is occurring.

Furthermore, to promptly identify and manage patients, staff or visitors with undiagnosed respiratory symptoms the following actions should be implemented:

- Facilities should identify patients with signs and symptoms of respiratory infections before they enter the treatment area.
 - Patients with symptoms of a respiratory infection should put on a facemask (i.e., surgical mask) at check-in and keep it on until they leave the facility. The facility should provide if needed.
 - Patients should inform staff of fever or respiratory symptoms immediately upon arrival at the facility (e.g., when they check in at the registration desk) (Note, the facility will likely also check patient temperature).
 - Have patients call ahead to report fever or respiratory symptoms so the facility can be prepared for their arrival or triage them to a more appropriate setting (e.g., an acute care hospital).
 - Post signs at entrances with instructions to patients with fever or symptoms of respiratory infection to alert staff so appropriate precautions can be implemented.

- Facilities should provide patients and staff with instructions (in appropriate languages) about hand hygiene, respiratory hygiene, and cough etiquette.
 - Instructions should include how to use facemasks or tissues to cover nose and mouth when coughing or sneezing, to dispose of tissues and contaminated items in waste receptacles, and how and when to perform hand hygiene
- Facilities should have the following supplies available to ensure adherence to hand and respiratory hygiene, and cough etiquette. These include tissues and no-touch receptacles for disposal of tissues and hand hygiene supplies (e.g., alcohol-based hand sanitizer)
- Visitors with signs and symptoms of a transmissible infection (e.g., a visitor is febrile and exhibiting signs and symptoms of an influenza-like illness) should defer visitation until he or she is no longer potentially infectious (e.g., 24 hours after resolution of fever without antipyretic medication).

How should facilities monitor or restrict dialysis facility staff?

The same screening performed for visitors should be performed for facility staff (numbers 1, 2, and 3 above).

- Dialysis staff who have signs and symptoms of a respiratory infection should not report to work. Facilities should implement sick leave policies that are non-punitive, flexible and consistent with public health policies that allow ill staff members to stay home.
- Any staff member that develops signs and symptoms of a respiratory infection, should:
 - Immediately stop work (if working), put on a facemask, and self-isolate at home;
 - Inform the facility administrator, and collect information on individuals, equipment, and locations the person came in contact with; and
 - Contact and follow the local health department recommendations for next steps (e.g., testing, locations for treatment).
- Refer to the CDC guidance for exposures that might warrant restricting asymptomatic healthcare personnel from reporting to work (<https://www.cdc.gov/coronavirus/2019-ncov/hcp/guidance-risk-assessment-hcp.html>).

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>).

Where should dialysis facilities place patients with undiagnosed respiratory symptoms and/or suspected or confirmed COVID 19?

Facilities should have space in waiting areas for ill patients to sit separated from other patients by at least 6 feet. Medically-stable patients who do not have other care needs have the option to wait in a personal vehicle or outside the healthcare facility where they can be contacted by mobile phone when it is their turn to be seen. Additional placement consideration include:

- Patients with respiratory symptoms should be brought back to a designated treatment area for evaluation as soon as possible in order to minimize time in common waiting areas.

- Facilities should maintain at least 6 feet of separation between masked, symptomatic patients and other patients and stations during dialysis treatment. Ideally, symptomatic patients would be dialyzed in a separate room (if available) with the door closed.
 - Hepatitis B isolation rooms may be used to dialyze patients if:
 - The patient with suspected or confirmed COVID-19 is hepatitis B surface antigen positive or;
 - The facility has no hepatitis B surface antigen positive patients who would require treatment in the isolation room.
 - If a separate room is not available, the patient should be treated at a corner or end-of-row station, away from the main flow of traffic (if available). The patient should be separated by at least 6 feet from the nearest patient stations (in all directions).

When transmission in the community is identified, the local medical system's capacity to accept hemodialysis patients for treatment may be exceeded. Public health authorities and dialysis facilities should refer to pandemic and emergency preparedness plans to help determine alternatives. Alternative options may include the need to continue dialysis in the outpatient hemodialysis setting if the patient's condition does not require a higher level of care. If a hemodialysis facility is dialyzing more than one patient with suspected or confirmed COVID-19, consideration should be given to cohorting these patients and the dialysis staff caring for them together in the unit and/or on the same shift (e.g., consider the last shift of the day). Additionally, per current CDC guidance, an airborne infection isolation room (AIIR) is not required for the evaluation or care of patients with suspected or confirmed COVID-19. AIIRs should be prioritized for patients who are critically ill or receiving aerosol-generating procedures.

What type of Personal Protective Equipment (PPE) should be used when caring for patients with undiagnosed respiratory symptoms?

