BOARD FOR LICENSING HEALTH CARE FACILITIES
HEALTH FACILITIES COMMISSION
BOARD/COMMISSION POLICIES

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PM 1

BOARD FOR LICENSING HEALTH CARE FACILITIES

POLICY MEMORANDUM NUMBER 1

SUBJECT: Hospitals in Penal Institutions

DATE: November 19, 1980

That: The interpretation of the Board is that hospitals in penal institutions do not come under jurisdiction of this Board.

PM 5

BOARD FOR LICENSING HEALTH CARE FACILITIES

POLICY MEMORANDUM NUMBER 5

SUBJECT: Change of Ownership Notification

DATE: March 17, 1982

That: The Board communicate to the health care facilities about changes in ownership requirements and bring before this Board anyone who does not properly notify the department of change in ownership.

PM 6

BOARD FOR LICENSING HEALTH CARE FACILITIES

POLICY MEMORANDUM NUMBER 6

SUBJECT: Night Light Switch

DATE: May 19, 1982

That: Matters regarding a continuously burning night light switch not be cited as a deficiency.

PM 7

BOARD FOR LICENSING HEALTH CARE FACILITIES

POLICY MEMORANDUM NUMBER 7

SUBJECT: Patient Room Door Closures

DATE: August 18, 1982

That: The Board recommend to the Task Force (on Fire Safety) that the requirement of self-closing devices for patient room doors be deleted from the regulations.

STATE OF TENNESSEE
DEPARTMENT OF HEALTH
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PM 8 Amended

Board for Licensing Health Care Facilities

Policy Memorandum

SUBJECT: Emergency Admissions

DATE: February 7, 2013

POLICY: The Board requires prior approval by Office of Health Care Facilities' staff for an increase in patients above the licensed bed capacity for Residential Homes for the Aged (RHA) and Assisted Care Living Facilities (ACLF).

EFFECTIVE: February 7, 2013

APPROVED:

Robert Gordon, Chairman Pro Tem
Board for Licensing Health Care Facilities

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

PM 9

BOARD FOR LICENSING HEALTH CARE FACILITIES

POLICY MEMORANDUM NUMBER 9

SUBJECT: Waiver Requests To Be From Chief Executive Officer

DATE: August 19, 1982

That: The waiver be granted subject to two conditions:
The first condition (to) be the receipt of a formal request from the Chief Executive Officer of the hospital,

and

The second request (condition) being that the Board be provided with a written report in one year of this project.

PM 10

BOARD FOR LICENSING HEALTH CARE FACILITIES

POLICY MEMORANDUM NUMBER 10

SUBJECT: Reports on Sibling Visitation Waivers

DATE: August 19, 1982

That: The Board direct Staff to not require the appearance of a representative when the experience has been positive with sibling visitations.

PM 11

BOARD FOR LICENSING HEALTH CARE FACILITIES

POLICY MEMORANDUM NUMBER 11

SUBJECT: Pre-Board Meeting(s) With Facilities

DATE: August 19, 1982

That: The Staff, especially the Engineering Staff, have at least one meeting with the proper authorities of each facility in question, and try to resolve the problems before they come to the Board.

PM 12

BOARD FOR LICENSING HEALTH CARE FACILITIES

POLICY MEMORANDUM NUMBER 12

SUBJECT: Home Health Agency Within Nursing Home

DATE: November 17, 1982

That: Staff be granted the authority to grant waiver requests which relate to locating a Home Health Agency within a long term care facility.

PM 17

BOARD FOR LICENSING HEALTH CARE FACILITIES

POLICY MEMORANDUM NUMBER 17

SUBJECT: Unannounced Inspections

DATE: April 6, 1983

That: All licensure inspections be made unannounced except those involving changes of ownerships or initial inspections.

BOARD FOR LICENSING HEALTH CARE FACILITIES

POLICY MEMORANDUM NUMBER 21

SUBJECT: CON Requirements for Home Health Agencies

DATE: January 7, 1985

CON is required or approval from the Health Facilities Commission:

1. *Change of ownership;
2. Sub-Units;
3. Addition of counties or service area;
4. New agencies;
5. To close or 60 days prior notice given.

CON is not required for:

1. Change of address only when in licensed service area;
2. Branch offices within licensed service area;
3. Addition of services.

*On a change of ownership a form called Notification of Intent to Acquire an Existing Health Care Institution is required by the Health Facilities Commission.

PM 23

BOARD FOR LICENSING HEALTH CARE FACILITIES

POLICY MEMORANDUM NUMBER 23

SUBJECT: Emergency Admission Policy

DATE: October 27, 1986

That: To comply with the Boards determination that prior approval be obtained for emergency admissions and that facilities that continually request such be brought before them. The following procedures will be followed:

1. Facility administrator to submit in writing a request with, medical and social information, statement of lack of beds in area and how the patient will be housed.

2. Review facility file to verify that the facility is not currently overbedded and how often facility is requesting emergency admissions.

3. Obtain approval from Medical Director.

4. Notify facility by telephone of decision.

5. Send approval letter.

6. Place information in log.

7. Facility to notify the Department in writing, when it returns to licensed bed capacity.

PM 24

BOARD FOR LICENSING HEALTH CARE FACILITIES
POLICY MEMORANDUM NUMBER 24

SUBJECT: EMS Personnel - In Hospital Emergency Rooms

DATE: November 17, 1987

The Board approved the following policy on September 9, 1987:

Employees of the ambulance service cannot be used within the hospital as licensed nursing staff. Ambulance service personnel such as paramedics shall not function in the hospital as a licensed nurse (doing nursing duties) or in place of a licensed nurse. Certified EMS personnel may assist in the emergency room under the direct supervision of a Registered Nurse.

If a hospital provides clinical facilities for the education and training of (Emergency Medical Technicians) or Paramedics, there must be a written agreement that defines the role and responsibility of the hospital, nursing service and the education program.

Emergency Department personnel shall be trained for their responsibilities through appropriate training and education programs. At a minimum, emergency room nursing staff must have ACLS training.

AN/G5127321

Board for Licensing Health
Care Facilities

Policy Memorandum Number 26

Subject: One (1) Residential Home for Aged Administrator May Serve More Than One (1) Licensed Facility

Date: March 27, 1991

That: One (1) administrator may serve more than one (1) licensed facility if all licensed facilities are on the same campus, or if all licensed facilities do not exceed fifty (50) beds, nor are more than fifty (50) miles apart from the administrator's location based on the "Tennessee Official Highway Map". Every facility however, must have a "responsible attendant".

In addition, the certified residential home for aged administrator must visit each of the areas where a "responsible attendant" is located at least one (1) day or eight (8) hours per week.

SF/GS081178

PM 28

BOARD FOR LICENSING HEALTH CARE FACILITIES

POLICY MEMORANDUM NUMBER 28

SUBJECT: Course Curriculums for Certified RHA Administrators

DATE: June 13, 1990

THAT: The Board grant Staff the authority to review and approve course curriculums to be offered to certified administrators of Residential Homes for the Aged.

If Staff has a problem with the curriculum of any courses, Staff is directed to present them to the Board at its next available meeting.

STATE OF TENNESSEE
BUREAU OF MANPOWER AND FACILITIES
DIVISION OF HEALTH CARE FACILITIES
283 PLUS PARK BLVD.
DEPARTMENT OF HEALTH
NASHVILLE, TENNESSEE 37247-0530

BOARD FOR LICENSING HEALTH CARE FACILITIES

POLICY MEMORANDUM NUMBER 29

SUBJECT: Consent Calendar

DATE: December 30, 1991

THAT: The Board Directs Staff to Develop a Consent Calendar.

The Board has requested that staff place certain types of waiver requests on the consent calendar. They are waiver requests which are recommended by staff for Board approval. The requests are well justified, do not have a detrimental effect on the health, safety, and welfare of the public and have routinely been approved by the Board.

A representative from the facility does not have to be present at the Board meeting.

Staff, as always, shall notify the facility of the Board's decision.

HB/G5071364

TENNESSEE DEPARTMENT OF HEALTH

OFFICE CORRESPONDENCE

DEC 02 1991

FROM	TO	DATE

DATE: 11-26-91

TO: John Bonkowski, HCF

FROM: Mary Beth Franklyn, OGC

SUBJECT: Consent Calendar

T.C.A. 68-11-209 gives the Board for Licensing Health Care Facilities the power to adopt and waive rules and regulations.

In reviewing the consent calendar, policy number 29; the policy states that "the Board grants staff the authority to waive regulations."

The Board was given this authority by the Legislature, and the Board cannot grant an agent (its staff) this power. The staff may recommend to the Board whether waivers should be granted. The problem results when the staff acts on behalf of the Board, granting the waiver, and the facility then acts on this waiver prior to the Board's approval of the recommendation.

The end result in this situation is a retroactive waiver. The consent calendar may be utilized to recommend to the Board waivers which the Board has reviewed and determines are appropriate waivers, which would not have a detrimental effect on the health, safety, and welfare of the public.

The facility should not act on the waiver, however, until the Board grants the waiver. The consent calendar policy, as written, violates the statutory authority granted to the Board only in T.C.A. 68-11-209. This policy should be modified to indicate the staff will recommend for approval the waivers, other than grant them.

FROM	DATE

TO

Please modify the policy, sending me a copy of your new draft. The intend is to change the language so that it reflects the power granted in the statute, and to avoid a problem with retroactive waivers.

Should you have any questions, please contact me.

cc: Les Brown
Mary E. Johnston

PH-0001
SR 2/77

Board for Licensing Health

Care Facilities

Policy Memorandum Number 31

Subject: Residential Home for Aged - Non Refundable Application Fee clause be deleted.

Date: March 27, 1991

Policy: Gives staff the authority to refund, if conditions warrant, the application fee for Residential Home for Aged, until such time as the regulations are amended to delete the non-refundability clause.

Approved: Helmut (John) Bonkowski, Director
Board for Licensing
Health Care Facilities

BF/G5141113

cc: LRB
BK
RB
AG
OGC

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www.tennessee.gov/health

PM 32 AMENDED

Board for Licensing Health Care Facilities

Policy Memorandum

SUBJECT: Authority for Staff to Grant Waivers for Facilities to Provide Outpatient Therapy.

DATE: August 2, 2006

POLICY: Gives staff authority to grant waivers, subject to Board ratification, to nursing homes and residential homes for the aged to provide outpatient physical therapy, occupational therapy, speech therapy to non-residents if proper guidelines, criteria, staffing and protocol are submitted.

Guidelines, criteria, staffing and protocol include, but are not limited to:

- *Facility maintains adequate staff to meet the needs of residents and outpatients.*
- *Outpatient therapy services are accessible via separate entrance or entrance without going through resident care areas.*
- *If therapy services are provided to a resident of the facility, services are provided only in rehab designated areas and not in resident's living quarters.*

APPLICABILITY: This policy will apply to Nursing Homes and Residential Homes for the Aged.

PROCEDURE: A facility shall make a request in writing to the Director, Board for Licensing Health Care Facilities. The request shall be placed on the Consent Calendar for the next scheduled Board Meeting.

APPROVED: Katy Gammon
Director
Health Care Facilities

STATE OF TENNESSEE
BUREAU OF MANPOWER AND FACILITIES
DIVISION OF HEALTH CARE FACILITIES
283 PLUS PARK BLVD.
DEPARTMENT OF HEALTH
NASHVILLE, TENNESSEE 37247-0530

Policy Memorandum Number 36

Date: July 24, 1992

Subject: Labor Delivery Recovery Post-Partum Waiver requests being placed on Consent Calendar

Policy: That the staff place waiver requests to build or construct Labor Delivery Recovery Post-Partum Rooms which have appropriate staffing, and are within close proximity to Surgery, on the Consent Calender.

Approved: Helmut (John) Bonkowski, Director
Board for Licensing Health Care Facilities

HJB/BF/G6132195

cc: LAB
EK
RB
AG
OGC
JOC

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PM 39

BOARD FOR LICENSING HEALTH CARE FACILITIES

POLICY MEMORANDUM
AMENDED

SUBJECT: Nursing Home Administrators permitted to serve as administrators of Residential Homes for Aged and Assisted Care Living Facilities.

DATE: May 12, 1999

POLICY: When a nursing home is adjacent or connected to a Home for Aged or Assisted Care Living Facility, a request for the administrator to serve both facilities may be placed on the Consent Calendar to be considered at the next board meeting.

APPROVED: Katy Gammon, Director
Board for Licensing
Health Care Facilities

STATE OF TENNESSEE
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DEPARTMENT OF HEALTH
NASHVILLE, TENNESSEE 37247-0530

PM 44

BOARD FOR LICENSING HEALTH CARE FACILITIES

POLICY MEMORANDUM NUMBER 44

SUBJECT: Transportation of Contaminated Waste

DATE: March 24, 1993

POLICY: That in lieu of Section 1200-8-2-.02(8)(e) of the hospital Regulations pertaining to the required incineration or proper disposal of infectious wastes, hospitals shall follow the applicable OSHA Regulations found at 29 C.F.R. 1910.1030, et seq. when transporting explanted breast implants or similar infectious wastes to another party until the regulations can be amended.

cc: JMF
RJB
RAB
MH
SJ
OGC
JOC

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NASHVILLE, TENNESSEE 37247-0530

PM 45

BOARD FOR LICENSING HEALTH CARE FACILITIES

POLICY MEMORANDUM 45

SUBJECT: Hospital Definitions for Licensure Purposes

DATE: December 14, 1994

POLICY: The definition of a hospital is: "A hospital means any institution, place, building or agency representing and held out to the general public as ready willing and able to furnish care, accommodations, facilities and equipment for the use and in connection with services of a physician or dentist for one or more non-related persons who may be suffering from deformities, injuries or disease or any other condition for which nursing, medical or surgical services would be appropriate for care, diagnosis or treatment."

The chronic disease classification is adopted for licensing of long term acute care hospitals until the regulations can be amended.

cc: JMF
HJB
RAB
MH
SJ
OGC
JOC

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DEPARTMENT OF HEALTH
NASHVILLE, TENNESSEE 37247-0520

PM 46

BOARD FOR LICENSING HEALTH CARE FACILITIES

POLICY MEMORANDUM 46

SUBJECT: Hospital Licenses

DATE: December 14, 1994

POLICY: The Board's policy is that when a second hospital license is issued within a previously licensed hospital institution that it is considered a separate license but not a separate facility and falls under existing previously approved fire codes, unless there is major renovation. If there is major renovation, the new hospital has to be brought up to current fire safety standards, with major renovation being defined as renovation of fifty percent (50%) or more of the footage of the newly licensed facility.

cc: JMF
HJB
RAB
MH
SJ
OGC
JOC

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NASHVILLE, TENNESSEE 37247-0530

PM 47

BOARD FOR LICENSING HEALTH CARE FACILITIES

POLICY MEMORANDUM 47

SUBJECT: Physician's Signature Requirement on Verbal Orders

DATE: March 15, 1995

POLICY: To extend the period of time for a physician to sign a verbal or telephone order from ten (10) days to thirty (30) days for Home Care Organizations.

cc: JMF
NJB
RAB
MH
SJ
OGC
JOC

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NASHVILLE, TENNESSEE 37247-0530

PM 48

BOARD FOR LICENSING HEALTH CARE FACILITIES

POLICY MEMORANDUM 48

SUBJECT: Waiver Requests

DATE: February 14, 1996

POLICY: All waiver requests must be received (stamped in) in this office no later than two (2) weeks prior to the Board meeting.

APPROVED: Helmut (John Bonkowski, Director
Board For Licensing
Health Care Facilities

cc: JMF
HJB
RAB
MH
SJ
OGC
JOC

STATE OF TENNESSEE
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PM 49

BOARD FOR LICENSING HEALTH CARE FACILITIES

POLICY MEMORANDUM

SUBJECT: Waiver Requests for Removal of Outdated Fire Protection Equipment

DATE: August 14, 1996

POLICY: Fire protection equipment such as deteriorating hose stored at facilities that local fire marshals have deemed no longer functional can be removed on the recommendation of the fire marshal.

APPROVED: Helmut (John) Bonkowski, Director
Board for Licensing
Health Care Facilities

cc: JMF
RB
MH
SJ
OGC
LH
CM

STATE OF TENNESSEE
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PM 51 (AMENDED)

BOARD FOR LICENSING HEALTH CARE FACILITIES

POLICY MEMORANDUM

SUBJECT: Nursing Homes and Hospitals sharing existing services/All facility types

DATE: August 14, 1996

POLICY: The Board's policy is that any licensed facility located within another licensed facility or located on the same campus be allowed to share the following services:

1. Dietary
2. Housekeeping
3. Laundry
4. Laboratory
5. Pharmacy
6. Maintenance
7. Security
8. Radiology
9. Physical Therapy
10. Speech Therapy
11. Respiratory Therapy
12. Occupational Therapy

The Board for Licensing Health Care Facilities request that staff place these waiver requests on the Consent Calendar when it does not pose a threat to public safety.

APPROVED: Melanie Hill, Director
Board for Licensing
Health Care Facilities

STATE OF TENNESSEE
BUREAU OF MANPOWER AND FACILITIES
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283 PLUS PARK BLVD.
DEPARTMENT OF HEALTH
NASHVILLE, TENNESSEE 37247-0510

PM 52

BOARD FOR LICENSING HEALTH CARE FACILITIES

POLICY MEMORANDUM

SUBJECT: Door Width Requirements for Residential Homes for the Aged and Institutional Homes for the Aged

DATE: August 14, 1996

POLICY: The Board's policy is to allow RHAs and IHAs to utilize thirty six inch (36") wide patient room doors.

The Board for Licensing Health Care Facilities request that staff place these waiver requests on the consent calendar when it does not pose a threat to public safety.

APPROVED: Helmut (John) Bonkowski, Director
Board for Licensing
Health Care Facilities

cc: JMF
RB
MH
SJ
OGC
LH
CM

TENNESSEE DEPARTMENT OF HEALTH
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PM 5B AMENDED

BOARD FOR LICENSING HEALTH CARE FACILITIES

POLICY MEMORANDUM

SUBJECT: Substantial Renovation

DATE: Proposed Amendment November 12, 1997; Amended February 7, 2007

POLICY: The following are criteria for which projects would require review by the engineering department under the substantial renovation requirement:

(1) Projects that renovate more than ten percent (10%) of any smoke compartment.

(2) Areas renovated less than ten percent (10%) must meet the following to be exempt from submitting plans to the engineering department:

(a) All work must be executed in accordance with currently adopted codes.
(b) Only one renovation shall be initiated during any one year period.
(c) No licensure deficiencies are cited as of last survey.
(d) Shall not involve combustible or medical gas or be classified as hazardous.
(e) Does not change or alter the existing life safety classification.
(f) Does not change or alter construction type or life safety of the facility.
(g) Does not alter any of the following systems:
1. Fire Alarm System
2. Fire Suppression System
3. Mechanical System
4. Electrical System

(3) Projects that are strictly cosmetic in nature need not be submitted provided that improvements are limited to surface treatments and do not change any existing life safety conditions and such improvements shall meet all applicable codes.

When any project meets that above criteria for exemption from plans submittal, the licensee shall submit a statement of the project scope and justification. Upon review of the data, the Director of Engineering may require additional information from an architect or engineer registered in the State of Tennessee.

EFFECTIVE: April 16, 2007

APPROVED: Ann Thompson, RN, Director
Board for Licensing Health Care Facilities
Board Approved February 7, 2007

STATE OF TENNESSEE
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Effective Date: June 24, 1998 PM 59

DRAFT BOARD POLICY MEMORANDUM
HOME CARE ORGANIZATIONS PROVIDING HOME HEALTH SERVICES

PURPOSE: To clarify the intent of the Board's regulations governing Home Care Organizations providing Home Health Services.