When providing dialysis care, facilities should continue to follow the infection control requirements at 42 CFR §494.30 including requirements for hand hygiene, PPE, isolation and routine cleaning and disinfection procedures.

- In general, dialysis staff caring for patients with undiagnosed respiratory infections should follow Standard, Contact, and Droplet Precautions with eye protection unless the suspected diagnosis requires Airborne Precautions (e.g., tuberculosis). This includes the use of:
 - Isolation gowns
 - The isolation gown should be worn over or instead of the cover gown (i.e., laboratory coat, gown, or apron with incorporate sleeves) that is normally worn by hemodialysis personnel. This is particularly important when initiating and terminating dialysis treatment, manipulating access needles or catheters, helping the patient into and out of the station, and cleaning and disinfection of patient care equipment and the dialysis station.
 - Remove and discard the gown in a dedicated container for waste or linen before leaving the dialysis station. Disposable gowns should be discarded after use. Cloth gowns should be laundered after each use.
 - Gloves
 - Facemask

- Eye protection (e.g., goggles, a disposable face shield that covers the front and sides of the face). Personal glasses and contact lenses are NOT considered adequate eye protection.

Please see discussion below of Expanded Respirator Guidance below for additional information.

How should facilities ensure appropriate cleaning and disinfection of environmental surfaces, medical devices and equipment?

- Facilities should continue to follow the infection control requirements related to cleaning and disinfection at 42 CFR §494.30 which include:
 - Ensuring items taken into the dialysis station either be disposed of, dedicated for use only on a single patient, or
 - Cleaned and disinfected per manufacturer’s directions for use before being taken to a common clean area or used on another patient.
- Facilities should implement routine cleaning and disinfection procedures which are appropriate for COVID-19 in healthcare settings which include:
 - Using cleaners and water to pre-clean surfaces prior to applying an EPA-registered, hospital-grade disinfectant to frequently touched surfaces or objects for appropriate contact times as indicated on the product’s label.
 - Using products with EPA-approved emerging viral pathogens claims are recommended for use against COVID-19. If there are no available EPA-registered products that have an approved emerging viral pathogen claim for COVID-19, products with label claims against human coronaviruses should be used according to label instructions.
- Facilities should provide additional work supplies to avoid sharing (e.g., pens, pads) and disinfect workplace areas (nurse’s stations, phones, internal radios, etc.).

When should the dialysis facility consider transferring a patient to an alternative site for treatment?

- If the facility cannot fully implement the recommended precautions or if the patient’s condition requires care that the dialysis facility is unable to provide, the patient should be transferred to another facility that is capable of implementation. Transport personnel and the receiving facility should be notified about the suspected diagnosis prior to transfer.
- While awaiting transfer, patients should wear a facemask and be separated from other patients. If stable, patients can be asked to wait in their vehicles or return home. If that is not possible, then they should be placed in a separate room with the door closed. Contact with patient should be minimized. Appropriate PPE should be used by healthcare personnel when coming within 6 feet of patients with known or suspected COVID-19.

Are there special considerations for Home Dialysis Patients?

Dialysis facilities should continue to follow the guidelines as required regarding monthly monitoring of home dialysis patients onsite at the facility. While we want to limit exposure for the home dialysis patients, COVID-19 is particularly aggressive in individuals who are elderly and those with chronic conditions including end-stage renal disease (ESRD). It is important that the home dialysis patients do not miss their onsite appointments to ensure that all dialysis procedures are followed to ensure a safe environment for the patient. Facilities should be vigilant in monitoring any changes in guidelines as new information is available.

Will dialysis facilities 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 their CMS Location.

CDC Resources:

- Guidance for Infection Prevention and Control Recommendations for Patients with Suspected or Confirmed COVID-19 in Outpatient Hemodialysis Facilities
<https://www.cdc.gov/coronavirus/2019-ncov/healthcare-facilities/dialysis.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>
- CDC guidance for dialysis safety including infection prevention tools:
<https://www.cdc.gov/dialysis/index.html>
- *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
- Weekly e-mails regarding COVID-19:
https://tools.cdc.gov/campaignproxyservice/subscriptions.aspx?topic_id=USCDC_2067

FDA Resources:

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

CMS Resources:

- Appendix H of the State Operations Manual- Guidance to Surveyors: End-Stage Renal Disease Facilities at: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_h_esrd.pdf

- Appendix Z of the State Operations Manual - Emergency Preparedness for All Provider and Certified Supplier Types Interpretive Guidance at: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_z_emergprep.pdf
- Dialysis resources on the CMS website including interpretative guidance at: <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/GuidanceforLawsAndRegulations/Dialysis>

Contact: Questions about this memorandum should be addressed to QSOG_EmergencyPrep@cms.hhs.gov. Questions about COVID-19 guidance/screening criteria should be addressed to the State Epidemiologist or other responsible state or local public health officials in your state.

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

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

Ref: QSO-20-18-HHA

DATE: March 10, 2020
TO: State Survey Agency Directors
FROM: Director
Quality, Safety & Oversight Group
SUBJECT: Guidance for Infection Control and Prevention Concerning Coronavirus Disease 2019 (COVID-19) in Home Health Agencies (HHAs)

Memorandum Summary

CMS is committed to protecting American patients and residents by ensuring health care facilities have up-to-date information to adequately respond to COVID-19 concerns.

- **Coordination with the Centers for Disease Control and Prevention (CDC) and local public health departments** - We encourage all Home Health Agencies 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>).
- **Home Health Guidance and Actions** - CMS regulations and guidance support Home Health Agencies taking appropriate action to address potential and confirmed COVID cases and mitigate transmission including screening, treatment, and transfer to higher level care (when appropriate). This guidance applies to both Medicare and Medicaid providers.

Background

The Centers for Medicare & Medicaid Services (CMS) is committed to the protection of patients in the home care setting from the spread of infectious disease. This memorandum responds to questions we have received and provides important guidance for all Medicare and Medicaid participating Home Health Agencies (HHAs) in addressing the COVID-19 outbreak and minimizing transmission to other individuals.

Guidance

HHAs should monitor the CDC website (see links below) for information and resources and contact their local health department when needed. Also, HHAs should be monitoring the health status of everyone (patients/residents/visitors/staff/etc.) in the homecare setting for signs or

symptoms of COVID-19. Per CDC, prompt detection, triage and isolation of potentially infectious patients are essential to prevent unnecessary exposures among patients, healthcare personnel, and visitors.

In addition to the overarching regulations and guidance, we have provided the following information (Frequently Asked Questions) about some specific areas related to COVID-19. This guidance is applicable to all Medicare and Medicaid HHA providers.

HHA Guidance for Admitting and Treating Patients with known or suspected COVID-19

Which patients are at risk for severe disease for COVID-19?

Based upon CDC data, older adults or those with underlying chronic medical conditions may be most at risk for severe outcomes.

How should HHAs screen patients for COVID-19?

When making a home visit, HHAs should identify patients at risk for having COVID-19 infection before or immediately upon arrival to the home. They should ask patients about the following:

1. International travel within the last 14 days to countries with sustained community transmission. For updated information on affected countries visit: <https://www.cdc.gov/coronavirus/2019-ncov/travelers/index.html>
2. Signs or symptoms of a respiratory infection, such as a fever, cough, and sore throat.
3. In the last 14 days, has had contact with someone with or under investigation for COVID-19, or are ill with respiratory illness.
4. Residing in a community where community-based spread of COVID-19 is occurring.

For ill patients, implement source control measures (i.e., placing a facemask over the patient's nose and mouth if that has not already been done).

Inform the HHA clinical manager, local and state public health authorities about the presence of a person under investigation (PUI) for COVID-19. Additional guidance for evaluating patients in U.S. for COVID-19 infection can be found on the CDC COVID-19 website.

CMS regulations requires that home health agencies provide the types of services, supplies and equipment required by the individualized plan of care. HHA's are normally expected to provide supplies for respiratory hygiene and cough etiquette, including 60%-95% alcohol-based hand sanitizer (ABHS). State and Federal surveyors should not cite home health agencies for not providing certain supplies (e.g., personal protective equipment (PPE) such as gowns, respirators, surgical masks and alcohol-based hand rubs (ABHR)) if they are having difficulty obtaining these supplies for reasons outside of their control. However, we do expect providers/suppliers 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.

How should HHAs monitor or restrict home visits for health care staff?

- Health care providers (HCP) who have signs and symptoms of a respiratory infection should not report to work.
- Any staff that develop signs and symptoms of a respiratory infection while on-the-job, should:

- Immediately stop work, put on a facemask, and self-isolate at home;
 - Inform the HHA clinical manager of information on individuals, equipment, and locations the person came in contact with; and
 - Contact and follow the local health department recommendations for next steps (e.g., testing, locations for treatment).
- Refer to the CDC guidance for exposures that might warrant restricting asymptomatic healthcare personnel from reporting to work (<https://www.cdc.gov/coronavirus/2019-ncov/hcp/guidance-risk-assessment-hcp.html>)

HHAs 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>

Do all patients with known or suspected COVID-19 infection require hospitalization?