The Board has voted to clarify the intent of the regulations pertaining to licensed Home Care Organizations providing Home Health Services by adopting the following policy as guidance in surveying such agencies:

POLICY:

The Board for Licensing Health Care Facilities "Standards for Home Care Organizations Providing Home Health Services" are not applicable if a patient served by the home care organization only receives homemaker services. It is the responsibility of the home care organization to identify such patients to the surveyor.

Example: A licensed home health agency is not required to develop a plan of care for anyone that is only receiving homemaker services from the agency.

EFFECTIVE: Until amended or revoked by the Board.

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PM 62

BOARD FOR LICENSING HEALTH CARE FACILITIES

POLICY MEMORANDUM

SUBJECT: Standards for Medical Equipment Providers

PURPOSE: To establish uniform standards for medical equipment providers

DATE: February 10,1999

POLICY: Medical equipment delivery technicians, who install respiratory equipment shall be deemed competent with their employer prior to independently delivering and setting up the respiratory equipment. The home medical equipment supplier must maintain documentation to demonstrate that competency requirements are met.

Standard competencies will include at a minimum the following: Role responsibilities; Cylinders; Pressure regulators/Flow controllers; Home liquid oxygen systems; Oxygen concentrators; Oxygen Administration; Oxygen Analyzers; Humidifiers; and Aerosol generators.

APPROVED: Katy Gammon, Director
Board for Licensing
Health Care Facilities

STATE OF TENNESSEE
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PM 68

BOARD FOR LICENSING HEALTH CARE FACILITIES

POLICY MEMORANDUM

SUBJECT: Consistent Board Definition of "Justified Emergency" for exceeding licensed bed capacity.

DATE: May 13, 1998

POLICY: In the event of a justified emergency, a hospital may exceed its licensed bed capacity. A "Justified emergency" includes, but is not limited to, the following events/emergencies:

1. An influx of mass casualties;
2. Localized and/or regional catastrophes, i.e., storms, earthquakes, tornadoes; and,
3. Epidemics or episodes of mass illness, i.e., influenza, salmonella, etc.

PROCEDURE: When a hospital determines the need to, and then does subsequently, exceed its licensed bed capacity the following procedures must be followed:

1. The hospital's administrator must make written notification to the Department within forty-eight (48) hours of exceeding its licensed bed capacity;

2. The notification must include a detailed description of the emergency including:

   a. Why the licensed bed capacity was exceeded, i.e., lack of hospital beds in vicinity, specialized resources only available at the facility, etc.;
   b. The estimated length of time the licensed bed capacity is expected to be exceeded; and,
   c. The number of admissions in excess of the facility's licensed bed capacity.

3. As soon as the hospital returns to its licensed bed capacity, the administrator must notify the Department in writing of the effective date of its return to compliance;

4. Staff will review all exceeding bed capacity notifications with the Chairman of the Board and if, upon review, Department staff concurs that a justified emergency existed, staff will notify the facility in writing and then report the occurrence to the Board at the next regularly scheduled Board meeting as information only.

PM 68 continued

5. However, if Department staff does not concur that a justified emergency existed, the facility will be notified in writing that a representative is required to appear at the next regularly scheduled Board meeting to justify the need for exceeding its licensed bed capacity.

EFFECTIVE: Until such time as the Board determines the need to modify the policy and/or procedure.

APPROVED: Katy Gammon, Director
Board for Licensing
Health Care Facilities

PM 71

Effective: May 12, 1999

PURPOSE: Allow the Department to use exceptions permitted by the codes.

POLICY: Allow the Department to apply the code related exception, whether more or less restrictive, when there are conflicts between the requirements in codes and regulations.

APPLICABILITY: This policy would apply to the following regulations

1. Hospitals	1200-8-2-.01(1)(a)
2. Homes for the Aged	1200-8-110.07(3)
3. A & D Res. Rehabilitation Treatment	1200-8-17-.09(l)(b)
4. A & D Primary Prevention Treatment	1200-8-20-.08(1)
5. A & D Non Res. Methadone Treatment	1200-8-21-.08(1)
6. A & D Halfway House Treatment	1200-8-22-.09(1)(b)
7. A & D Res. Detoxification Treatment	1200-8-23-.09(l)(b)
8. Birthing Centers	1200-8-24-.07(4)
9. Assisted Care Living	1200-8-25-.07(3)

Language stated in the above regulations is: Where there are conflicts between Requirements in the above listed codes* and regulations and provisions of this Chapter, the most restrictive shall apply.

Proposed Language for amendments to regulations are: Where there are conflicts between requirements in the above listed codes, regulations and provisions of this chapter, the Department shall have the option to apply the exceptions.

*Codes includes: Standard Building Codes, Handicap Code as required by T.C.A. 68-120-204(a), the 1997 edition of the Standard Mechanical Code, Standard Plumbing Code, Standard Gas Code, the most current edition of the ASHRAE Handbook of Fundamentals, and the 1997 edition of the National Fire Protection Code (NFPA), NFPA 1 including Annex A which code incorporates the 1997 edition of the Life Safety Code and the 1997 National Electrical Code.

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PM 73

BOARD FOR LICENSING HEALTH CARE FACILITIES

POLICY MEMORANDUM

SUBJECT: Testing Skills for Nurse Aides

DATE: February 5, 2003

POLICY: Nurse aide candidates be required to pass five critical testing skills selected randomly for each registrant from a pool of skills evaluation tasks ranked according to degree of difficulty, with at least one task selected from each degree of difficulty.

EFFECTIVE: Until such time as the Nursing Home Regulations are amended to reflect this revision and become effective.

APPROVED: Cathy Green, Director
Board for Licensing
Health Care Facilities

approved 2/5/03 (CG)

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PM 74

Board for Licensing Health Care Facilities

Policy Memorandum

SUBJECT: Dantrolene in ASTC

DATE: February 4, 2004

POLICY: If a licensed Ambulatory Surgical Treatment Center does not administer general anesthesia, the ASTC shall not be required to maintain thirty-six (36) ampules of dantrolene for injection on site as required in ~~1200-8-10-.06(g)~~. 1200-8-10-.06(2)(g).

EFFECTIVE: February 4, 2004

APPROVED: Cathy Green, RN, Director
Board for Licensing Health Care Facilities
Board Approved February 4, 2004

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PM 76

Board for Licensing Health Care Facilities

Policy Memorandum

SUBJECT: Licensure Approval by Board

DATE: March 12, 2008

POLICY: Health Care Facilities administrative staff shall initially approve licensure applications without disqualifying information. These applications shall be presented at the next scheduled Board meeting for ratification by the Board.

Applications presenting with disqualifying information shall be presented at the next scheduled Board meeting for review and subsequent approval or denial by the Board.

EFFECTIVE: March 12, 2008

APPROVED:

Larry Arnold, M.D., Chairman
Board for Licensing Health Care Facilities

Ann R. Thompson

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

STATE OF TENNESSEE
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PM 77 Amended

Board for Licensing Health Care Facilities

Policy Memorandum

SUBJECT: Granted Waiver Request by the Board

DATE: January 14, 2016

POLICY: After a waiver request has been granted by the Board for Licensing Health Care Facilities, a Board letter is sent to the requesting facility informing them their waiver has been granted. The letter includes a request that the facility notify the Board for Licensing Health Care Facilities in writing when there is a change in the waiver status. A copy of this Board Policy will be attached with and referenced within the letter granting the waiver. Granted waivers are recorded in the Waiver Request notebook with the expiration date of the waiver.

Health Care Facilities' administrative staff performs an initial review of the Waiver Request notebook for those granted waiver requests with an expiration occurring within the upcoming quarter. A notification of status update letter is submitted to those facilities that have a granted waiver expiring within the upcoming quarter. All points of contact with the facility will be recorded in this Waiver Request notebook. A second review of the Waiver Request notebook will occur prior to the next scheduled Board meeting. After this review, OHCF administrative staff notifies those facilities continuing with waivers by telephone of the waivers upcoming expiration date. Any facility that has not satisfied the waiver requirement will then notify the Board for Licensing Health Care Facilities in writing requesting a waiver extension. The waiver extension request will be presented at the next scheduled Board meeting for consideration by the Board. If no waiver extension request is received in writing, Board administrative staff will presume the facility is in compliance and will be held to the standards of their licensure type.

Facilities that have been granted a waiver and who are now in compliance with the regulations shall notify the Board for Licensing Health Care Facilities in writing that they are now meeting all requirements.

APPROVED:

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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PM 78

Board for Licensing Health Care Facilities

Policy Memorandum

SUBJECT: Department Authority on Change of Ownership (CHOWS) Applications

DATE: January 20, 2010

POLICY: Public Chapter 323 codified as Tennessee Code Annotated 68-11-1630 authorizes the Board for Licensing Health Care Facilities to grant the Department the authority to issue a new license to a successor/owner of a health care facility when there has been a change of ownership or control provided the Department determines that the successor/owner meets the following qualifications for licensure:

(1) The successor/owner meets the qualifications for license;

(2) The health care facility has no outstanding license or certification deficiencies; and

(3) The successor/owner already owns or controls at least one (1) other health care facility in the state.

EFFECTIVE: January 20, 2010

APPROVED:

Larry Arnold, M.D., Chairman
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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PM 79

Board for Licensing Health Care Facilities

Policy Memorandum

SUBJECT: POST Form and 2013 Legislation

DATE: May 1, 2013

POLICY: Board approves that individuals referenced in SB257/HB1019 may sign their name and list their credentials on the line designated on the POST Form for the physician's signature until the form is amended for all licensed facility types.

EFFECTIVE: May 1, 2013

APPROVED:

Larry Arnold, M.D., Chairman
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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PM 80

Board for Licensing Health Care Facilities

Policy Memorandum

SUBJECT: Fire Sprinkler/NFPA 13

DATE: January 23, 2014

POLICY: Consistent with CMS requirements and practices of surrounding states who utilize the IBC Core Code without modification allow a single facility separated into individual buildings by common firewalls can be served by a single sprinkler system and riser subject to NFPA 13 codes.

EFFECTIVE: January 23, 2014

APPROVED:

Robert Gordon, Chairman Pro Tem
Board for Licensing Health Care Facilities

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

***Attached are supporting CMS requirements and practices of surrounding states.

I. CMS – Question and Response

The following question was sent to CMS in Baltimore.

Question to CMS:

> "In a single existing or new nursing home under 52,000 sq. ft. under one roof/owner that has multiple fire areas separated by 4 hour fire walls would CMS allow the building to be supplied by a single sprinkler riser and allow the interior sprinkler piping to penetrated the 4 hour fire walls if the penetrations were properly protected and the sprinkler system installed in accordance with the applicable edition of NFPA 13?"

Answer from CMS:

> *"I spoke to the Atlanta RO about this and they were aware of this and have told TN that it is not a CMS requirement but the State insists that it is a building code requirement and that is how they are citing it. States can have a more stringent requirement although this one is bit much and pretty costly too. I have asked our leadership where we want to go with your request. I should know in a day or so what we want to do."*
>
> From:
>
> James Merrill
> DEPARTMENT OF HEALTH
> & HUMAN SERVICES
> Centers for Medicare & Medicaid Services
> 7500 Security Boulevard, Mail Stop C2-21-16
> Baltimore, Maryland 21244-1850
> 410-786-6998
> James.Merrill@cms.hhs.gov

II. State AHJ – Question and Responses

Question to State AHJ

The following question was sent to several state agencies that regulate nursing home construction around Tennessee.

> "In a single existing or new nursing home under 52,000 SQ. FT. and under one roof/owner that has multiple fire areas separated by 4 hour fire rated (or 3 or 2 hour fire rated as now permitted by IBC) Fire Walls, would you allow the building to be supplied by a single sprinkler riser and allow the interior sprinkler piping to penetrate the 4 hour fire rated (or 3 or 2 hour fire rated as now permitted by IBC) Fire Walls if the penetrations were properly protected and the sprinkler system was installed in accordance with the applicable edition of NFPA 13?"

The following answers are from the various jurisdictional authorities that regulate the design and construction of nursing homes.

Responses from State AHJ

Alabama: YES

Vic Hunt, Director
Office of Facilities Management
The Alabama Department of Public Health
The RSA Tower, Suite 1550
PO Box 303017
Montgomery, AL 36130-3017
Phone 334-206-5218
victor.hunt@adph.state.al.us

Comment: *Our practice will typically be to show the number of the code paragraph that a facility is not complying with. If you can't do that, you are likely to enforce your opinions, good ideas and bad ideas. Philosophically, when a jurisdiction adopts a code to be enforced, the jurisdiction's employees don't have the authority to enforce their ideas and opinions.*

Arkansas: YES

Paul Acre, PE
Manager Health Facilities
Arkansas Department of Health
4815 West Markham Street
Little Rock, Arkansas 72205
501-661-2201
paul.acre@arkansas.gov

Comment: *To answer your statement/question, we would not have any issues with penetration of Fire Barriers, Fire Barrier Walls, or even Fire Walls, unless they were Party Walls, regardless of the rating.*

Florida: YES

Wayne Young, AIA
Bureau Chief
Office of Plans and Construction
Agency for Health Care Administration
Tallahassee, Florida 32303
850-412-4470
wayne.young@AHCA.myflorida.com

Comment: None

Texas: YES

Fred Worley, Architect
Architectural Unit Manager
Survey Operations Section
Regulatory Services Division
Texas Department of Aging and Disability Services
512-438-2311
fred.worley@dads.state.tx.us

Comment: NFPA 13 system protection areas limit systems with single risers to 52,000 square feet. NFPA 101 penetrations and miscellaneous openings in fire barriers must be protected with materials or devices capable of maintaining the fire resistance of the fire barrier. Texas DADS would approve the single system riser with sprinkler pipe penetrations through four-hour walls for a nursing facility.

Virginia: YES

Ed Altizer, P. E.
State Fire Marshal
State Fire Marshal's Office
VA Department of Fire Programs
1005 Technology Park Drive
Glen Allen, Virginia 23059
804-612-7267
ed.altizer@vdfp.virginia.gov

Comment: *In response to your question, the Virginia SFMO in applying the Life Safety Code to health care buildings would be guided by Section 8.2.4 of NFPA 13- 2013.*

8.2.4 Multiple buildings attached by canopies, covered breezeways, common roofs, or a common wall(s) shall be permitted to be supplied by a single fire sprinkler riser.

I think this clearly defines that two buildings or portions of one building may be supplied from one riser if their combined areas do not exceed the maximum square footage allowance. This is our interpretation of the code and we would be guided by it for both new and retrofit installations even though CMS uses the 2000 LSC. Editions of NFPA 13 prior to the 2007 edition did not include the above language. However, I have been guided by that intent for many years.

I also must point out that our state code also must be considered. As you know, the Virginia Uniform Statewide Building Code (USBC) applies to all new and retrofit construction in Virginia. I would point out that Section 706.1.1 of the USBC would not allow penetrations of a party wall except for mall buildings. I do not believe this would be an issue in the LSC though.

In answer to your question, the bottom line is that we would not require a separate riser for those health care buildings subject to the LSC and under one roof, attached by a common wall, or connected by breezeways or canopies. We would also advise that NFPA 13 would permit a single riser not to exceed the maximum per floor area specified in NFPA 13. I

would also opine that the Virginia Building and Fire Codes would not require a separate riser unless the maximum floor areas are exceeded or a party wall is breached. The rating of the wall is not an issue only if it is a party wall, so a 4 hour fire wall would also be OK. However, again I would point out that the Building Official may have a different opinion.

FYI Claude Hutton copied above is an engineer with the SFMO and has extensive sprinkler experience. I asked him to look at what I have said just to see if I have missed anything. He pointed out the USBC party wall requirement and researched other items along with me. We wanted to make sure we did not miss anything.

Georgia: YES

Dwayne Garriss
State Fire Marshall
Office of State Fire Marshal
Office of Regulatory Services
Georgia Department of Regulatory Services
2 Martin Luther King Drive, 7th Floor West
Tower, Room 916
Atlanta, Georgia 30334
404-657-1168 Email: dgarriss@sfm.ga.gov

Comment: Based on discussions with Mr. Garriss by Thomas Jaeger, Georgia allows a single riser to to supply multiple fire areas in a single building that is installed in accordance with NFPA 13 and allows sprinkler piping to penetrate fire walls, other than party walls, to include 4 hour rated fire walls. See attached letter sent to Mr. Jaeger.

Mississippi: YES

Dwayne Madison, Director
Div. of Health Facilities
Fire Safety and Construction
Mississippi State Dept of Health
P.O. Box 1700
Jackson, Mississippi 39215
601-364=1111 Email: Dwayne.madison@msdh.state.ms.us

Comment: *To the question: "In a single existing or new nursing home under 52K ft² under one roof/owner that has multiple fire areas separated by 4 hour fire walls would CMS allow the building to be supplied by a single sprinkler riser and allow the interior sprinkler piping to penetrate the 4 hour fire walls if the penetrations were properly protected and the sprinkler system installed in accordance with the applicable edition of NFPA 13?") I can, with complete confidence, respond with the statement below.*

Based on a 22 year application of CMS life and fire safety requirements, I find nothing under the jurisdiction of the Mississippi State Department of Health, Bureau of Health Facilities Licensure and Certification, or CMS, that precludes penetration of a four-hour, fire rated separation by fire sprinkler piping notwithstanding the qualifiers for such an action as mentioned in your query. Also, please accept this as attestation that no record of such action was ever suggested, proposed, ordered, or enforced in Mississippi.

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Board for Licensing Health Care Facilities PM81

Policy Memorandum

SUBJECT: Unexpected Loss of Nursing Home Administrator

DATE: April 5, 2022

POLICY: To align with revised Nursing Home Administrator regulations, this policy allows the Board to waive the requirement for a Tennessee licensed nursing home administrator for a period of six (6) months to coincide with scheduled Board meetings, if one of the following guidelines are met for a temporary nurse home administrator:

- A full-time administrator licensed in Tennessee or any other state;
- One or more part-time administrators licensed in Tennessee, employed no less than 20 hours per week;
- A full-time candidate for licensure as a Tennessee administrator who has completed the required training;
- If temporary administrator seeking nursing home administrator licensure in Tennessee, is eligible for Tennessee Nursing Home Administrator licensure and date of BENHA Board presentation.

A facility's application for waiver shall include the number for licensed beds, the date of the last day of employment of previous administrator, date of hire and name of temporary administrator, if the temporary administrator will become the permanent administrator, list of states in which the temporary administrator has a nursing home administrator's license with its status, and any information required by the Board. The Board will assess the circumstances and may grant, refuse, or condition a waiver as necessary to protect the health, safety, and welfare of the patients in the facility. If the temporary administrator were to change, notice must be made to the Board for Licensing Health Care Facilities within thirty (30) days.

EFFECTIVE: April 5, 2022

APPROVED:

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

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PM 82

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**
***SEPTEMBER 8, 2020**
***OCTOBER 7, 2020**
***DECEMBER 17, 2020**
***FEBRUARY 3, 2021**
***JUNE 2, 2021**
***OCTOBER 5, 2021**

APPROVED: **MARCH 13, 2020**
APRIL 1, 2020
SEPTEMBER 8, 2020
OCTOBER 7, 2020
DECEMBER 17, 2020
FEBRUARY 3, 2021
JUNE 2, 2021
OCTOBER 5, 2021

The Board updates this policy to facilitate the treatment and containment of COVID-19 and to provide consistency with recently updated Tennessee Department of Health (TDH) and Centers for Medicare and Medicaid Services (CMS) guidance as well as the expiration of Governor Bill Lee's Executive Order No. 77, which expired on May 31, 2021. See Attachment A. Effective February 28, 2021, the Tennessee Department of Health lifted all of its state specific restrictions regarding visitation, activities, and dining in long term care facilities.

The Board interprets its rules related to maintaining patient and resident safety as requiring that all licensed facility types, both federally certified and state-licensed only facilities, appropriately screen and monitor patients, residents, staff, and visitors for any symptoms of COVID-19 using the most up to date guidance from The Centers for Disease Control and Prevention (CDC).guidance found at See Attachment B.

On April 27, 2021, CMS updated its August 26, 2020 policy memo entitled "Interim Final Rule (IFC), CMS-3401-IFC, Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency Related to Long Term Care (LTC) Facility Requirements and COVID-19 Focused Survey Tool", QSO-20-38-NH, which implemented CMS' rule on testing. https://www.cms.gov/files/document/qso-20-38-nh.pdf

The QSO also provides regulatory guidance on the requirements of the CMS rule, including frequency of the testing, testing in light of community spread, testing for outbreaks, and testing of symptomatic individuals. CMS QSO-20-38-NH shall be followed regarding testing of patients/residents for COVID-19 in CMS skilled nursing facilities/nursing facilities. See Attachment C.

On April 27, 2021, CMS also revised its September 17, 2020 policy memo entitled "Nursing Home Visitation – COVID-19," QSO-20-39-NH, updating its visitation guidance in CMS skilled nursing facilities/nursing facilities. *See* Attachment D. CMS QSO-20-39 NH shall be followed regarding visitation of patients/residents during the COVID-19 pandemic in CMS skilled nursing facilities/nursing facilities.

All federally certified facility types are to follow CMS guidance.

When staffing shortages are occurring, healthcare facilities and employers (in collaboration with human resources and occupational health services) may need to implement crisis capacity strategies, in accordance with CDC guidance, to continue to provide patient care.

When there are no longer enough staff to provide safe patient care:

- Implement regional plans to transfer patients with COVID-19 to designated healthcare facilities, or alternate care sites with adequate staffing
- Allow asymptomatic HCP who are not fully vaccinated and have had a higher-risk exposure to SARS-CoV-2 but are not known to be infected to continue to work onsite throughout their 14-day post-exposure period.
- If permitted to work, these HCP should be monitored for symptoms. If shortages continue despite other mitigation strategies, consider implementing criteria to allow HCP with suspected or confirmed COVID-19 who are asymptomatic willing to work, but have not met all CDC Return to Work Criteria[1] to work. If HCP are allowed to work before meeting all criteria, facilities should consider prioritizing their duties in the following order:
    - If not already done, allow HCP with suspected or confirmed SARS-CoV-2 infection to perform job duties where they do not interact with others (e.g., patients or other HCP), such as in telemedicine services.
    - Allow HCP with confirmed SARS-CoV-2 infection to provide direct care only for patients with confirmed SARS-CoV-2 infection, preferably in a cohort setting.

[1] Return to Work Criteria for Healthcare Personnel Infected with SARS-CoV-2 Infection (Interim Guidance); updated February 26, 2021: www.cdc.gov/coronavirus/2019-ncov/hcp/return-to-work.html

- Allow HCP with confirmed SARS-CoV-2 infection to provide direct care for patients with suspected SARS-CoV-2 infection.

- As a last resort, allow HCP with confirmed SARS-CoV-2 infection to provide direct care for patients without suspected or confirmed SARS-CoV-2 infection. If this is being considered, this should be used only as a bridge to longer term strategies that do not involve care of uninfected patients by potentially infectious HCP and strict adherence to all other recommended infection prevention and control measures (e.g., use of respirator or well-fitting facemask for source control) is essential.If HCP are permitted to return to work before meeting all Return to Work criteria, they should still adhere to all Return to Work Practices and Work Restrictions recommendations described in that guidance. These include:

    - Wear an N-95 facemask for source control at all times while in the healthcare facility until they meet the full Return to Work criteria and all symptoms are completely resolved or at baseline. After this time period, these HCP should revert to their facility policy regarding universal source control during the pandemic.

        - A facemask for source control does not replace the need to wear an N95 or higher-level respirator (or other PPE) when indicated, including when caring for patients with suspected or confirmed COVID-19.

    - They should be reminded that in addition to potentially exposing patients, they could also expose their co-workers.

        - Facemasks should be worn even when they are in non-patient care areas such as breakrooms.

        - If they must remove their facemask, for example, in order to eat or drink, they should separate themselves from others by at least six (6) feet.

    - They should self-monitor for symptoms and seek re-evaluation from occupational health if respiratory symptoms recur or worsen.

    - NOTE: A facility cannot require a COVID-19 positive HCP to report for duty.

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 E - COVID-19 Facility Requirements - Temporary Structures.

This policy shall remain in effect until the Board's June 2022 Board Meeting or at an earlier date as determined by the Board.

Dr. Rene Saunders, Chair
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. 77, issued February 26, 2020; Executive Order No. 80, issued April 27, 2021
Attachment B	Interim Infection Prevention and Control Recommendations to Prevent SARS-CoV-2 Spread in Nursing Homes; Updated March 29, 2021
Attachment C	CMS QSO-20-38-NH - Interim Final Rule (IFC), CMS-3401-IFC, Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency related to Long Term Care (LTC) Facility requirements and COVID-19 Focused Survey Tool; updated April 27, 2021
Attachment D	CMS QSO-20-39 NH – Nursing Home Visitation – COVID-19; updated April 27, 2021
Attachment E	COVID 19 Facility Requirements – Temporary Structures

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PM 82

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**
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APRIL 1, 2020
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The Board updates this policy to facilitate the treatment and containment of COVID-19 and to provide consistency with recently updated Tennessee Department of Health (TDH) and Centers for Medicare and Medicaid Services (CMS) guidance as well as the expiration of Governor Bill Lee's Executive Order No. 77, which expired on May 31, 2021. See Attachment A. Effective February 28, 2021, the Tennessee Department of Health lifted all of its state specific restrictions regarding visitation, activities, and dining in long term care facilities.

The Board interprets its rules related to maintaining patient and resident safety as requiring that all licensed facility types, both federally certified and state-licensed only facilities, appropriately screen and monitor patients, residents, staff, and visitors for any symptoms of COVID-19 using the most up to date guidance from The Centers for Disease Control and Prevention (CDC).guidance found at See Attachment B.

On April 27, 2021, CMS updated its August 26, 2020 policy memo entitled "Interim Final Rule (IFC), CMS-3401-IFC, Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency Related to Long Term Care (LTC) Facility Requirements and COVID-19 Focused Survey Tool", QSO-20-38-NH, which implemented CMS' rule on testing. https://www.cms.gov/files/document/qso-20-38-nh.pdf

The QSO also provides regulatory guidance on the requirements of the CMS rule, including frequency of the testing, testing in light of community spread, testing for outbreaks, and testing of symptomatic individuals. CMS QSO-20-38-NH shall be followed regarding testing of patients/residents for COVID-19 in CMS skilled nursing facilities/nursing facilities. See Attachment C.

On April 27, 2021, CMS also revised its September 17, 2020 policy memo entitled "Nursing Home Visitation – COVID-19," QSO-20-39-NH, updating its visitation guidance in CMS skilled nursing facilities/nursing facilities. *See* Attachment D. CMS QSO-20-39 NH shall be followed regarding visitation of patients/residents during the COVID-19 pandemic in CMS skilled nursing facilities/nursing facilities.

All federally certified facility types are to follow CMS guidance.

When staffing shortages are occurring, healthcare facilities and employers (in collaboration with human resources and occupational health services) may need to implement crisis capacity strategies, in accordance with CDC guidance, to continue to provide patient care.

When there are no longer enough staff to provide safe patient care:

- Implement regional plans to transfer patients with COVID-19 to designated healthcare facilities, or alternate care sites with adequate staffing
- Allow asymptomatic HCP who are not fully vaccinated and have had a higher-risk exposure to SARS-CoV-2 but are not known to be infected to continue to work onsite throughout their 14-day post-exposure period.
- If permitted to work, these HCP should be monitored for symptoms. If shortages continue despite other mitigation strategies, consider implementing criteria to allow HCP with suspected or confirmed COVID-19 who are asymptomatic willing to work, but have not met all CDC Return to Work Criteria[1] to work. If HCP are allowed to work before meeting all criteria, facilities should consider prioritizing their duties in the following order:
    - If not already done, allow HCP with suspected or confirmed SARS-CoV-2 infection to perform job duties where they do not interact with others (e.g., patients or other HCP), such as in telemedicine services.
    - Allow HCP with confirmed SARS-CoV-2 infection to provide direct care only for patients with confirmed SARS-CoV-2 infection, preferably in a cohort setting.

[1] Return to Work Criteria for Healthcare Personnel Infected with SARS-CoV-2 Infection (Interim Guidance); updated February 26, 2021: www.cdc.gov/coronavirus/2019-ncov/hcp/return-to-work.html

        - Allow HCP with confirmed SARS-CoV-2 infection to provide direct care for patients with suspected SARS-CoV-2 infection.

- As a last resort, allow HCP with confirmed SARS-CoV-2 infection to provide direct care for patients without suspected or confirmed SARS-CoV-2 infection. If this is being considered, this should be used only as a bridge to longer term strategies that do not involve care of uninfected patients by potentially infectious HCP and strict adherence to all other recommended infection prevention and control measures (e.g., use of respirator or well-fitting facemask for source control) is essential.If HCP are permitted to return to work before meeting all Return to Work Criteria, they should still adhere to all Return to Work Practices and Work Restrictions recommendations described in that guidance. These include:
    - Wear an N-95 facemask for source control at all times while in the healthcare facility until they meet the full Return to Work Criteria and all symptoms are completely resolved or at baseline. After this time period, these HCP should revert to their facility policy regarding universal source control during the pandemic.
        - A facemask for source control does not replace the need to wear an N95 or higher-level respirator (or other PPE) when indicated, including when caring for patients with suspected or confirmed COVID-19.
    - They should be reminded that in addition to potentially exposing patients, they could also expose their co-workers.
        - Facemasks should be worn even when they are in non-patient care areas such as breakrooms.
        - If they must remove their facemask, for example, in order to eat or drink, they should separate themselves from others by at least six (6) feet.
    - They should self-monitor for symptoms and seek re-evaluation from occupational health if respiratory symptoms recur or worsen.
    - NOTE: A facility cannot require a COVID-19 positive HCP to report for duty.

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 E – COVID-19 Facility Requirements – Temporary Structures.

This policy shall remain in effect until the Board's October 2021 Board Meeting or at an earlier date as determined by the Board.

Dr. Rene Saunders, Chair
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. 77, issued February 26, 2020; Executive Order No. 80, issued April 27, 2021
Attachment B	Interim Infection Prevention and Control Recommendations to Prevent SARS-CoV-2 Spread in Nursing Homes; Updated March 29, 2021
Attachment C	CMS QSO-20-38-NH - Interim Final Rule (IFC), CMS-3401-IFC, Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency related to Long Term Care (LTC) Facility requirements and COVID-19 Focused Survey Tool; updated April 27, 2021
Attachment D	CMS QSO-20-39 NH – Nursing Home Visitation – COVID-19; updated April 27, 2021
Attachment E	COVID 19 Facility Requirements – Temporary Structures

STATE OF TENNESSEE
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PM 82

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**
***SEPTEMBER 8, 2020**
***OCTOBER 7, 2020**
***DECEMBER 17, 2020**
***FEBRUARY 3, 2021**

APPROVED: **MARCH 13, 2020**
APRIL 1, 2020
SEPTEMBER 8, 2020
OCTOBER 7, 2020
DECEMBER 17, 2020
FEBRUARY 3, 2021

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.

On August 25, 2020, the Centers for Medicare and Medicaid Services (CMS) published an interim final rule entitled "Medicare and Medicaid Programs, Clinical Laboratory Improvement

Amendments of 1988 and Patient Protection and Affordable Care Act; Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency." On August 26, 2020, CMS published a policy memo entitled "Interim Final Rule (IFC), CMS-3401-IFC, Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency Related to Long Term Care (LTC) Facility Requirements and COVID-19 Focused Survey Tool", QSO-20-38-NH, implementing the testing rule. https://www.cms.gov/files/document/qso-20-38-nh.pdf

The QSO also provides regulatory guidance on the requirements of the CMS rule, including frequency of the testing, testing in light of community spread, testing for outbreaks, and testing of symptomatic individuals. CMS QSO-20-38-NH shall be followed regarding testing of patients/residents for COVID-19 in CMS skilled nursing facilities/nursing facilities. See Attachment K.

On or about September 17, 2020, CMS published a policy memo entitled "Nursing Home Visitation – COVID-19," QSO-20-39-NH, implementing visitation guidance in CMS skilled nursing facilities/nursing facilities. *See* Attachment L. CMS QSO-20-39 NH shall be followed regarding visitation of patients/residents during the COVID-19 pandemic in CMS skilled nursing facilities/nursing facilities.

All federally certified facility types are to follow CMS guidance.

On or about September 17, 2020, the Tennessee Department of Health published COVID-19 LTCF Visitation Guidelines and LTCF Activities & Dining Guidelines. *See* Attachments M & N. Assisted care living facilities and residential homes for the aged shall comply the Department of Health's LTCF Visitation Guidelines and LTCF Activities & Dining Guidelines.

When staffing shortages are occurring, healthcare facilities and employers (in collaboration with human resources and occupational health services) may need to implement crisis capacity strategies to continue to provide patient care.

When there are no longer enough staff to provide safe patient care:

- Implement regional plans to transfer patients with COVID-19 to designated healthcare facilities, or alternate care sites with adequate staffing
- If not already done, implement plans (see contingency capacity strategies above) to allow asymptomatic health care providers ("HCP")who have had exposure to SARS-CoV-2 but are not known to be infected to continue to work.
    - If HCP are tested and found to be infected with SARS-CoV-2, they should be excluded from work until they meet all CDC Return to Work Criteria[1] (unless they are allowed to work as described below).
- If shortages continue despite other mitigation strategies, consider implementing criteria to allow HCP with suspected or confirmed COVID-19 who are asymptomatic willing to work, but have not met all CDC Return to Work Criteria to work. If HCP are allowed to work before meeting all criteria, facilities should consider prioritizing their duties in the following order:

[1] Return-to-Work Criteria for Healthcare Workers | CDC

1. If not already done, allow HCP with suspected or confirmed COVID-19 to perform job duties where they do not interact with others (e.g., patients or other HCP), such as in telemedicine services.
2. Allow HCP with confirmed COVID-19 to provide direct care only for patients with confirmed COVID-19, preferably in a cohort setting.

If HCP are permitted to return to work before meeting all Return to Work Criteria, they should still adhere to all Return to Work Practices and Work Restrictions recommendations described in that guidance. These include:

- Wear an N-95 facemask for source control at all times while in the healthcare facility until they meet the full Return to Work Criteria and all symptoms are completely resolved or at baseline. After this time period, these HCP should revert to their facility policy regarding universal source control during the pandemic.
  - A facemask for source control does not replace the need to wear an N95 or higher-level respirator (or other PPE) when indicated, including when caring for patients with suspected or confirmed COVID-19.
- They should be reminded that in addition to potentially exposing patients, they could also expose their co-workers.
  - Facemasks should be worn even when they are in non-patient care areas such as breakrooms.
  - If they must remove their facemask, for example, in order to eat or drink, they should separate themselves from others by at least six (6) feet.
- They should self-monitor for symptoms and seeking re-evaluation from occupational health if respiratory symptoms recur or worsen.
- NOTE: A facility cannot involuntarily require a COVID-19 positive HCP to report for duty.

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 the Board's June 2021 Board Meeting or at an earlier date as determined by the Board.

Dr. Rene Saunders, Chair
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
Attachment K	CMS QSO-20-38-NH - Interim Final Rule (IFC), CMS-3401-IFC, Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency related to Long Term Care (LTC) Facility requirements and COVID-19 Focused Survey Tool.
Attachment L	CMS QSO-20-39 NH – Nursing Home Visitation – COVID-19
Attachment M	Tennessee Department of Health, LTCF Visitation Guidelines
Attachment N	Tennessee Department of Health, LTCF Activities & Dining Guidelines

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PM 82

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**
***SEPTEMBER 8, 2020**
***OCTOBER 7, 2020**
***DECEMBER 17, 2020**

APPROVED: **MARCH 13, 2020**
APRIL 1, 2020
SEPTEMBER 8, 2020
OCTOBER 7, 2020
DECEMBER 17, 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.

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Regulatory Revisions in Response to the COVID-19 Public Health Emergency." On August 26, 2020, CMS published a policy memo entitled "Interim Final Rule (IFC), CMS-3401-IFC, Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency Related to Long Term Care (LTC) Facility Requirements and COVID-19 Focused Survey Tool", QSO-20-38-NH, implementing the testing rule. https://www.cms.gov/files/document/qso-20-38-nh.pdf

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- NOTE: A facility cannot involuntarily require a COVID-19 positive HCP to report for duty.

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 the Board's February 2021 Board Meeting or at an earlier date as determined by the Board.

Rene Saunders MD

Dr. Rene Saunders, Chair
Board for Licensing Health Care Facilities

Ann R. Reed

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
Attachment K CMS QSO-20-38-NH - Interim Final Rule (IFC), CMS-3401-IFC, Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency related to Long Term Care (LTC) Facility requirements and COVID-19 Focused Survey Tool.
Attachment L CMS QSO-20-39 NH – Nursing Home Visitation – COVID-19
Attachment M Tennessee Department of Health, LTCF Visitation Guidelines
Attachment N Tennessee Department of Health, LTCF Activities & Dining Guidelines

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PM 82

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**
***SEPTEMBER 8, 2020**
***OCTOBER 7, 2020**

APPROVED: **MARCH 13, 2020**
APRIL 1, 2020
SEPTEMBER 8, 2020
OCTOBER 7, 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.

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2020, CMS published a policy memo entitled "Interim Final Rule (IFC), CMS-3401-IFC, Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency Related to Long Term Care (LTC) Facility Requirements and COVID-19 Focused Survey Tool", QSO-20-38-NH, implementing the testing rule. https://www.cms.gov/files/document/qso-20-38-nh.pdf

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All federally certified facility types are to follow CMS guidance.

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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 the Board's February 2021 Board Meeting or at an earlier date as determined by the Board.

Rene C Saunders MD

Dr. Rene Saunders, Chair
Board for Licensing Health Care Facilities

Ann R Reed

Ann R. Reed, RN, BSN, MBA
Director of Licensure
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AMENDED 82

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**
***SEPTEMBER 8, 2020**

APPROVED: **MARCH 13, 2020**
APRIL 1, 2020
SEPTEMBER 8, 2020

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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.

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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

Attachment K CMS QSO-20-38-NH - Interim Final Rule (IFC), CMS-3401-IFC, Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency related to Long Term Care (LTC) Facility requirements and COVID-19 Focused Survey Tool.