Patients may not require hospitalization and can be managed at home if they are able to comply with monitoring requests. More information is available here:
<https://www.cdc.gov/coronavirus/2019-ncov/hcp/guidance-home-care.html>

What are the considerations for determining when patients *confirmed* with COVID-19 are safe to be treated at home?

Although COVID-19 patients with mild symptoms may be managed at home, the decision to remain in the home should consider the patient’s ability to adhere to isolation recommendations, as well as the potential risk of secondary transmission to household members with immunocompromising conditions. More information is available here:
<https://www.cdc.gov/coronavirus/2019-ncov/hcp/guidance-home-care.html>

When should patients *confirmed* with COVID-19 who are receiving HHA services be considered for transfer to a hospital?

Initially, symptoms may be mild and not require transfer to a hospital as long as the individual with support of the HHA can follow the infection prevention and control practices recommended by CDC. (<https://www.cdc.gov/coronavirus/2019-ncov/infection-control/control-recommendations.html>)

The patient 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 hospital should be alerted to the patient’s diagnosis, and precautions to be taken including placing a facemask on the patient during transfer. If the patient does not require hospitalization they can be discharged back to home (in consultation with state or local public health authorities) if deemed medically and environmentally appropriate. Pending transfer or discharge, place a facemask on the patient and isolate him/her in a room with the door closed.

What are the implications of the Medicare HHA Discharge Planning Regulations for Patients with COVID-19?

Medicare’s Discharge Planning Regulations (which were updated in November 2019)

requires that HHA assess the patient's needs for post-HHA services, and the availability of such services. When a patient is discharged, all necessary medical information (including communicable diseases) must be provided to any other service provider. For COVID-19 patients, this must be communicated to the receiving service provider prior to the discharge/transfer and to the healthcare transport personnel.

What are recommended infection prevention and control practices, including considerations for family member exposure, when evaluating and caring for patients with known or suspected COVID-19?

The CDC advises the patient to stay home except to get medical care, separate yourself from other people and animals in the home as much as possible (in a separate room with the door closed), call ahead before visiting your doctor, and wear a facemask in the presence of others when out of the patient room.

For everyone in the home, CDC advises covering coughs and sneezes followed by hand washing or using an alcohol-based hand rub, not sharing personal items (dishes, eating utensils, bedding) with individuals with known or suspected COVID-19, cleaning all "high-touch" surfaces daily, and monitoring for symptoms. We would ask that HHA's share additional information with families. Please see <https://www.cdc.gov/coronavirus/2019-ncov/hcp/guidance-prevent-spread.html> and <https://www.cdc.gov/coronavirus/2019-ncov/community/home/index.html>.

Detailed infection prevention and control recommendations are available in 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>

Are there specific considerations for patients requiring therapeutic interventions?

Patients with known or suspected COVID-19 should continue to receive the intervention appropriate for the severity of their illness and overall clinical condition. Because some procedures create high risks for transmission (close patient contact during care) precautions include: 1) HCP should wear all recommended PPE, 2) the number of HCP present should be limited to essential personnel, and 3) any supplies brought into, used, and removed from the home must be cleaned and disinfected in accordance with environmental infection control guidelines.

What Personal Protective Equipment should home care staff routinely use when visiting the home of a patient suspected of COVID-19 exposure or confirmed exposure?

If care to patients with respiratory or gastrointestinal symptoms who are confirmed or presumed to be COVID-19 positive is anticipated, then HHAs should refer to the Interim Guidance for Public Health Personnel Evaluating Persons Under Investigation (PUIs) and Asymptomatic Close Contacts of Confirmed Cases at Their Home or Non-Home Residential Settings: <https://www.cdc.gov/coronavirus/2019-ncov/php/guidance-evaluating-pui.html>

Hand hygiene should be performed before putting on and after removing PPE using alcohol-based hand sanitizer that contains 60 to 95% alcohol.

PPE should ideally be put on outside of the home prior to entry into the home. If unable to put on all PPE outside of the home, it is still preferred that face protection (i.e., respirator and eye protection) be put on before entering the home. Alert persons within the home that the public health personnel will be entering the home and ask them to move to a different room, if possible, or keep a 6-foot distance in the same room. Once the entry area is clear, enter the home and put on a gown and gloves.

Ask person being tested if an external trash can is present at the home, or if one can be left outside for the disposal of PPE. PPE should ideally be removed outside of the home and discarded by placing in external trash can before departing location. PPE should not be taken from the home of the person being tested in public health personnel's vehicle.