Attachment L CMS QSO-20-39 NH – Nursing Home Visitation – COVID-19

Attachment M Tennessee Department of Health, LTCF Visitation Guidelines

Attachment N Tennessee Department of Health, LTCF Activities & Dining Guidelines

Survey Tool", QSO-20-38-NH, implementing the testing rule. https://www.cms.gov/files/document/qso-20-38-nh.pdf

The QSO also provides regulatory guidance on the requirements of the CMS rule, including frequency of the testing, testing in light of community spread, testing for outbreaks, and testing of symptomatic individuals. CMS QSO-20-38-NH shall be followed regarding testing of patients/residents for COVID-19 in CMS skilled nursing facilities/nursing facilities. See Attachment K.

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)
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.

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.

Dr. Rene Saunders, Chair
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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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**

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* 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

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

Ann R. Reed, RN, BSN, MBA
Director of Licensure
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Attachment D-J	CMS Letters Providing Guidance to Federally Certified Facilities

Health

STATE OF TENNESSEE
DEPARTMENT OF HEALTH
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PM 82

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**

EFFECTIVE: **MARCH 13, 2020**

APPROVED: **MARCH 13, 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)
HIV Supportive Living Centers	Tenn. Comp. R. & Reg. 1200-08-28-.12(c)

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.

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

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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APR 27 2021
Secretary of State
Tre Hargett

STATE OF TENNESSEE

EXECUTIVE ORDER

BY THE GOVERNOR

No. 80

AN ORDER AMENDING EXECUTIVE ORDER NO. 77

WHEREAS, individuals, businesses, local governments, faith communities, and other entities across the State responded to COVID-19 by changing behaviors and operations to protect our most vulnerable populations while continuing to provide the goods and services necessary to support our communities and our economy; and

WHEREAS, our healthcare infrastructure has adapted, and is continuing to adapt pursuant to pending legislation that is anticipated to become law during the remainder of the legislative session, to facilitate the treatment and containment of COVID-19; and

WHEREAS, safe and effective COVID-19 vaccines are now readily available for walkup administration without an appointment, and a large number of Tennesseans have already been vaccinated; and

WHEREAS, as a result of infrastructure advancements, vaccine availability, and public awareness of best practices to prevent the spread of COVID-19, Tennessee citizens and businesses are empowered to responsibly confront and manage the risks of COVID-19.

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 including Tennessee Code Annotated § 58-2-107, do hereby declare a continuing limited state of emergency and incorporate the provisions of Executive Order No. 77 subject to the amendments herein:

Executive Order No. 77, Section C, regarding delegation of local authority for face coverings, is deleted.

The "Tennessee Pledge" should no longer be considered an independent source of information or recommendations, recognizing that guidance and information is available and should be sought from traditional public health agencies, and thus all references to the Pledge in Executive Order No. 77 are deleted.

Executive Order No. 77, Section D, Paragraph 3, is hereby amended as follows:

3. Term and effective date. This Order shall remain in effect until 11:59 p.m., Central Time, on May 31, 2021.

IN WITNESS WHEREOF, I have subscribed my signature and caused the Great Seal of the State of Tennessee to be affixed this 27th day of April, 2021, and hereby order that this Executive Order No. 80 shall go into effect at 11:59 p.m., Central Time, on April 28, 2021.

GOVERNOR

ATTEST:

SECRETARY OF STATE

STATE OF TENNESSEE

EXECUTIVE ORDER

BY THE GOVERNOR

No. 77

AN ORDER TO FACILITATE THE CONTINUED RESPONSE TO COVID-19 BY EXTENDING EXECUTIVE ORDER NO. 73, AS AMENDED

WHEREAS, ongoing regulatory flexibility and other provisions in Executive Order No. 73, as otherwise amended herein, are required to address the continuing effects, risks, and persistent negative economic conditions in order to assist Tennessee's citizens, health care systems, industries, small businesses, local and state governments, and religious and non-profit institutions combat and recover from the long-term effects of COVID-19; and

WHEREAS, given the continuing effects from COVID-19, Tennesseans have a personal responsibility to protect themselves and others by following health guidelines to slow the spread of this virus, and therefore, all venues, employers, businesses, and organizations should be mindful of the guidance issued by the Governor's Economic Recovery Group (i.e., the Tennessee Pledge), which are available at the following web address and may be periodically updated: https://www.tn.gov/governor/covid-19/economic-recovery.html; and

WHEREAS, in addition to the other powers granted by law, Tennessee Code Annotated, Section 58-2-107, provides, among other things, that during a state of emergency, the Governor is authorized to suspend laws and rules if necessary to cope with an emergency, utilize all available state and local resources needed to combat an emergency, and take measures concerning the conduct of civilians; and

WHEREAS, pursuant to this authority and the general emergency management powers of the Governor under law, such measures, including the measures contained herein, are necessary to facilitate the response to the ongoing effects of COVID-19.

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 continuing state of emergency and major disaster in order to facilitate the response to COVID-19 and accordingly extend and order the following:

A. **Restated provisions that originated in Executive Order No. 36 (as amended in other orders or herein) and similar provisions added in this Order:**

1. Activation of Tennessee Emergency Management Plan. 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. Out of state health care providers may practice in Tennessee. 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 the 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, including treating routine or other medical conditions. The Commissioner of Health shall provide the requisite form for practicing under this Paragraph on the Department of Health's Health Professional Boards webpage.

7.3 Retired medical professionals can easily reenter the health care workforce. The provisions of Tennessee Code Annotated, Titles 63 and 68, and related rules and policies are hereby suspended to the extent necessary to give the Commissioner of Health the authority to grant a license, certificate, or registration to a health care professional, such as a retired health care professional, who has been out of practice for a period of time without requiring that individual to demonstrate continued competency or submit to an interview before a licensing board or other licensing authority, provided that the individual satisfies all other requirements for licensure, certification, or registration.

7.4 In-person and live continuing education requirements are suspended for health care professionals. The provisions of the rules and policies adopted pursuant to Tennessee Code Annotated, Titles 63 and 68, regarding continuing education credits and hours for health care professionals are hereby suspended to the extent necessary to suspend the requirement that any continuing education credits and hours be obtained in-person or at a live event for credit and hours earned from March 12, 2020, through the expiration of this Order. Such rules and policies are further suspended to the extent necessary to allow the Commissioner of Health to adopt policies necessary to comply with the suspension of in-person and live continuing education requirements, and the Commissioner of Health is hereby directed to adopt policies to that effect. Nothing in this provision suspends the requirements that health care professionals obtain a certain number of continuing education credits or hours.

7.5 Laboratory inspections are suspended to allow for immediate COVID-19 testing. The provisions of Tenn. Comp. R. & Regs. 1200-06-03-.03(3) and 1200-06-03-

.04(2) are hereby suspended to the extent necessary to give the Commissioner of the Department of Health the authority to suspend any required onsite inspections of laboratories to the extent necessary to allow laboratories to immediately begin testing for COVID-19.

7.6 Health care licensing inspections and investigations are suspended to increase resources available to fight COVID-19 and to protect public health. The provisions of Tennessee Code Annotated, Titles 63 and 68, and related rules and policies are hereby suspended to the extent necessary to suspend any requirement that the Department of Health conduct inspections or investigations of a licensee, including, but not limited to, complaint investigations, routine surveys, and site visits. However, the Department of Health retains the authority to conduct any inspection or investigation when, in the Department's sole discretion, the public health, safety, or welfare necessitates such inspection or investigation.

7.9 Inspections of health care facilities are suspended. The provisions of Tennessee Code Annotated, Section 68-11-210(a)(1), are hereby suspended to the extent necessary to suspend the requirement that the Department of Health conduct inspections of facilities applying for licensure if the applicant facility is physically located in the same location as another licensed facility where patients have been seen within the thirty (30) days preceding the submission of the application. In instances where the Department of Health elects to not inspect a facility applying for licensure, such provisions requiring a facility applying for licensure to be inspected are hereby suspended.

7.10 Inspections of medical laboratories are suspended. The provisions of Tennessee Code Annotated, Section 68-29-106, are hereby suspended to the extent necessary to suspend the requirement that the Department of Health conduct inspections for medical laboratory applicants for licensure if the applicant laboratory is physically located in the same location where another licensed medical laboratory was located within the thirty (30) days preceding the submission of the new application. In instances where the Department of Health elects to not inspect a medical laboratory applying for licensure, such provisions requiring a medical laboratory applying for licensure to be inspected are hereby suspended.

7.13 Live human examinations are suspended for dentistry applicants. The requirements under Tennessee Code Annotated, Title 63, Chapter 5, and Tenn. Comp R. & Regs. 0460-02-.05 that persons applying for licensure as a dentist complete a live human patient examination component is hereby suspended to permit the Board of Dentistry to grant licensure to persons graduating in 2020 or 2021 from a dental school accredited by the Commission on Dental Accreditation (CODA), if such persons have completed the other licensure requirements, met all of the requirements for competency promulgated by the CODA, and been certified by the dean of their CODA-accredited dental school as qualified, competent, and fit to practice dentistry.

7.16 Nursing graduates may practice under supervision without examination. The provisions of Tennessee Code Annotated, Title 63, Chapters 6 and 7, and related rules and policies are hereby suspended to the extent necessary to give the Commissioner of Health the authority and discretion to allow a person who has graduated on or after December 1, 2019, from an approved registered or practical nursing education program, and who has applied and fulfilled all other requirements for licensure as a nurse but has yet to take the National Council Licensure Exam (NCLEX), to practice nursing under the supervision of a licensed registered nurse.

8. Pharmacists can process prescriptions remotely. The relevant portions of Tennessee Code Annotated, Title 63, Chapter 10, and Tenn. Comp. R. & Regs. 1140-02-.01 through Tenn. Comp. R. & Regs. 1140-02-.02 are hereby suspended to the extent necessary to allow pharmacy technicians and pharmacists to complete computer-based processing of prescriptions at alternative locations, including from the residence of the pharmacy technician or pharmacist. Such computer-based processing shall be conducted utilizing adequate security to ensure all aspects of the Health Insurance Privacy and Accountability Act of 1996 are followed. No laws pertaining to licensed pharmacy practice sites, the storage of drugs, recordkeeping, or dispensing processes are waived or limited by this Order.

8.1 Each pharmacist can supervise more pharmacy technicians. The provisions of Tenn. Comp. R. & Regs. 1140-02-.02(7) are hereby suspended so that there is no restriction on the ratio of pharmacy technicians to pharmacists while this Order is in effect. All statutes and rules regarding the supervision of a pharmacy technician by a licensed pharmacist remain in full force and effect, including, but not limited to, the requirement that a licensed pharmacist supervise, direct, and verify the accuracy of all pharmacy technician functions pursuant to Tenn. Comp. R. & Regs. 1140-02-.02(9).

9. Degree holders in science fields can work as laboratory personnel under supervision. The relevant portions of Tennessee Code Annotated, Title 68, Chapter 29, and related rules are hereby suspended to the extent necessary to give the Commissioner of Health the discretion to allow individuals required to be licensed under Title 68, Chapter 29, as medical laboratory technologists, medical laboratory technicians, or special analysts to work without a license while employed by a licensed medical laboratory and working under the supervision of a medical laboratory director; provided, that, such an individual has obtained a bachelor's degree in a biology or chemistry science field. The Commissioner of Health shall provide the requisite form for practicing under this Paragraph on the Department of Health's Health Professional Boards webpage.

9.1 Medical laboratory directors can monitor facilities remotely. The provisions of Tenn. Comp. R. & Regs. 1200-06-01-.20(5)(c) are hereby suspended to the extent necessary to suspend the requirement that a medical laboratory director make certain periodic in-person, onsite visits to the facilities the director oversees, so long

as the director utilizes other technological means of maintaining and exercising oversight.

9.2 Pre-license, graduate or doctoral level mental or behavioral health professionals can provide telehealth services under supervision. 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 authority to allow persons who have completed or are actively enrolled in a program to obtain a master's degree or doctoral degree in a behavioral or mental health field, or in a field of study required for a license allowing the individual to diagnose behavioral or mental health disorders, to treat diagnosed behavioral or mental health conditions without a license and through use of telemedicine services; provided, that the person is, at all times, supervised by a person licensed under Title 63 or Title 68, Chapter 24 with authorization to diagnose a behavioral or mental health condition. The Commissioner of Health shall provide the requisite form for practicing under this Paragraph 9.2 on the Department of Health's Health Professional Boards webpage.

9.3 Medical laboratory personnel can work remotely. The provisions of Tenn. Comp. R. & Regs. 1200-06-03-.02(1)(b) are hereby suspended to allow medical laboratory personnel to remotely review electronic data and report laboratory results without having a separate laboratory license for each remote location. Such personnel must be employed by a licensed medical laboratory and working under the supervision of a laboratory director. This suspension does not otherwise alter or amend any licensee's scope of practice or recordkeeping requirements.

9.4 Pre-license, graduate or doctoral level audiology and speech language pathology professionals can provide telehealth services under supervision. The relevant provisions of Tennessee Code Annotated, Title 63, and related rules are hereby suspended to the extent necessary to give the Commissioner of Health the authority to allow persons who have completed or are actively enrolled in a program to obtain a master's degree or doctoral degree in the field of audiology or speech language pathology to practice without a license and through use of telemedicine services; provided, that the person is, at all times, supervised by a person licensed under Title 63 in that field. The Commissioner of Health shall provide the requisite form for practicing under this Paragraph 9.4 on the Department of Health's Health Professional Boards webpage.

10. Increased number of hospital beds available for COVID-19 patients. The provisions of Tennessee Code Annotated, Section 68-11-1607, are hereby suspended to the extent necessary to allow hospitals, nursing homes, and home health agencies that would otherwise be subject to certificate of need requirements to temporarily increase their number of licensed hospital beds at any location or temporarily establish hospital, nursing home, home-based, and diagnostic services at any location, if necessary for the treatment of COVID-19 patients, as well as to the

extent necessary to facilitate activity authorized by the provisions of this Order and any subsequent order concerning COVID-19.

10.2 **Medical professional staffing flexibility** is permitted pursuant to an approved plan to relieve the capacity strain on certain staffing functions. In order to relieve the capacity strain on bedside care and support resulting from staffing shortages (nurses, respiratory therapists, etc.), additional temporary regulatory flexibility measures are necessary to cope with the emergency. To this end, the provisions of Title 63 and Title 68, Chapter 140, are hereby suspended to the extent necessary to authorize professionals licensed under Title 63 or Title 68, Chapter 140, to perform tasks outside of their licensed scope of practice if such tasks are performed in a hospital licensed under Title 68 pursuant to a facility-specific, COVID-19-related plan of delegation that has been submitted by the facility's chief medical officer and approved by the Commissioner of Health or the Commissioner's designee. Such a plan of delegation must include the specific types of licensees covered, the specific tasks outside of their licensed scope of practice that are permitted, and the specific circumstances and directives under which such tasks are permitted. The Commissioner or the Commissioner's designee may approve such plan subject to conditions and may rescind such approval in the Commissioner's or Commissioner's designee's sole discretion. For purposes of regulation and disciplinary action, licensees performing tasks pursuant to this provision remain subject to regulation and disciplinary action as if they were acting within their licensed scope of practice.

10.3 **Discretion to utilize National Guard and State Guard members in connection with certain health care and emergency services operations.** This Paragraph 10.3 is issued for the limited purpose of authorizing personnel recognized under Tennessee Code Annotated, Sections 58-1-203, 58-1-204, and 58-1-402 (collectively, "Personnel"), to serve in certain health care and emergency services roles to reduce system capacity strain resulting from COVID-19. Namely, Personnel may: (1) perform authorized diagnostic testing for COVID-19 in health care settings, including but not to limited to hospitals, emergency departments, and alternate care sites (collectively, "Facilities"); (2) perform authorized nursing and other functions in Facilities; and (3) operate public or privately owned, permitted ambulance service vehicles with a licensed service. Accordingly, the following provisions are hereby suspended to the extent necessary to facilitate this Paragraph 10.3: Tennessee Code Annotated, Titles 63 and Title 68, and related rules, with respect to licensure, continuing education, and other requirements for Personnel or Facilities utilizing Personnel; Title 68, Chapter 140, Part 3, with respect to Personnel and licensed ambulance services utilizing Personnel; and any other state or local law, order, rule, or regulation that would limit the application of this Paragraph 10.3 is hereby suspended to the extent necessary to facilitate this Paragraph 10.3. This Paragraph 10.3 is subject to the following conditions:

a. No Personnel shall operate under this Paragraph 10.3 unless designated by the Adjutant General upon request or order of the Governor;

b. Personnel operating pursuant to this Paragraph 10.3 shall have the appropriate training or skills in the area(s) pertaining to their designations;

c. The Adjutant General and Commissioner of Health, or their designees, shall determine the Facilities to which Personnel are assigned, based on need and other reasonable factors, in their sole discretion;

d. Any Facility to which Personnel are assigned must submit, in writing to the Commissioner of Health, the responsibilities and tasks that Personnel will be undertaking while operating pursuant to this Paragraph 10.3;

e. A list of Personnel designated to operate under this Paragraph 10.3 and the Facility or setting in which such Personnel will be operating shall be provided to the Commissioner of Health by the Adjutant General, and this list shall be updated from time to time as necessary;

f. Any authority, duties, or scope of practice suspensions extended to Personnel pursuant to this Paragraph 10.3 shall terminate and be of no further force and effect upon the expiration or termination of Paragraph 10.3 or other order of the Governor to that effect; and

g. This Paragraph 10.3 shall not affect the requirements and provisions of the suspended statutory and rule provisions with respect to any other person or facility.

10.4 Regulatory flexibility for ambulance transport services. In order to relieve the capacity strain on emergency medical services, temporary regulatory flexibility measures are necessary for nonemergency ambulance transport services. To this end, the provisions of Tennessee Code Annotated, Title 68, Chapter 140, and Tenn. Comp. R. & Reg. 1200-12-01-.14(3)(c)(2)(iii) & (iv) are hereby suspended to the extent necessary to authorize that Level 3 transports may be staffed with one AEMT and Level 4 transports may be staffed with one EMT, provided that there is an ambulance operator in addition to the AEMT or EMT who satisfies the ambulance driver requirements of Tenn. Comp. R. & Reg. 1200-12-01-.10. All other statutes and rules regarding patient transport services remain in full force and effect.

10.5 Delegation of nursing tasks to medical assistants under the supervision of a registered nurse is permitted to relieve the capacity strain on vaccination and other staffing functions. In order to ensure prompt administration of a COVID-19 vaccination and relieve the capacity strain on bedside care and support resulting from staffing shortages due to COVID-19, additional temporary regulatory flexibility measures are necessary to cope with the emergency. The provisions of Title 63 and related rules are hereby suspended to the extent necessary to authorize a registered nurse, licensed in Tennessee or working in Tennessee on a multi-state privilege to practice, to delegate to medical assistants certified or registered by the

American Association of Medical Assistants, American Medical Technologists, National Association for Health Professionals, National Center for Competency Testing, or National Healthcareer Association tasks that would normally be within the practical nurse scope of practice, including, but not limited to, administration of COVID-19 vaccinations, under the supervision of the registered nurse. Tasks delegated to certified medical assistants and performed under the supervision of the delegating registered nurse are required to have been ordered and authorized by a Tennessee licensed practitioner with prescriptive authority.

10.6 Behavioral health inpatient psychiatric, residential, and crisis care staffing flexibility is permitted pursuant to an approved plan to relieve the capacity strain on certain staffing functions. In order to relieve the capacity strain on bedside care and support resulting from staffing shortages (physician assistants, nurse practitioners, registered nurses, licensed practical nurses, etc.), additional temporary regulatory flexibility measures are necessary to cope with the emergency. To this end, the provisions of Title 33, Title 63, and Title 68, Chapter 140, and related rules are hereby suspended to the extent necessary to authorize professionals licensed under Title 63 or Title 68, Chapter 140, to perform tasks outside of their licensed scope of practice or restricted under Title 33 if such tasks are performed in an inpatient psychiatric facility, in a behavioral health residential facility, or by a behavioral health crisis services provider licensed under Title 33 pursuant to a facility or provider-specific, COVID-19-related plan of delegation that has been submitted by the facility's or provider's chief medical or chief executive officer and jointly approved by the Commissioner of Mental Health and Substance Abuse Services or the Commissioner's designee and the Commissioner of Health or the Commissioner's designee. Such approval by either Commissioner or Commissioner's designee may be subject to conditions or may be subsequently rescinded in that person's sole discretion. Such a plan of delegation must include the specific types of licensees covered, the specific tasks outside of their licensed scope of practice or restricted under Title 33 that are permitted, and the specific circumstances and directives under which such tasks are permitted. For purposes of regulation and disciplinary action, licensees performing tasks pursuant to this provision remain subject to regulation and disciplinary action as if they were acting within their licensed scope of practice.

10.7 Health care student staffing flexibility is permitted in inpatient acute care and rehabilitation and emergency settings pursuant to an approved plan to relieve the capacity strain on certain staffing functions. In order to relieve the capacity strain on bedside care resulting from staffing shortages related to inpatient acute care, inpatient behavioral health, and emergency care, additional temporary regulatory flexibility measures are necessary to cope with the emergency. To this end, the provisions of Title 63 and Title 68, Chapter 140, and related rules are hereby suspended to the extent necessary to authorize students actively enrolled in a graduate school program or an undergraduate respiratory care program, the educational standards of which meet the training requirements for a license under Title 63 or Title 68, Chapter 140, to perform supervised tasks within the licensed

scope of practice of such a license, if such tasks are performed in an inpatient acute care or inpatient rehabilitation setting or emergency department pursuant to a facility-specific, COVID-19-related plan of delegation that has been submitted by the facility's chief medical officer and approved by the Commissioner of Health or the Commissioner's designee. Such a plan of delegation must include the specific types of programs in which a student must be enrolled to perform tasks in accordance with this Paragraph 10.7, the specific tasks within the relevant scope of practice that the student is permitted to perform, and the specific circumstances and directives under which such tasks are permitted. The Commissioner or the Commissioner's designee may approve such plan subject to conditions and may rescind such approval in the Commissioner's or Commissioner's designee's sole discretion. Students performing tasks pursuant to this Paragraph 10.7 may be subject to disciplinary action upon applying for a license for actions inconsistent with the practice act for the licensed scope of practice in which they are operating.

10.8 Health care student staffing flexibility is permitted in inpatient psychiatric and behavioral health settings pursuant to an approved plan to relieve the capacity strain on certain staffing functions. In order to relieve the capacity strain on bedside care resulting from staffing shortages related to inpatient acute care, inpatient behavioral health, and emergency care, additional temporary regulatory flexibility measures are necessary to cope with the emergency. To this end, the provisions of Title 33, Title 63, and Title 68, Chapter 140, and related rules are hereby suspended to the extent necessary to authorize students actively enrolled in a graduate school program or an undergraduate respiratory care program, the educational standards of which meet the training requirements for a license under Title 63 or Title 68, Chapter 140, to perform supervised tasks within the licensed scope of practice of such a license or restricted under Title 33, if such tasks are performed in an inpatient psychiatric facility, in a behavioral health residential facility, or by a behavioral health crisis services provider licensed under Title 33 pursuant to a facility or provider-specific, COVID-19-related plan of delegation that has been submitted by the facility's or provider's chief medical or chief executive officer and jointly approved by the Commissioner of Mental Health and Substance Abuse Services or the Commissioner's designee and the Commissioner of Health or the Commissioner's designee. Such a plan of delegation must include the specific types of programs in which a student must be enrolled to perform tasks in accordance with this Paragraph 10.8, the specific tasks within the relevant scope of practice or restricted under Title 33 that the student is permitted to perform, and the specific circumstances and directives under which such tasks are permitted. Such approval by either Commissioner or Commissioner's designee may be subject to conditions or may be subsequently rescinded in that person's sole discretion. Students performing tasks pursuant to this Paragraph 10.8 may be subject to disciplinary action upon applying for a license for actions inconsistent with the practice act for the licensed scope of practice in which they are operating.

11. Testing for COVID-19 can occur at more medical laboratory facilities. The provisions of Tenn. Comp. R. & Regs. 1200-06-03-.16 are suspended to allow

testing necessary for the diagnosis, treatment, and containment of COVID-19 to occur 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.

12. Temporary quarantine and isolation facilities may be constructed. 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.

16.1 Unemployment benefits for persons affected by COVID-19. The provisions of Tennessee Code Annotated, Title 50, Chapter 7, and related rules are hereby suspended to the extent necessary to allow the Commissioner of Labor and Workforce Development to comply with, and maximize the benefits to the State from, federal legislation related to emergency unemployment benefits, including any extension of, or modification to, the Coronavirus Aid, Relief, and Economic Security Act enacted on March 27, 2020, as Public Law No. 116-136.

21. Board of Parole may modify procedures to protect public health. The provisions of Tennessee Code Annotated, Section 40-28-118(a) and (b), Section 40-28-121(b) and (d), Section 40-28-122(a), (c), and (f), and Section 40-35-503(d), (e), (f), and (h), requiring the Tennessee Board of Parole to take certain actions and conduct certain proceedings, the provisions of Tennessee Code Annotated, Section 40-28-502(a)(1), requiring that hearings be open to the public, the notification requirements of Tennessee Code Annotated, Section 40-28-505(b), (c), (e), and (g), and any related provisions of Tenn. Comp. R. & Regs. 1100-01-01-.01 through Tenn. Comp. R. & Regs. 1100-01-01-.16 and Board of Parole policies adopted pursuant to Tennessee Code Annotated, Section 40-28-104, are hereby suspended. However, the Board of Parole is directed to use all available processes, alternatives, and technology to maintain continuity of services and hearings to the greatest extent practicable while maintaining the health and safety of all persons involved.

21.1 Suspends temporary application of safety valve provisions resulting from the temporary decrease in TDOC prisoners. The provisions of Tennessee Code Annotated, Sections 41-1-505(a) and 41-1-508(c), requiring the automatic reversion of release eligibility dates of certain felony offenders to the dates in existence prior to their reductions pursuant to Title 41, Chapter 1, Part 5 upon attainment of ninety percent (90%) of the relevant designated capacity of the state correctional facilities are hereby suspended.

23.6 Commercial diver licenses with medical cards are extended. Consistent with the February 16, 2021, Federal Motors Carrier Safety Administration waivers, the provisions of Tennessee Code Annotated, Section 55-50-413, are hereby

suspended, as follows, to the extent necessary to delay the cancellation of a Class A, B, or C driver license with a medical card issued for more than ninety (90) days: Class A, B, and C driver license holders whose medical cards were set to expire from December 1, 2020, through March 29, 2021, will have until March 29, 2021, to submit a new medical card to the Department of Safety and Homeland Security to avoid cancellation, regardless of other termination dates that may be specified in the federal waiver. Renewal requirements shall return to their original schedule in subsequent years. Drivers who, since their last medical certificate was issued, have been diagnosed with a medical condition that would disqualify the driver from operating in interstate commerce, or who, since their last medical certificate was issued, have developed a condition that requires an exemption or Skill Performance Evaluation from FMCSA are not covered under the suspension in this paragraph.

27. Educational and training deadlines administered by the Department of Commerce and Insurance may be extended. The provisions governing the initial issuance and renewal of licenses, permits, and certifications issued by the Department of Commerce and Insurance and the boards, commissions, and agencies administratively attached to the Department are suspended to the extent necessary to give the Commissioner of Commerce and Insurance and the boards, commissions, and agencies discretion to reasonably extend the deadline for obtaining the required testing, education, continuing education, or in-service credits as necessary to respond to the effects of COVID-19.

28. Deadlines for building code, building plan, electrical, and residential inspections may be extended. The provisions governing building plans review or building code requirements or electrical or residential inspections under the purview of the Department of Commerce and Insurance are suspended to the extent necessary to give the Commissioner of Commerce and Insurance discretion to reasonably extend the deadline for compliance with such provisions as necessary to respond to the effects of COVID-19.

33. Inspections of mental health and substance abuse facilities and services are suspended. The provisions of Tennessee Code Annotated, Section 33-2-413(a), are hereby suspended to the extent necessary to give the Commissioner of Mental Health and Substance Abuse Services the authority to suspend the required unannounced life safety and environmental inspections of licensed services or facilities, absent the death of a service recipient at the service or facility with an indication of possible abuse or neglect by the service or facility or its employees or a request for placement assistance from law enforcement or state or federal agencies regarding the service or facility.

33.1 Telephonic assessments for involuntary commitment cases are permitted. The provisions of Tennessee Code Annotated, Section 33-4-108, are hereby suspended to the extent necessary to allow the issuance of a certificate of need under Tennessee Code Annotated, Section 33-6-404, for the emergency involuntary commitment of a person with a mental illness or serious emotional disturbance based upon a

telephone assessment of such person by a mandatory pre-screening agent designated pursuant to Tennessee Code Annotated, Sections 33-6-104 and 33-6-127, if the following conditions are met:

a. The mandatory pre-screening agent is not reasonably able to conduct an evaluation in-person or via readily available telehealth services; and

b. The mandatory pre-screening agent determines in the agent's professional judgment that conducting the assessment via telephone with the person is clinically appropriate.

34. TennCare policies adjusted to prevent coverage disruptions. 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.

34.1 Designation and Payment for Certain Nursing Facilities as "COVID-19 Skilled Nursing Facilities/Units." The provisions of Tennessee Code Annotated, Titles 4, 68, and 71 and related rules, regulations, and policies are hereby suspended to the extent necessary to provide the Department of Health and the Division of TennCare the necessary authority and discretion to select, designate, and reimburse certain nursing facilities, or units within certain nursing facilities, as "COVID-19 Skilled Nursing Facilities/Units."

34.2 Medicaid Payments to "COVID-19 Skilled Nursing Facilities/Units." The provisions and requirements of Tennessee Code Annotated, Section 71-5-105, are hereby suspended to the extent necessary to permit the Division of TennCare to implement additional acuity-based payments for Medicaid members in nursing facilities designated as "COVID-19 Skilled Nursing Facilities/Units".

38. Telemedicine access is expanded. Health insurance carriers are urged to provide coverage for the delivery of clinically appropriate, medically necessary covered services via telemedicine to all providers, irrespective of network status or originating site. Providers are urged to follow the new guidance from the federal Centers for Medicare and Medicaid Services regarding equipment and everyday communications technologies that may be used for the provision of telemedicine services. Carriers are urged not to impose prior authorization requirements on medically necessary treatment related to COVID-19 delivered by in-network providers via telemedicine. Health care professionals licensed in another state who are authorized pursuant to this Order to temporarily practice in this State are permitted to engage in telemedicine services with patients in Tennessee to the extent the scope of practice of the applicable professional license in this State would authorize the professional to diagnose and treat humans. Tennessee Code Annotated, Section 63-1-155(c)(3), is hereby suspended to allow telemedicine

services by pain management clinics, as defined in Tennessee Code Annotated, Section 63-1-301(7), and in the case of chronic nonmalignant pain treatment.

38.1 All licensed health care providers can practice telemedicine. The provisions of Tennessee Code Annotated, Section 63-1-155(a)(1), are hereby suspended to the extent necessary to allow telehealth or telemedicine services to be provided by any provider licensed under Title 63, regardless of the provider's authority to diagnose. This suspension does not otherwise alter or amend any licensee's scope of practice or record keeping requirements.

38.2 Licensed alcohol and drug abuse counselors can practice telemedicine. The provisions of Tennessee Code Annotated, Section 63-1-155(a)(1), and any other state or local law, order, rule, or regulation that would limit the application of this Paragraph 38.2 are hereby suspended, retroactively to March 26, 2020, when Paragraph 38.1 of Executive Order No. 36 suspended provisions of law to permit telemedicine by other licensed health care providers, to the extent necessary to allow telehealth or telemedicine services to be provided by an alcohol and drug abuse counselor licensed under Title 68. This suspension does not otherwise alter or amend an alcohol and drug abuse counselor's scope of practice or record keeping requirements.

38.3 **Hospital-level care in home** program and telemedicine access expansion is encouraged. In order to relieve the capacity strain on inpatient care due to COVID-19, health insurance carriers are urged to provide equivalent inpatient reimbursement to all providers for the delivery of clinically appropriate, medically necessary covered services via programs in which patients receive hospital-level care in home, irrespective of network status or originating site. Providers are urged to follow the new guidance from the federal Centers for Medicare and Medicaid Services regarding equipment and everyday communications technologies that may be used for the provision of telemedicine services. Carriers are urged to not impose additional prior authorization requirements on medically necessary treatment related to COVID-19 delivered via programs in which patients receive hospital-level care in home.

39. Collaborative pharmacy practice agreement for vaccinations. The chief medical officer of the Department of Health is authorized to implement a statewide collaborative pharmacy practice agreement specific to the administration and dispensing of the COVID-19 vaccine with any pharmacist licensed in and practicing in Tennessee. The provisions of Title 63 and related rules are hereby suspended to the extent necessary to authorize a pharmacist licensed under Title 63 to enter into the collaborative practice agreement with the chief medical officer of the Department of Health. A pharmacist entering into the statewide collaborative pharmacy practice agreement must attest and maintain proof that the pharmacist satisfies all of the requirements to qualify as a "covered person" under 42 U.S.C. § 247d-6d(i)(8)(B) pursuant to the HHS Guidance dated September 3, 2020. For each intern or technician for whom the pharmacist is the supervising qualified

pharmacist, the pharmacist must attest and maintain proof that the intern or technician satisfies all of the requirements to qualify as a "qualified person" under 42 U.S.C. § 247d-6d(i)(8)(B), pursuant to HHS Guidance dated October 20, 2020. For purposes of regulation and disciplinary action, licensees performing tasks pursuant to this provision remain subject to regulation and disciplinary action as if they were acting within their licensed scope of practice. Students performing tasks pursuant to this paragraph may be subject to disciplinary action upon applying for a license for actions inconsistent with the licensed scope of practice for which they are operating.

B. **Restated provisions that originated in Executive Order No. 38 (as amended in other orders or herein):**

11. Sports and athletics. Local education agencies and schools shall, notwithstanding any orders or provisions to the contrary, have the authority to permit, but are not required to permit, school-sponsored sporting events and activities, provided that all such activities, including practices and games or competition, must be conducted in a manner consistent with COVID-19-related guidance and rules adopted by the Tennessee Secondary Schools Athletic Association. Non-school-sponsored athletics, including practices and games or competition, must be conducted in a manner consistent with guidance from the Tennessee Economic Recovery Group (i.e., Tennessee Pledge). Collegiate and professional sporting events and activities must be conducted pursuant to the rules or guidelines of their respective governing bodies.

12. Take-out alcohol sales by restaurants and limited-service restaurants to continue in order to encourage carryout or delivery orders. The provisions of Tennessee Code Annotated, Title 57, and related rules and other state or local laws, orders, rules, or regulations are temporarily suspended to the extent necessary to allow restaurants and limited service restaurants, as defined in Tennessee Code Annotated, Section 57-4-102, and wine-only restaurants, as permitted by Tennessee Code Annotated, Section 57-4-101(c), to sell for take-out or delivery alcoholic beverages or beer, so long as the following conditions are met:

a. Any sale of an alcoholic beverage or beer is for consumption off of the premises of the restaurant, limited service restaurant, or wine-only restaurant (collectively referred to hereafter as "restaurant") and is accompanied by the sale of food in the same order;

b. An alcoholic beverage or beer sold under this Paragraph 12 must be packaged in a container or bottle with a secure lid or cap and in a manner designed to prevent consumption without removal of the lid or cap, and customers shall not remove such lids or caps while operating a motor vehicle;

c. Single servings of alcoholic beverages or beer and multi-serving bottles or containers of beer or wine normally sold by the restaurant may be sold under this Paragraph 12, but not bottles of spirits or liquor;

d. A restaurant selling alcoholic beverages or beer under this Paragraph 12 shall prominently post a warning in a manner reasonably calculated to provide notice to customers of open container laws, which must include the following language from Tennessee Code Annotated, Section 55-10-416: "No driver shall consume any alcoholic beverage or beer or possess an open container of alcoholic beverage or beer while operating a motor vehicle in this state.";

e. An employee or contractor of a restaurant providing or delivering alcoholic beverages or beer to a customer under this Paragraph 12 shall not provide or deliver such beverages to any person under twenty-one (21) years of age and may not provide or deliver such beverages to a person who is visibly intoxicated. Any such employee providing or delivering alcoholic beverages or beer must visually inspect a valid government-issued document deemed acceptable to the restaurant that includes the photograph and birth date of the adult consumer attempting to make an alcoholic beverage purchase and confirms that the person is at least twenty-one (21) years of age;

f. A person delivering alcoholic beverages or beer under this Paragraph 12 must be at least twenty-one (21) years of age and must have a valid driver license; and

g. An alcoholic beverage or beer sold under this Paragraph 12 must be sold during current operating hours.

12.1 Waiver of application fee to expand premises. The provisions of Tennessee Code Annotated, Title 57, and related rules and other state or local laws, orders, rules, or regulations are temporarily suspended to the extent necessary to waive the $300.00 application fee for restaurants, limited service restaurants, and all other establishments licensed under Title 57, Chapter 4, that apply to the Alcoholic Beverage Commission to expand the boundary of their premises covered under such license to sell alcoholic beverages for on-premises consumption in response to COVID-19.

13. Local orders.

a. No local orders permitted regarding dental or medical procedures. In order to ensure a comprehensive approach to the measures needed to conserve personal protective equipment, which is an issue that is statewide in scale, no local official or local governmental entity shall issue an order or measure

regarding the provision of medical, dental, or oral procedures because of COVID-19 absent authority delegated by the Governor.

b. Local orders in 89 counties without a locally run county health department (all counties except for Davidson, Hamilton, Knox, Madison, Shelby, and Sullivan). The provisions of this Order shall exclusively govern on the subjects they concern in the 89 counties that do not have a locally run county health department, and this Order shall supersede and preempt any emergency order, health order, or other order issued by a local official or local governmental entity that contravenes or would limit the application of the provisions of this Order.

c. Local orders in six counties with a locally run county health department (Davidson, Hamilton, Knox, Madison, Shelby, and Sullivan). The six locally run county health departments in Davidson, Hamilton, Knox, Madison, Shelby, and Sullivan counties shall have authority to issue additional orders or measures related to the containment or management of the spread of COVID-19, which may permit to a greater degree, or restrict to a greater degree, the opening, closure, or operation of businesses, organizations, or venues in those counties or the gathering of persons; provided that no local official or local governmental entity shall issue an order or measure regarding places of worship or an order or measure that contravenes Paragraphs 6, 9, or 10 of Executive Order No. 38, as restated herein. This Order shall govern on all subjects it concerns, except to the extent that the locally run county health department has issued differing local orders or measures regarding the opening, closure, or operation of businesses, organizations, or venues or the gathering of persons as provided for in this Paragraph 13.

d. Local orders of a proprietary nature. Nothing in this Order shall affect or limit local orders that do not contravene or limit the application of the provisions of this Order, such as orders or measures in which a local governmental entity acts in a proprietary capacity—for example, with respect to the opening or closure of governmental buildings, employee measures, or government operations.