If unable to remove all PPE outside of the home, it is still preferred that face protection (i.e., respirator and eye protection) be removed after exiting the home. If gown and gloves must be removed in the home, ask persons within the home to move to a different room, if possible, or keep a 6-foot distance in the same room. Once the entry area is clear, remove gown and gloves and exit the home. Once outside the home, perform hand hygiene with alcohol-based hand sanitizer that contains 60 to 95% alcohol, remove face protection and discard PPE by placing in external trash can before departing location. Perform hand hygiene again.

When is it safe to discontinue Transmission-based Precautions for home care patients with COVID-19?

The decision to discontinue Transmission-Based Precautions for home care patients with COVID-19 should be made in consultation with clinicians, infection prevention and control specialists, and public health officials. This decision should consider disease severity, illness signs and symptoms, and results of laboratory testing for COVID-19 in respiratory specimens. For more details, please refer to: <https://www.cdc.gov/coronavirus/2019-ncov/hcp/disposition-in-home-patients.html>.

Considerations to discontinue in-home isolation include all of the following:

- Resolution of fever, without use of antipyretic medication
- Improvement in illness signs and symptoms
- Negative results of an FDA Emergency Use Authorized molecular assay for COVID-19 from at least two consecutive sets of paired nasopharyngeal and throat swabs specimens collected ≥ 24 hours apart* (total of four negative specimens—two nasopharyngeal and two throat). See [Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens from Patients Under Investigation \(PUIs\) for 2019 Novel Coronavirus \(2019-nCoV\)](#) for specimen collection guidance.

*Initial guidance is based upon limited information and is subject to change as more information becomes available. In persons with a persistent productive cough, SARS-CoV-2-RNA might be detected for longer periods in sputum specimens than in upper respiratory tract (nasopharyngeal swab and throat swab) specimens.

Protocols for Coordination and Investigation of Home Health Agencies with Actual or Suspected COVID-19 Cases

During a home health agency survey, when a COVID-19 confirmed case or suspected case (including PUI) is identified, the surveyors will confirm that the agency has reported the case to public health officials as required by state law and will work with the agency to review infection prevention and education practices. Confirm that the HHA has the most recent information provided by the CDC.

- The State should notify the appropriate CMS Regional Office of the HHA who has been identified as providing services to a person with confirmed or suspected COVID-19 (including persons under investigation) who do not need to be hospitalized;
- The State should notify the appropriate CMS Regional Office of the HHA who has been identified as providing services to a person with confirmed COVID-19 who were hospitalized and determined to be medically stable to go home.

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 providers/suppliers for not having certain supplies (e.g., personal protective equipment (PPE) such as gowns, respirators, surgical masks and alcohol-based hand rubs (ABHR)) if they are having difficulty obtaining these supplies for reasons outside of their control. However, we do expect providers/suppliers 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 appropriate local authorities notifying them of the shortage, follow national guidelines for optimizing their current supply, or identify the next best option to care for patients. 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 Office.

Important CDC Resources:

CDC Resources for Health Care Facilities and Home and Community Based Settings:

- CDC Resources for Health Care Facilities: <https://www.cdc.gov/coronavirus/2019-ncov/healthcare-facilities/index.html>
- CDC FAQ for COVID-19: <https://www.cdc.gov/coronavirus/2019-ncov/infection-control/infection-prevention-control-faq.html>
- CDC Guidance for Preventing Spread in Home and Community Settings <https://www.cdc.gov/coronavirus/2019-ncov/hep/guidance-prevent-spread.html>
- Strategies for Optimizing the Supply of N95 Respirators: https://www.cdc.gov/coronavirus/2019-ncov/hep/respirators-strategy/index.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fcoronavirus%2F2019-ncov%2Fhep%2Frespirator-supply-strategies.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>
- Resources for Households <https://www.cdc.gov/coronavirus/2019-ncov/community/home/index.html>

FDA Resources:

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

CMS Resources:

Home Health Agency Infection Control and Prevention regulations and guidance: 42 CFR 484.70, Infection Prevention and Control, Appendix B of the State Operations Manual, Infection Prevention and Control. https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_b_hha.pdf

CDC Updates:

<https://www.cdc.gov/coronavirus/2019-ncov/whats-new-all.html>

Sign up for the newsletter to receive weekly emails about the coronavirus disease 2019 (COVID-19) https://tools.cdc.gov/campaignproxyservice/subscriptions.aspx?topic_id=USCDC_2067

Contact: Questions about this memorandum should be addressed to QSOG_EmergencyPrep@cms.hhs.gov. Questions about COVID-19 guidance/screening criteria should be addressed to the State Epidemiologist or other responsible state or local public health officials in your state.

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