C. **Restated provisions that originated in Executive Order No. 54 (as amended in other orders or herein):**

2. Specific delegation of authority to issue orders concerning face coverings. Notwithstanding anything to the contrary in Paragraph 13.b. of Executive Order No. 38, as restated herein, county mayors in the 89 counties that do not have a locally run county health department shall have the authority to issue orders or measures requiring or recommending the wearing of face coverings within their jurisdictions, consistent with Paragraph 3 of Executive Order No. 54, as restated herein.

3. Contents of local orders. Orders or measures issued by county mayors pursuant to this Order should be consistent with CDC guidance and may have such exemptions as deemed advisable, provided that, at a minimum, there shall be no requirement that a face covering be worn:

i. Within one's residence or automobile, unless transporting others for hire;

ii. By a child twelve (12) years of age or younger;

iii. By someone who has trouble breathing due to an underlying health condition or another bona fide medical or health-related reason for not wearing a face covering;

iv. By someone who is incapacitated or otherwise unable to remove the cloth face covering without assistance;

v. While eating or drinking;

vi. While outdoors, unless the person cannot substantially maintain appropriate social distancing from others outside of the person's household;

vii. While working under conditions where appropriate social distancing from others outside of the person's household is substantially maintained;

viii. In situations in which wearing a face covering poses a safety or security risk;

ix. While in a house of worship unless required by that house of worship, but wearing a face covering in such locations is strongly encouraged; or

x. While in a voting site for the purpose of voting or administering an election, but wearing a face covering in such locations is strongly encouraged.

5. Nothing preempts or supersedes any authority of bodies in six counties with a locally run county health department. Nothing herein or in Paragraphs 5 or 13 of Executive Order No. 38, as restated herein, preempts or supersedes any existing authority, as provided by executive order, statute, charter, or otherwise, of a locally run county health department, board of health, official, or local legislative body, located in a county with a locally run county health department, to issue or enact orders, ordinances, rules, or law regarding face coverings to mitigate the spread of COVID-19.

6. Effect of Order. A local order promulgated under the authority delegated by this Order constitutes an order, rule, or regulation promulgated pursuant to Tennessee

Code Annotated, Title 58, Chapter 2, Part 1, for purposes of Tennessee Code Annotated, Section 58-2-120.

D. General Provisions:

1. Suspension of laws that would limit application of this Order. Any law, order, rule, or regulation that would otherwise limit the enforceability of this Order is hereby suspended, pursuant to Tennessee Code Annotated, Section 58-2-107.

2. Severability. If any provision of this Order or its application to any person or circumstance is held invalid, the invalidity does not affect other provisions or applications of this Order which can be given effect without the invalid provision or application, and to that end the provisions of this Order are declared to be severable.

3. Term and effective date. This Order takes effect at 11:59 p.m., Central Time, on February 27, 2021, and shall remain in effect until 11:59 p.m., Central Time, on April 28, 2021.

IN WITNESS WHEREOF, I have subscribed my signature and caused the Great Seal of the State of Tennessee to be affixed this 26th day of February, 2020.

GOVERNOR

ATTEST:

SECRETARY OF STATE

Interim Infection Prevention and Control Recommendations to Prevent SARS-CoV-2 Spread in Nursing Homes

Nursing Homes & Long-Term Care Facilities

Updated Mar. 29, 2021 Print

This guidance summarizes the core infection prevention and control practices for nursing homes during the SARS-CoV-2 pandemic. Some of these recommendations can be modified in response to COVID-19 vaccination. Those modifications, which will be regularly updated, are posted in CDC's Updated Healthcare Infection Prevention and Control Recommendations in Response to COVID-19 Vaccination.

Summary of Recent Changes

Updates as of March 29, 2021

- Two prior guidance documents, "Responding to COVID-19 in Nursing Homes" and "Performing Facility-wide SARS-CoV-2 Testing in Nursing Homes" were merged with this guidance.
- The criteria for health department notification was updated to be consistent with Council of State and Territorial Epidemiologist (CSTE) guidance for reporting.
- Information on the importance of vaccinating residents and healthcare personnel (HCP) was added along with links to vaccination resources.
- Visitation and physical distancing measures were updated.
- Added proper use and handling of personal protective equipment (PPE).
- Added universal PPE use to align with the interim infection prevention and control guidance for HCP.
- Added considerations for situations when it might be appropriate to keep the room door open for a resident with suspected or confirmed SARS-CoV-2 infection.
- A description was included about when it may be appropriate for a resident with a suspected SARS-CoV-2 infection to "shelter-in-place."
- Added management of residents who had close contact with someone with SARS-CoV-2 infection which includes a description of quarantine recommendations including resident placement, recommended PPE, and duration of quarantine.
- Added addressing circumstances when quarantine is recommended for residents who leave the facility.
- Added responding to a newly identified SARS-CoV-2-infected HCP or resident.
- Added addressing quarantine and work exclusion considerations for asymptomatic residents and HCP who are within 90 days of resolved infection.

Key Points

- Older adults living in congregate settings are at high risk of being affected by respiratory and other pathogens, such as SARS-CoV-2.
- A strong infection prevention and control (IPC) program is critical to protect both residents and healthcare personnel (HCP).
- Even as nursing homes resume normal practices and begin relaxing restrictions, nursing homes must sustain core IPC practices and remain vigilant for SARS-CoV-2 infection among residents and HCP in order to prevent spread and protect residents and HCP from severe infections, hospitalizations, and death.
- These recommendations supplement CDC's Interim Infection Prevention and Control Recommendations for Healthcare Personnel During the Coronavirus Disease 2019 (COVID-19) Pandemic and are specific for nursing homes, including skilled nursing facilities, but may also apply to other long-term care and residential settings.

This guidance summarizes the core infection prevention and control practices for nursing homes during the SARS-CoV-2 pandemic. Some of these recommendations can be modified in response to COVID-19 vaccination. Those modifications, which will be regularly updated, are posted in CDC's Updated Healthcare Infection Prevention and Control Recommendations in Response to COVID-19 Vaccination.

Introduction

Given their congregate nature and resident population served (e.g., older adults often with underlying chronic medical conditions), nursing home populations are at high risk of being affected by respiratory pathogens like SARS-CoV-2 and other pathogens, including multidrug-resistant organisms (e.g., carbapenemase-producing organisms, *Candida auris*). As demonstrated by the COVID-19 pandemic, a strong infection prevention and control (IPC) program is critical to protect both residents and healthcare personnel (HCP). Even as nursing homes resume more normal practices and begin relaxing restrictions, nursing homes must sustain core IPC practices and remain vigilant for SARS-CoV-2 infection among residents and HCP in order to prevent spread and protect residents and HCP from severe infections, hospitalizations, and death.

This guidance has been updated and organized according to IPC practices that should remain in place whether or not nursing homes are experiencing outbreaks of SARS-CoV-2. Additional guidance is included to assist nursing homes and public health authorities with resident placement and cohorting decisions when responding to SARS-CoV-2 infections and exposures.

These recommendations supplement CDC's Interim Infection Prevention and Control Recommendations for Healthcare Personnel During the Coronavirus Disease 2019 (COVID-19) Pandemic and are specific for nursing homes, including skilled nursing facilities, but may also be applicable to other long-term care and residential settings.

Unless noted in the Updated Healthcare Infection Prevention and Control Recommendations in Response to COVID-19 Vaccination, this guidance applies regardless of vaccination status and level of vaccination coverage in the facility.

This guidance summarizes the core infection prevention and control practices for nursing homes during the SARS-CoV-2 pandemic. Some of these recommendations can be modified in response to COVID-19 vaccination. Those modifications, which will be regularly updated, are posted in CDC's Updated Healthcare Infection Prevention and Control Recommendations in Response to COVID-19 Vaccination.

Infection Prevention and Control Program

Assign One or More Individuals with Training in Infection Control to Provide On-Site Management of the IPC Program

- This should be a full-time role for at least one person in facilities that have more than 100 residents or that provide on-site ventilator or hemodialysis services. Smaller facilities should consider staffing the IPC program based on the

resident population and facility service needs identified in the IPC risk assessment.

- CDC has created an online training course that can orient individuals to this role in nursing homes.

Provide Supplies Necessary to Adhere to Recommended Infection Prevention and Control Practices

- Hand Hygiene Supplies:
  - Put FDA-approved alcohol-based hand sanitizer with 60-95% alcohol in every resident room (ideally both inside and outside of the room) and other resident care and common areas (e.g., outside dining hall, in therapy gym).
  - Unless hands are visibly soiled, performing hand hygiene using an alcohol-based hand sanitizer is preferred over soap and water in most clinical situations (e.g., before and after touching a resident) due to evidence of better compliance compared to soap and water. Hand rubs are generally less irritating to hands and, in the absence of a sink, are an effective method of cleaning hands.
  - Make sure that sinks are well-stocked with soap and paper towels for handwashing.
- Personal Protective Equipment (PPE):
  - Employers should select appropriate PPE and provide it to HCP in accordance with Occupational Safety and Health Administration (OSHA) PPE standards (29 CFR 1910 Subpart I)
  - Facilities should have supplies of facemasks, N95 or higher-level respirators, gowns, gloves, and eye protection (i.e., face shield or goggles).
  - Implement a respiratory protection program that is compliant with the OSHA respiratory protection standard (29 CFR 1910.134) for employees if not already in place. The program should include medical evaluations, training, and fit testing.
  - Perform and maintain an inventory of PPE in the facility.
    - Monitor daily PPE use to identify when supplies will run low; use the PPE burn rate calculator or other tools.
    - Identify health department or healthcare coalition contacts for getting assistance during PPE shortages.
    - Use the Supplies and PPE pathway in the National Healthcare Safety Network (NHSN) Long-term Care Facility (LTCF) COVID-19 Module to indicate critical PPE shortages (i.e., less than one week supply remaining despite use of CDC PPE optimization strategies).
  - Make necessary PPE available in areas where resident care is provided.
    - Consider designating staff responsible for stewarding those supplies and monitoring and providing just-in-time feedback, promoting appropriate use by staff.
  - Position a trash can near the exit inside the resident room to make it easy for staff to discard PPE prior to exiting the room or before providing care for another resident in the same room.
  - Follow CDC PPE optimization strategies, which offer a continuum of options for use when PPE supplies are stressed, running low, or exhausted.
- Environmental Cleaning and Disinfection:
  - Develop a schedule for regular cleaning and disinfection of shared equipment, frequently touched surfaces in resident rooms and common areas.
  - Ensure EPA-registered, hospital-grade disinfectants are available to allow for frequent cleaning of high-touch surfaces and shared resident care equipment.
  - Use an EPA-registered disinfectant from List N:disinfectants for coronavirus (COVID-19) on the EPA website to disinfect surfaces that might be contaminated with SARS-CoV-2. Ensure HCP are appropriately trained on its use and follow the manufacturer's instructions for all cleaning and disinfection products (e.g., concentration, application method, and contact time).

Educate Residents, Healthcare Personnel, and Visitors about SARS-CoV-2, Current Precautions Being Taken in the Facility, and Actions They Should Take to Protect Themselves

- Provide culturally and linguistically tailored information about SARS-CoV-2 infection, including the signs and symptoms that could signal infection.
- Provide information about strategies for managing stress and anxiety.

- Regularly review CDC's Interim Infection Control Recommendations for Healthcare Personnel During the COVID-19 Pandemic for current information and ensure staff and residents are updated when this guidance changes.
- Educate and train HCP, including facility-based and consultant personnel (e.g., rehabilitation therapy, wound care, podiatry, barber), ombudsman, and volunteers who provide care or services in the facility. Including consultants is important since they commonly provide care in multiple facilities where they can be exposed to and serve as a source of SARS-CoV-2.
  - Educate HCP about any new policies or procedures.
  - Reinforce sick leave policies and remind HCP not to report to work when ill.
  - Reinforce adherence to standard IPC measures including hand hygiene and selection and correct use of PPE. Have HCP demonstrate competency with putting on and removing PPE and monitor adherence by observing their resident care activities.
    - CDC has created training resources for front-line staff that can be used to reinforce recommended practices for preventing transmission of SARS-CoV-2 and other pathogens.
- Educate residents and families through educational sessions and written materials on topics including information about SARS-CoV-2, actions the facility is taking to protect them and their loved ones, any visitor restrictions that are in place, and actions they should take to protect themselves in the facility, emphasizing the importance of source control, physical distancing and hand hygiene.
- Have a plan and mechanism to regularly communicate with residents, families and HCP, including if cases of SARS-CoV-2 infection are identified among residents or HCP.

Find the contact information for the healthcare-associated infections program in your state health department as well as your local health department

Notify HCP, residents, and families about outbreaks, and report SARS-CoV-2 infection, facility staffing, testing, and supply information to public health

- Notify the health department promptly about any of the following:
  - ≥ 1 residents or HCP with suspected or confirmed SARS-CoV-2 infection,
  - Resident with severe respiratory infection resulting in hospitalization or death, or≥ 3 residents or HCP with acute illness compatible with COVID-19 with onset within a 72 hour period
- Notify HCP, residents, and families promptly about identification of SARS-CoV-2 in the facility and maintain ongoing, frequent communication with residents, families, and HCP with updates on the situation and facility actions.
- Report SARS-CoV-2 infections, facility staffing and supply information, and point of care testing data to the National Healthcare Safety Network (NHSN) Long-term Care Facility (LTCF) COVID-19 Module weekly. CDC's NHSN provides long-term care facilities with a secure reporting platform to track infections and prevention process measures in a systematic way.
  - Weekly data submission to NHSN will meet the Centers for Medicare and Medicaid Services (CMS) COVID-19 reporting requirements

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Vaccinations

Vaccinate Residents and HCP against SARS-CoV-2

- Receiving a COVID-19 vaccination is an important step to prevent getting sick with COVID-19 disease. CDC continues to stress the importance of getting vaccinated when it is offered to you.
- The Long-Term Care Facility Toolkit: Preparing for COVID-19 Vaccination at Your Facility provides resources including information on preparing for vaccination, vaccination safety monitoring and reporting, frequently asked questions, and printable tools.
- Weekly vaccination numbers of nursing home residents and HCP can be reported into the NHSN LTCF Weekly HCP & Resident COVID-19 Vaccination Reporting module.
- Guidance on adjustment to IPC recommendations following vaccination is available in CDC's Updated Healthcare Infection Prevention and Control Recommendations in Response to COVID-19 Vaccination.

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Source Control and Distancing Measures

Implement Source Control Measures

- Source control refers to use of well-fitting cloth masks, facemasks, or respirators to cover a person's mouth and nose to prevent spread of respiratory secretions when they are breathing, talking, sneezing, or coughing. In addition to providing source control, these devices also offer varying levels of protection against exposure to infectious droplets and particles produced by infected people. Fit-tested respirators are most protective for the wearer. Ensuring a proper fit is important to optimize both the source control and protection offered. Because of the potential for asymptomatic and pre-symptomatic transmission, source control measures are recommended for everyone in a healthcare facility, even if they do not have symptoms of COVID-19.
- Residents, if tolerated, should wear a well-fitting form of source control upon arrival and throughout their stay in the facility. Residents may remove their source control when in their rooms but should put it back on when around others (e.g., HCP or visitors enter the room) and whenever they leave their room, including when in common areas or when outside of the facility. More information on options to improve fit is available from CDC.
  - Source control should not be placed on anyone who cannot wear a mask safely, such as someone who has a disability or an underlying medical condition that precludes wearing a mask or who has trouble breathing, or anyone who is unconscious, incapacitated, or otherwise unable to remove the mask without assistance.
- For additional guidance on recommended source control for HCP, refer to section: Implement Universal Use of Personal Protective Equipment below.
  - HCP should wear well-fitting source control at all times while they are in the healthcare facility, including in breakrooms or other spaces where they might encounter co-workers.
  - To reduce the number of times HCP must touch their face and potential risk for self-contamination, HCP should consider continuing to wear the same respirator or well-fitting facemask throughout their entire work shift when the respirator or facemask is used for source control.
  - HCP should remove their respirator or facemask, perform hand hygiene, and put on their community source control (i.e., mask), when leaving the facility at the end of their shift.
- Visitors and others who enter the facility (e.g., contractors, people making deliveries), if permitted into the facility, should wear a well-fitting form of source control while in the facility.

Implement Physical Distancing Measures

- Although most care activities require close physical contact between residents and HCP, when possible, maintaining physical distance between people (at least 6 feet) is an important strategy to prevent SARS-CoV-2 transmission.
- Remind HCP to practice physical distancing and wear source control when in break rooms or common areas.
- The following activities can be considered for residents who do not have current suspected or confirmed SARS-CoV-2 infection, including those who have fully recovered, and residents who have not had close contact with a

person with SARS-CoV-2 infection:

- Communal dining and group activities at the facility
  - As activities are occurring in communal spaces and could involve individuals who have not been fully vaccinated, residents should practice physical distancing, wear source control (if tolerated), and perform frequent hand hygiene.
- Social excursions outside the facility
  - Residents and their families should be educated about potential risks of public settings, particularly if they have not been fully vaccinated, and reminded to avoid crowds and poorly ventilated spaces.
  - They should practice physical distancing, wear source control (if tolerated), and perform frequent hand hygiene.
  - Considerations for fully vaccinated residents who are visiting friends or family in a private setting outside the facility are described in the Interim Public Health Recommendations for Fully Vaccinated People
- They should inform the facility if they have close contact with a person with SARS-CoV-2 infection while outside the facility
- Quarantine considerations for residents who leave the facility are described in Create a Plan for Residents who leave the Facility

This guidance summarizes the core infection prevention and control practices for nursing homes during the SARS-CoV-2 pandemic. Some of these recommendations can be modified in response to COVID-19 vaccination. Those modifications, which will be regularly updated, are posted in CDC's Updated Healthcare Infection Prevention and Control Recommendations in Response to COVID-19 Vaccination.

Visitation

Have a Plan for Visitation

- Have a facility plan for managing visitation, including use of restrictions when necessary.
- While facilities are encouraged to facilitate in-person visits whenever possible, the CMS visitation memo describes situations requiring temporary restriction of indoor visitors, except for compassionate care reasons. Please refer to CMS visitation memo, CDC Updated Healthcare IPC Recommendations in Response to COVID-19 Vaccination, as well as your state and local health department for additional guidance.
- Send letters or emails to families reminding them not to visit when ill or if they have had close contact with someone with SARS-CoV-2 infection in the prior 14 days.
- Post signs at the entrances to the facility advising visitors to check-in with the front desk to be assessed for symptoms prior to entry.
- Symptoms of COVID-19
- Fever of 100.0 °F or higher or report feeling feverish
- Close contact to someone with COVID-19 during the prior 14 days
- Undergoing evaluation for COVID-19 (such as pending viral test) due to exposure or close contact to a person with COVID-19
- Diagnosis of COVID-19 in the prior 10 days
- Ask visitors to inform the facility if they develop fever or symptoms consistent with COVID-19 within 14 days of visiting the facility.
- When visitation is restricted:
  - Send letters or emails to families advising them of the restrictions
  - Facilitate and encourage alternative methods for visitation (e.g., video conferencing) and communication with the resident

This guidance summarizes the core infection prevention and control practices for nursing homes during the SARS-CoV-2 pandemic. Some of these recommendations can be modified in response to COVID-19 vaccination. Those modifications, which will be regularly updated, are posted in CDC's Updated Healthcare Infection Prevention and Control Recommendations In Response to COVID-19 Vaccination.

Personal Protective Equipment

Ensure Proper Use and Handling of Personal Protective Equipment

- Facilities should have policies and procedures addressing:
  - Which PPE is required in which situations (e.g., residents with suspected or confirmed SARS-CoV-2 infection, residents placed in quarantine)
  - Recommended sequence for safely donning and doffing PPE
- Any reusable PPE must be properly cleaned, decontaminated, and maintained after and between uses.
- Bundle care activities to minimize the number of HCP entries into a room.
- If PPE shortages are anticipated or exist, implement CDC PPE optimization strategies CDC Strategies for Optimizing the Supply of PPE during Shortages offer a continuum of options for use when PPE supplies are stressed, running low, or exhausted, and are intended to be implemented sequentially (i.e., implementing contingency strategies prior to implementing crisis strategies).
- Additional information is available:
  - Interim Infection Prevention and Control Recommendations for Healthcare Personnel During the Coronavirus Disease 2019 (COVID-19) Pandemic
  - Personal Protective Equipment: Questions and Answers.
  - Summary for Healthcare Facilities: Strategies for Optimizing the Supply of PPE during Shortages | CDC

Implement Universal Use of Personal Protective Equipment

- Transmission from asymptomatic or pre-symptomatic residents with SARS-CoV-2 infection can occur in healthcare settings, particularly in geographic areas with moderate to substantial community transmission.
- The fit of the medical device used to cover the wearer's mouth and nose is a critical factor in the level of source control (preventing exposure of others) and level of the wearer's exposure to infectious particles. Respirators offer the highest level of both source control and protection against inhalation of infectious particles in the air. Facemasks that conform to the wearer's face so that more air moves through the material of the facemask rather than through gaps at the edges are more effective for source control than facemasks with gaps and can also reduce the wearer's exposure to particles in the air. Improving how a facemask fits can increase the facemask's effectiveness for decreasing particles emitted from the wearer and to which the wearer is exposed.
- HCP working in facilities located in areas with moderate to substantial community transmission are more likely to encounter asymptomatic or pre-symptomatic residents with SARS-CoV-2 infection. If SARS-CoV-2 infection is not suspected in a resident (based on symptom and exposure history):
  - HCP should follow Standard Precautions (and Transmission-Based Precautions if required based on the suspected diagnosis; for example, use an N95 respirator or equivalent or higher level respirator if the patient is suspected to have tuberculosis).
  - Additionally, HCP should use PPE as described below:
    - N95 respirators or equivalent or higher-level respirators should be used for
      - All aerosol generating procedures (refer to Which procedures are considered aerosol generating procedures in healthcare settings FAQ)
    - One of the following should be worn by HCP while in the facility and for protection during resident care encounters:
      - A NIOSH-approved N95 respirator OR
      - A respirator approved under standards used in other countries that are similar to NIOSH-approved N95 filtering facepiece respirators OR
      - A well-fitting facemask (e.g., selection of a facemask with a nose wire to help the facemask conform to the face; selection of a facemask with ties rather than ear loops; use of a mask fitter; tying the

facemask's ear loops and tucking in the side pleats; fastening the facemask's ear loops behind the wear's head; use of a cloth mask over the facemask to help it conform to the wearer's face)

- Additional information about strategies to improve fit and filtration are available in Improve the Fit and Increase the Filtration of Your Mask to Reduce the Spread of COVID-19.
- If implementing new strategies or equipment to improve fit, HCP should receive training on how to safely don and doff their facemask and the facility protocol for cleaning and disinfecting any reusable equipment (e.g., fitter). They should also ensure that any new strategies do not impede their vision or ability to breathe.

- Eye protection should be worn during patient care encounters to ensure the eyes are also protected from exposure to respiratory secretions.

- HCP working in areas with minimal to no community transmission should continue to adhere to Standard and Transmission-Based Precautions based on anticipated exposures and suspected or confirmed diagnoses. This might include use of eye protection, an N95 or equivalent or higher-level respirator, as well as other PPE. In addition, universal use of a well-fitting facemask for source control is recommended for HCP if not otherwise wearing a respirator.

Additional considerations for universal use of PPE in facilities where transmission of SARS-CoV-2 is suspected or identified is described in the section: Respond to a Newly Identified SARS-CoV-2-infected Healthcare Personnel or Resident.

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Testing

Create a Plan for Testing Residents and Healthcare Personnel for SARS-CoV-2

- Guidance addressing when to test residents and HCP for SARS-CoV-2 and how to interpret results of antigen tests is available at the following links:
  - Testing Guidelines for Nursing Homes
  - Interim Guidance on Testing Healthcare Personnel for SARS-CoV-2
  - SARS-CoV-2 Antigen Testing in Long Term Care Facilities
- The plan should align with state and federal requirements for testing residents and HCP for SARS-CoV-2 and address:
  - Triggers for performing testing (e.g., a resident or HCP with symptoms consistent with COVID-19, a resident or HCP with SARS-CoV-2 in the facility, routine testing)
  - Access to tests capable of detecting the virus and an arrangement with laboratories to process tests or capacity to conduct and process point-of care tests onsite
  - Process for and capacity to perform SARS-CoV-2 testing of all residents and HCP
  - Training for HCP on how to collect and process specimens correctly, including correct use of PPE
  - A procedure for addressing residents or HCP who decline or are unable to be tested (e.g., maintaining Transmission-Based Precautions until symptom-based criteria are met for a symptomatic resident who refuses testing)
  - A plan to respond to results of the testing prior to initiating testing, for additional information see section: Respond to a Newly Identified SARS-CoV-2-infected Healthcare Personnel or Resident
- Additional information about testing of residents and HCP is available:
  - Performing Broad-Based Testing for SARS-CoV-2 in Congregate Settings, which includes considerations for health departments and nursing homes for facility-wide testing
  - Interim Final Rule (IFC), CMS-3401-IFC, Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency related to Long-Term Care (LTC) Facility Testing Requirements and Revised COVID-19 Focused Survey Tool

This guidance summarizes the core infection prevention and control practices for nursing homes during the SARS-CoV-2 pandemic. Some of these recommendations can be modified in response to COVID-19 vaccination. Those modifications, which will be regularly updated, are posted in CDC's Updated Healthcare Infection Prevention and Control Recommendations in Response to COVID-19 Vaccination.

Evaluating and Managing Personnel and Residents

Evaluate and Manage Healthcare Personnel

- Implement sick leave policies that are non-punitive, flexible, and consistent with public health policies that support HCP to stay home when ill.
- Create an inventory of all volunteers and personnel who provide care in the facility. Use that inventory to determine which personnel are non-essential and whose services can be delayed if such restrictions are necessary to prevent or control transmission.
- Establish a process to ensure HCP (including consultant personnel and ancillary staff such as environmental and dietary services) entering the facility are assessed for symptoms of COVID-19 or close contact outside the facility to others with SARS-CoV-2 infection and that they are practicing source control.
  - Options could include (but are not limited to): individual screening on arrival at the facility; or implementing an electronic monitoring system in which, prior to arrival at the facility, HCP report absence of fever and symptoms of COVID-19, absence of a diagnosis of SARS-CoV-2 infection in the prior 10 days, and confirm they have not had close contact with others with SARS-CoV-2 infection during the prior 14 days.
    - Fever can be either measured temperature ≥100.0°F or subjective fever. People might not notice symptoms of fever at the lower temperature threshold that is used for those entering a healthcare setting, so they should be encouraged to actively take their temperature at home or have their temperature taken upon arrival.
- HCP who report symptoms should be excluded from work and should notify occupational health services to arrange for further evaluation. In addition, asymptomatic HCP who report close contact with others with SARS-CoV-2 infection might need to be excluded from work.
  - If HCP develop fever (Temperature ≥100.0˚F) or symptoms consistent with COVID-19 while at work they should inform their supervisor and leave the workplace.
- Have a plan for how to respond to HCP with SARS-COV-2 infection who worked while ill (e.g., identifying exposed residents and co-workers and initiating an outbreak investigation in the unit or area of the building where they worked).
- Healthcare facilities must be prepared for potential staffing shortages and have plans and processes in place to mitigate these, including providing resources to assist HCP with anxiety and stress. Strategies to mitigate staffing shortages are available.
- Information about when non-essential personnel should have limited entry into facilities can be found in the CMS Re-opening Memo .
- Information about when HCP with suspected or confirmed SARS-CoV-2 infection may return to work is available in the Interim Guidance on Criteria for Return to Work for Healthcare Personnel with Confirmed or Suspected COVID-19.
- Information about risk assessment and work restrictions for HCP exposed to SARS-CoV-2 is available in the Interim U.S. Guidance for Risk Assessment and Work Restrictions for Healthcare Personnel with Potential Exposure to Coronavirus Disease 2019 (COVID-19).

Identify Space in the Facility that Could be Dedicated to Monitor and Care for Residents with Confirmed SARS-CoV-2 Infection

- Determine the location of the COVID-19 care unit and create a staffing plan.
  - Doing this before residents or HCP with SARS-CoV-2 infection are identified in the facility will allow time for residents to be relocated to create space for the unit and to identify HCP to work on this unit.
  - Facilities that have already identified cases of SARS-CoV-2 infection among residents but have not developed a COVID-19 care unit should work to create one unless the proportion of residents with SARS-CoV-2 infection

makes this impossible (e.g., the majority of residents in the facility are already infected).

- The location of the COVID-19 care unit should ideally be physically separated from other rooms or units housing residents without confirmed SARS-CoV-2 infection. This could be a dedicated floor, unit, or wing in the facility or a group of rooms at the end of the unit that will be used to cohort residents with SARS-CoV-2 infection.
- Identify HCP who will be assigned to work only on the COVID-19 care unit when it is in use. At a minimum this should include the primary nursing assistants (NAs) and nurses assigned to care for these residents. If possible, HCP should avoid working on both the COVID-19 care unit and other units during the same shift.
  - To the extent possible, restrict access of ancillary personnel (e.g., dietary) to the unit.
  - Ideally, environmental services (EVS) staff should be dedicated to this unit, but to the extent possible, EVS staff should avoid working on both the COVID-19 care unit and other units during the same shift.
  - To the extent possible, HCP dedicated to the COVID-19 care unit (e.g., NAs and nurses) will also be performing cleaning and disinfection of high-touch surfaces and shared equipment when in the room for resident care activities. HCP should bring an Environmental Protection Agency (EPA)-registered disinfectant (e.g., wipe) from List N into the room and wipe down high-touch surfaces (e.g., light switch, doorknob, bedside table) before leaving the room.
- HCP working on the COVID-19 care unit should have access to a restroom, break room, and work area that are separate from HCP working in other areas of the facility.
  - Ensure HCP practice source control measures and physical distancing in the break room and other common areas (i.e., other than while eating, HCP wear a respirator or source control and sit at least 6 feet apart while on break).
  - Ensure that high-touch surfaces in staff break rooms and work areas are frequently cleaned and disinfected (e.g., each shift).
- CDC PPE optimization strategies should be followed during shortages. Guidance addressing placement, duration, and recommended PPE when caring for residents with SARS-CoV-2 infection is described in Section: Manage Residents with Suspected or Confirmed SARS-CoV-2 infection.

Older adults with SARS-CoV-2 infection may not show common symptoms such as fever or respiratory symptoms. Less common symptoms can include new or worsening malaise, headache, or new dizziness, nausea, vomiting, diarrhea, loss of taste or smell. Additionally, more than two temperatures >99.0˚F might also be a sign of fever in this population. Identification of these symptoms should prompt isolation and further evaluation for SARS-CoV-2 infection.

Evaluate Residents at least Daily

- Ask residents to report if they feel feverish or have symptoms consistent with COVID-19.
- Actively monitor all residents upon admission and at least daily for fever (temperature ≥100.0˚F) and symptoms consistent with COVID-19. Ideally, include an assessment of oxygen saturation via pulse oximetry. If residents have fever or symptoms consistent with COVID-19, implement precautions described in the section: Manage Residents with Suspected or Confirmed SARS-CoV-2 Infection.
  - Refer to CDC resources for performing respiratory infection surveillance in long-term care facilities during an outbreak.
- Information about the clinical presentation and course of patients with SARS-CoV-2 infection is described in the Interim Clinical Guidance for Management of Patients with Confirmed Coronavirus Disease 2019 (COVID-19). CDC has also developed Testing Guidelines for Nursing Homes.

Manage Residents with Suspected or Confirmed SARS-CoV-2 Infection

- Residents with suspected SARS-CoV-2 infection should be prioritized for testing.
- Residents with suspected or confirmed SARS-CoV-2 infection do not need to be placed into an airborne infection isolation room (AIIR) but should be cared for HCP using an N95 or higher-level respirator, eye protection (i.e., goggles or a face shield that covers the front and sides of the face), gloves, and gown.
  - CDC PPE optimization strategies include a hierarchy of strategies to implement when PPE are in short supply or unavailable (e.g., use of a respirator approved under standards used in other countries that are similar to

NIOSH-approved N95 filtering facepiece respirators or a well-fitting facemask when NIOSH-approved N95 or equivalent or higher-level respirators are not available).

- Ideally a resident with suspected SARS-CoV-2 infection should be moved to a single-person room with a private bathroom while test results are pending.
  - In general, it is recommended that the door to the room remain closed to reduce transmission of SARS-CoV-2. This is especially important for residents with suspected or confirmed SARS-CoV-2 infection being cared for outside of the COVID-19 care unit. However, in some circumstances (e.g., memory care units), keeping the door closed may pose resident safety risks and the door might need to remain open. If doors must remain open, work with facility engineers to implement strategies to minimize airflow into the hallway.
- If limited single rooms are available or if numerous residents are simultaneously identified to have known SARS-CoV-2 exposures or symptoms concerning for COVID-19, residents should shelter-in-place at their current location pending return of test results.
- Residents should only be placed in a COVID-19 care unit if they have confirmed SARS-CoV-2 infection.
- Roommates of residents with SARS-CoV-2 infection should be considered exposed and potentially infected and, if at all possible, should not share rooms with other residents while they are in quarantine (i.e., for the 14 days following the date their roommate was moved to the COVID-19 care unit).

- Increase monitoring of residents with suspected or confirmed SARS-CoV-2 infection, including assessment of symptoms, vital signs, oxygen saturation via pulse oximetry, and respiratory exam, to at least 3 times daily to identify and quickly manage serious infection.
- For decisions on removing residents who have had SARS-CoV-2 infection from Transmission-Based Precautions refer to the Interim Guidance for Discontinuation of Transmission-Based Precautions and Disposition of Hospitalized Patients with COVID-19.

If a resident requires a higher level of care or the facility cannot fully implement all recommended infection control precautions, the resident 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.

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Managing Residents with Close Contact

Manage Residents who had Close Contact with Someone with SARS-CoV-2 Infection

- Residents who have had close contact with someone with SARS-CoV-2 infection should be placed in quarantine for 14 days after their exposure.

- Residents in quarantine should be placed in a single-person room. If limited single rooms are available or if numerous residents are simultaneously identified to have known SARS-CoV-2 exposures or symptoms concerning for COVID-19, residents should shelter-in-place at their current location while being monitored for evidence of SARS-CoV-2 infection.
  - Residents should only be placed in a COVID-19 care unit if they have confirmed SARS-CoV-2 infection. Placing a resident without confirmed SARS-CoV-2 infection (i.e., with symptoms concerning for COVID-19 pending testing or with known exposure) in a dedicated COVID-19 care unit could put them at higher risk of exposure to SARS-CoV-2.
- HCP should wear an N95 or higher-level respirator, eye protection (i.e., goggles or a face shield that covers the front and sides of the face), gloves, and gown when caring for these residents.
  - CDC PPE optimization strategies include a hierarchy of strategies to implement when PPE are in short supply or unavailable (e.g., use of a respirator approved under standards used in other countries that are similar to

NIOSH-approved N95 filtering facepiece respirators or a well-fitting facemask when NIOSH-approved N95 or equivalent or higher-level respirators are not available).

- Residents can be transferred out of quarantine if they remain with no fever and without symptoms for 14 days.
  - Alternatives to the 14-day quarantine period are described in the Options to Reduce Quarantine for Contacts of Persons with SARS-CoV-2 Infection Using Symptom Monitoring and Diagnostic Testing. Healthcare facilities could consider these alternatives as a measure to mitigate staffing shortages, space limitations, or PPE supply shortages but, due to the special nature of healthcare settings (e.g., patients at risk for worsening outcomes, critical nature of HCP, challenges with physical distancing), they are not the preferred option. Healthcare facilities should understand that shortening the duration of quarantine might pose additional transmission risk.

Guidance addressing quarantine and testing during an outbreak is described in Section: Respond to a Newly Identified SARS-CoV-2-infected Healthcare Personnel or Resident.

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New Admissions and Residents who Leave the Facility

Create a Plan for Managing New Admissions and Readmissions

- Residents with confirmed SARS-CoV-2 infection who have not met criteria for discontinuation of Transmission-Based Precautions should be placed in the designated COVID-19 care unit.
- In general, all other new admissions and readmissions should be placed in a 14-day quarantine, even if they have a negative test upon admission.
  - Exceptions include residents within 3 months of a SARS-CoV-2 infection and fully vaccinated residents as described in CDC's Updated Healthcare Infection Prevention and Control Recommendations in Response to COVID-19 Vaccination.
  - Facilities located in areas with minimal to no community transmission might elect to use a risk-based approach for determining which residents require quarantine upon admission. Decisions should be based on whether the resident had close contact with someone with SARS-CoV-2 infection while outside the facility and if there was consistent adherence to IPC practices in healthcare settings, during transportation, or in the community prior to admission.

Guidance addressing placement, duration, and recommended PPE when caring for residents in quarantine is described in Section: Manage Residents who have had Close Contact with Someone with SARS-CoV-2 Infection.

Create a Plan for Residents who leave the Facility

- Residents who leave the facility should be reminded to follow all recommended IPC practices including source control, physical distancing, and hand hygiene and to encourage those around them to do the same.
  - Individuals accompanying residents (e.g., transport personnel, family members) should also be educated about these IPC practices and should assist the resident with adherence.
- For residents going to medical appointments, regular communication between the medical facility and the nursing home (in both directions) is essential to help identify residents with potential exposures or symptoms of COVID-19 before they enter the facility so that proper precautions can be implemented.
- In most circumstances, quarantine is not recommended for residents who leave the facility for less than 24 hours (e.g., for medical appointments, community outings with family or friends) and do not have close contact with someone with SARS-CoV-2 infection.
  - Quarantining residents who regularly leave the facility for medical appointments (e.g., dialysis, chemotherapy) would result in indefinite isolation of the resident that likely outweighs any potential benefits

of quarantine.

- Facilities might consider quarantining residents who leave the facility if, based on an assessment of risk, uncertainty exists about their adherence or the adherence of those around them to recommended IPC measures.
- Residents who leave the facility for 24 hours or longer should generally be managed as described in the New Admission and Readmission section.

Guidance addressing placement, duration, and recommended PPE when caring for residents in quarantine is described in Section: Manage Residents who have had Close Contact with Someone with SARS-CoV-2 Infection.

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New Infection in Healthcare Personnel or Resident

Respond to a Newly Identified SARS-CoV-2-infected Healthcare Personnel or Resident

- Because of the high risk of unrecognized infection among residents, a single new case of SARS-CoV-2 infection in any HCP or a nursing home-onset SARS-CoV-2 infection in a resident should be evaluated as a potential outbreak.
  - Consider increasing monitoring of all residents from daily to every shift to more rapidly detect those with new symptoms.
- Implement facility-wide testing along with the following recommended infection prevention precautions:
  - HCP should care for residents using an N95 or higher-level respirator, eye protection (i.e., goggles or a face shield that covers the front and sides of the face), gloves, and gown.
  - Residents should generally be restricted to their rooms and serial SARS-CoV-2 testing performed.
  - Consideration should be given to halting social activities and communal dining; if these activities must continue for uninfected residents, they should be conducted using source control and physical distancing for all participants.
  - Guidance about visitation during facility outbreaks is available from CMS . Residents could leave their rooms to permit visitation; visitors should be informed about the outbreak in order to make informed decisions about visitation.
  - For additional information about visitation, see section: Have a Plan for Visitation and CMS visitation memo .
  - Restrict non-essential HCP for areas where CMS limits indoor visitation .
    - Consider implementing telehealth to offer remote access to healthcare.
- Continue repeat viral testing of all previously negative residents in addition to testing of HCP, generally every 3 days to 7 days, until the testing identifies no new cases of SARS-CoV-2 infection among residents or HCP for a period of at least 14 days since the most recent positive result.
- Recommended precautions should be continued for residents until no new cases of SARS-CoV-2 infection have been identified for at least 14 days.
- The incubation period for SARS-CoV-2 infection can be up to 14 days and the identification of a new case within that period after starting the interventions does not necessarily represent a failure of the interventions implemented to control transmission.

Considerations for Residents and HCP who are within 3 months of prior Infection

- CDC currently recommends that asymptomatic residents who have recovered and are within 3 months of a positive test for SARS-CoV-2 infection may not need to be quarantined or tested following re-exposure to someone with SARS-CoV-2 infection. However, there might be clinical scenarios in which the uncertainty about a prior infection or the durability of the immune response exist, for which providers could consider testing for SARS-CoV-2 and quarantine following exposure that occurs less than 3 months after their initial infection, Examples could include:

- Residents with underlying immunocompromising conditions (e.g., patient after organ transplantation) or who become immune compromised (e.g., receive chemotherapy) in the 3 months following SARS-CoV-2 infection and who might have an increased risk for reinfection. However, data on which specific conditions may lead to higher risk and the magnitude of risk are not available.
- Residents for whom there is concern that their initial diagnosis of SARS-CoV-2 infection might have been based on a false positive test result (e.g., resident was asymptomatic, antigen test positive, and a confirmatory nucleic acid amplification test (NAAT) was not performed).
- Residents for whom there is evidence that they were exposed to a novel SARS-CoV-2 variant (e.g., exposed to a person known to be infected with a novel variant) for which the risk of reinfection might be higher.

CDC continues to actively investigate the frequency of reinfection and the circumstances surrounding these episodes, including the role that new variants might play in reinfection, and will adjust guidance as necessary as more information becomes available.

Definitions

Healthcare Personnel (HCP): HCP refers to all paid and unpaid persons serving in healthcare settings who have the potential for direct or indirect exposure to patients or infectious materials, including body substances (e.g., blood, tissue, and specific body fluids); contaminated medical supplies, devices, and equipment; contaminated environmental surfaces; or contaminated air. HCP include, but are not limited to, emergency medical service personnel, nurses, nursing assistants, home healthcare personnel, physicians, technicians, therapists, phlebotomists, pharmacists, students and trainees, contractual staff not employed by the healthcare facility, and persons not directly involved in patient care, but who could be exposed to infectious agents that can be transmitted in the healthcare setting (e.g., clerical, dietary, environmental services, laundry, security, engineering and facilities management, administrative, billing, and volunteer personnel).

Healthcare settings: Places where healthcare is delivered and includes, but is not limited to, acute care facilities, long term acute care facilities, inpatient rehabilitation facilities, nursing homes and assisted living facilities, home healthcare, vehicles where healthcare is delivered (e.g., mobile clinics), and outpatient facilities, such as dialysis centers, physician offices, and others.

Source Control: Use of well-fitting cloth masks, facemasks, or respirators to cover a person's mouth and nose to prevent spread of respiratory secretions when they are breathing, talking, sneezing, or coughing. Cloth masks, facemasks, and respirators should not be placed on children under age 2, anyone who cannot wear one safely, such as someone who has a disability or an underlying medical condition that precludes wearing a cloth mask, facemask, or respirator safely, or anyone who is unconscious, incapacitated, or otherwise unable to remove their cloth mask, facemask, or respirator without assistance. Face shields alone are not recommended for source control.

Cloth mask: Textile (cloth) covers that are intended primarily for source control. They are not personal protective equipment (PPE) appropriate for use by healthcare personnel as the degree to which cloth masks protect the wearer is unclear. Guidance on design, use, and maintenance of cloth masks is available.

Facemask: Facemasks are PPE and are often referred to as surgical masks or procedure masks. Use facemasks according to product labelling and local, state, and federal requirements. FDA-cleared surgical masks are designed to protect against splashes and sprays and are prioritized for use when such exposures are anticipated, including surgical procedures. Facemasks that are not regulated by FDA, such as some procedure masks, which are typically used for isolation purposes, may not provide protection against splashes and sprays.

Respirator: A respirator is a personal protective device that is worn on the face, covers at least the nose and mouth, and is used to reduce the wearer's risk of inhaling hazardous airborne particles (including dust particles and infectious agents), gases, or vapors. Respirators are certified by CDC/NIOSH, including those intended for use in healthcare.

Minimal to no community transmission of SARS-CoV-2: Sustained transmission with high likelihood or confirmed exposure within communal settings and potential for rapid increase in cases

Substantial community transmission of SARS-CoV-2: Large scale community transmission, including communal settings (e.g., schools, workplaces)

Close Contact: Someone who was within 6 feet of an infected person for a cumulative total of 15 minutes or more over a 24-hour period* starting from 2 days before illness onset (or, for asymptomatic patients, 2 days prior to test specimen collection) until the time the patient is isolated.

*Individual exposures added together over a 24-hour period (e.g., three 5-minute exposures for a total of 15 minutes). Data are limited, making it difficult to precisely define "close contact;" however, 15 cumulative minutes of exposure at a distance of 6 feet or less can be used as an operational definition for contact investigation. Factors to consider when defining close contact include proximity (closer distance likely increases exposure risk), the duration of exposure (longer exposure time likely increases exposure risk), whether the infected individual has symptoms (the period around onset of symptoms is associated with the highest levels of viral shedding), if the infected person was likely to generate respiratory aerosols (e.g., was coughing, singing, shouting), and other environmental factors (crowding, adequacy of ventilation, whether exposure was indoors or outdoors). Because the general public has not received training on proper selection and use of respiratory PPE, such as an N95, the determination of close contact should generally be made irrespective of whether the contact was wearing respiratory PPE. At this time, differential determination of close contact for those using fabric face coverings is not recommended.

- Information about risk assessment and work restrictions for HCP exposed to SARS-CoV-2 is available in the Interim U.S. Guidance for Risk Assessment and Work Restrictions for Healthcare Personnel with Potential Exposure to Coronavirus Disease 2019 (COVID-19).
- Risk assessment considerations for residents who are exposed in a healthcare setting is available in the FAQs for Infection Control

More Information

Considerations for Memory Care Units in Long-Term Care Facilities

Infection Prevention and Control Assessment Tool for Nursing Homes Preparing for COVID-19

Long-Term Care Facility Toolkit: Preparing for COVID-19 Vaccination at Your Facility

NHSN LTCF Weekly HCP & Resident COVID-19 Vaccination Reporting

Updated Healthcare Infection Prevention and Control Recommendations in Response to COVID-19 Vaccination

Sample Notification Letter to Residents and Families: COVID-19 Transmission Identified PDF | DOC

Long-term Care Facility Letter to Residents, Families, Friends and Volunteers

CMS Emergency Preparedness & Response Operations

Supporting Your Loved One in a Long-Term Care Facility [472 KB, 1 page]

Infection Prevention Success Stories

Applying COVID-19 Infection Prevention and Control Strategies in Nursing Homes (Recorded Webinar)

COVID-19 Data Tracker Integrated County View

References

- Interim Infection Prevention and Control Recommendations for Healthcare Personnel During the Coronavirus Disease 2019 (COVID-19) Pandemic
- Council of State and Territorial Epidemiologists (CSTE) Proposed Investigation/Reporting Thresholds and Outbreak Definitions for COVID-19 in Healthcare Settings
- CMS Nursing Home Reopening Guidance for State and Local Officials Memorandum
- CMS Nursing Home Visitation COVID-19 Memorandum
- OSHA PPE standards (29 CFR 1910 Subpart I)
- Optimizing Supply of PPE and Other Equipment during Shortages
- Improve the Fit and Filtration of Your Mask to Reduce the Spread of COVID-19

- Testing Guidelines for Nursing Homes
- Interim Guidance on Testing Healthcare Personnel for SARS-CoV-2
- SARS-CoV-2 Antigen Testing in Long Term Care Facilities
- Performing Broad-Based Testing for SARS-CoV-2 in Congregate Settings
- Return to Work Criteria for Healthcare Personnel with SARS-CoV-2 Infection (Interim Guidance)
- Interim U.S. Guidance for Risk Assessment and Work Restrictions for Healthcare Personnel with Potential Exposure to SARS-CoV-2
- Strategies to Mitigate Healthcare Personnel Staffing Shortages
- Interim Clinical Guidance for Management of Patients with Confirmed Coronavirus Disease 2019 (COVID-19)
- Discontinuation of Transmission-Based Precautions and Disposition of Patients with SARS-COV-2 Infection in Healthcare Settings
- Options to Reduce Quarantine for Contacts of Persons with SARS-CoV-2 Infection Using Symptom Monitoring and Diagnostic Testing

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CENTERS FOR MEDICARE & MEDICAID SERVICES

Center for Clinical Standards and Quality/Survey & Certification Group

Ref: QSO-20-38-NH

DATE: **August 26, 2020** ***REVISED 04/27/2021***

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: **Interim Final Rule (IFC), CMS-3401-IFC, Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency related to Long-Term Care (LTC) Facility Testing Requirements and Revised COVID-19 Focused Survey Tool**

Memorandum Summary

- CMS is committed to taking critical steps to ensure America's healthcare facilities continue to respond effectively to the Coronavirus Disease 2019 (COVID-19) Public Health Emergency (PHE).
- On August 25, 2020, CMS published an interim final rule with comment period (IFC). This rule establishes **Long-Term Care (LTC) Facility Testing Requirements for Staff and Residents.** Specifically, facilities are required to test residents and staff, including individuals providing services under arrangement and volunteers, for COVID-19 based on parameters set forth by the HHS Secretary. This memorandum provides guidance for facilities to meet the new requirements.
- **Revised COVID-19 Focused Survey Tool** - To assess compliance with the new testing requirements, CMS has revised the survey tool for surveyors. We are also adding to the survey process the assessment of compliance with the requirements for facilities to designate one or more individual(s) as the infection preventionist(s) (IPs) who are responsible for the facility's infection prevention and control program (IPCP) at 42 CFR § 483.80(b). In addition, we are making a number of revisions to the survey tool to reflect other COVID-19 guidance updates.

On August 25, 2020, CMS published an interim final rule with comment period (IFC), CMS-3401-IFC, entitled "Medicare and Medicaid Programs, Clinical Laboratory Improvement Amendments of 1988 (CLIA), and Patient Protection and Affordable Care Act; Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency". CMS's recommendation below to test with authorized nucleic acid or antigen detection assays is an important addition to other infection prevention and control (IPC) recommendations aimed at preventing COVID-19 from entering nursing homes, detecting cases quickly, and stopping transmission. Swift identification of confirmed COVID-19 cases allows the facility to take immediate action to remove exposure risks to nursing home residents and staff. CMS has added

42 CFR § 483.80(h) which requires that the facility test all residents and staff for COVID-19. Guidance related to the requirements is located below. Noncompliance related to this new requirement will be cited at new tag F886.

§ 483.80 Infection control

* * * * *

§ 483.80(h) *COVID-19 Testing*. The LTC facility must test residents and facility staff, including individuals providing services under arrangement and volunteers, for COVID-19. At a minimum, for all residents and facility staff, including individuals providing services under arrangement and volunteers, the LTC facility must:

(1) Conduct testing based on parameters set forth by the Secretary, including but not limited to:

(i) Testing frequency;

(ii) The identification of any individual specified in this paragraph diagnosed with COVID-19 in the facility;

(iii) The identification of any individual specified in this paragraph with symptoms consistent with COVID-19 or with known or suspected exposure to COVID-19;

(iv) The criteria for conducting testing of asymptomatic individuals specified in this paragraph, such as the positivity rate of COVID-19 in a county;

(v) The response time for test results; and

(vi) Other factors specified by the Secretary that help identify and prevent the transmission of COVID-19.

(2) Conduct testing in a manner that is consistent with current standards of practice for conducting COVID-19 tests;

(3) For each instance of testing:

(i) Document that testing was completed and the results of each staff test; and

(ii) Document in the resident records that testing was offered, completed (as appropriate to the resident's testing status), and the results of each test.

(4) Upon the identification of an individual specified in this paragraph with symptoms consistent with COVID-19, or who tests positive for COVID-19, take actions to prevent the transmission of COVID-19.

(5) Have procedures for addressing residents and staff, including individuals providing services under arrangement and volunteers, who refuse testing or are unable to be tested.

(6) When necessary, such as in emergencies due to testing supply shortages, contact state and local health departments to assist in testing efforts, such as obtaining testing supplies or processing test results.

F886

DEFINITIONS

***"Fully vaccinated"** refers to a person who is ≥2 weeks following receipt of the second dose in a 2-dose series, or ≥2 weeks following receipt of one dose of a single-dose vaccine.*

"Unvaccinated" refers to a person who does not fit the definition of "fully vaccinated," including people whose vaccination status is not known, for the purposes of this guidance.

GUIDANCE

Testing of Nursing Home Staff and Residents

To enhance efforts to keep COVID-19 from entering and spreading through nursing homes, facilities are required to test residents and staff based on parameters and a frequency set forth by the HHS Secretary.

Facilities can meet the testing requirements through the use of rapid point-of-care (POC) diagnostic testing devices or through an arrangement with an offsite laboratory. POC Testing is diagnostic testing that is performed at or near the site of resident care. For a facility to conduct these tests with their own staff and equipment (including POC devices provided by the Department of Health and Human Services), the facility must have a CLIA Certificate of Waiver. Information on obtaining a CLIA Certificate of Waiver can be found here.

Facilities without the ability to conduct COVID-19 POC testing should have arrangements with a laboratory to conduct tests to meet these requirements. Laboratories that can quickly process large numbers of tests with rapid reporting of results (e.g., within 48 hours) should be selected to rapidly inform infection prevention initiatives to prevent and limit transmission.

"Facility staff" includes employees, consultants, contractors, volunteers, and caregivers who provide care and services to residents on behalf of the facility, and students in the facility's nurse aide training programs or from affiliated academic institutions. For the purpose of testing "individuals providing services under arrangement and volunteers," facilities should prioritize those individuals who are regularly in the facility (e.g., weekly) and have contact with residents or staff. We note that the facility may have a provision under its arrangement with a vendor or volunteer that requires them to be tested from another source (e.g., their employer or on their own). However, the facility is still required to obtain documentation that the required testing was completed during the timeframe that corresponds to the facility's testing frequency, as described in Table 2 below.

Regardless of the frequency of testing being performed or the facility's COVID-19 status, the facility should continue to screen all staff (each shift), each resident (daily), and all persons entering the facility, such as vendors, volunteers, and visitors, for signs and symptoms of COVID-19.

When prioritizing individuals to be tested, facilities should prioritize individuals with signs and symptoms of COVID-19 first, then perform testing triggered by an outbreak (as specified below).

Table 1: Testing Summary

Testing Trigger	Staff	Residents
Symptomatic individual identified	Staff, *vaccinated and unvaccinated,* with signs and symptoms must be tested	Residents, *vaccinated and unvaccinated,* with signs and symptoms must be tested

Outbreak (Any new case arises in facility)	Test all staff, *vaccinated and unvaccinated,* that previously tested negative until no new cases are identified*	Test all residents, *vaccinated and unvaccinated,* that previously tested negative untilno new cases are identified*
Routine testing	According to Table 2 below	Not recommended, unless the resident leaves the facility routinely.

*For outbreak testing, all staff and residents should be tested, *regardless of vaccination status,* and all staff and residents that tested negative should be retested every 3 days to 7 days until testing identifies no new cases of COVID-19 infection among staff or residents for a period of at least 14 days since the most recent positive result. For more information, please review the section below titled, "Testing of Staff and Residents in Response to an Outbreak."

Testing of Staff and Residents with COVID-19 Symptoms or Signs

Staff with symptoms or signs of COVID-19, *vaccinated or not vaccinated,* must be tested *immediately* and are expected to be restricted from the facility pending the results of COVID-19 testing. If COVID-19 is confirmed, staff should follow Centers for Disease Control and Prevention (CDC) guidelines "Criteria for Return to Work for Healthcare Personnel with SARS-CoV2 Infection." Staff who do not test positive for COVID-19 but have symptoms should follow facility policies to determine when they can return to work.

Residents who have signs or symptoms of COVID-19, *vaccinated or not vaccinated,* must be tested *immediately*. While test results are pending, residents with signs or symptoms should be placed on transmission-based precautions (TBP) in accordance with CDC guidance. Once test results are obtained, the facility must take the appropriate actions based on the results.

Note: Concerns related to initiating and/or maintaining TBP should be investigated under F880, Infection Control.

Testing of Staff and Residents with an Exposure

For information on testing staff and resident who may have been exposed to COVID-19, see the CDC's Updated Healthcare Infection Prevention and Control Recommendations in Response to COVID-19 Vaccination.

Testing of Staff and Residents in Response to an Outbreak

An outbreak is defined as a new COVID-19 infection in any healthcare personnel (HCP) or any nursing home-onset COVID-19 infection in a resident. In an outbreak investigation, rapid identification and isolation of new cases is critical in stopping further viral transmission. A resident who is admitted to the facility with COVID-19 does not constitute a facility outbreak.

Upon identification of a single new case of COVID-19 infection in any staff or residents, all staff and residents, *regardless of vaccination status,* should be tested *immediately*, and all staff and residents that tested negative should be retested every 3 days to 7 days until testing identifies no new cases of COVID-19 infection among staff or residents for a period of at least 14 days since the most recent positive result. See CDC guidance "Testing Guidelines for Nursing Homes" section Non-diagnostic testing of asymptomatic residents without known or suspected exposure to an individual infected with SARS-CoV-2.

For individuals who test positive for COVID-19, repeat testing is not recommended. A symptom-based strategy is intended to replace the need for repeated testing. Facilities should follow the CDC guidance Discontinuation of Transmission-Based Precautions and Disposition of Patients with SARS-CoV-2 Infection in Healthcare Settings for residents and Criteria for Return to Work for Healthcare Personnel with SARS-CoV2 Infection.

Routine Testing of Staff

Routine testing *of unvaccinated staff* should be based on the extent of the virus in the community. *Fully vaccinated staff do not have to be routinely tested.* Facilities should use their county positivity rate in the prior week as the trigger for staff testing frequency. Reports of COVID-19 county-level positivity rates *are* available on the following website (see section titled, "COVID-19 Testing"): https://data.cms.gov/stories/s/COVID-19-Nursing-Home-Data/bkwz-xpvg

Table 2: Routine Testing Intervals Vary by Community COVID-19 Activity Level

Community COVID-19 Activity	County Positivity Rate in the past week	Minimum Testing Frequency *of Unvaccinated Staff*[+]
Low	<5%	Once a month
Medium	5% - 10%	Once a week*
High	>10%	Twice a week*

[+] *Vaccinated staff do not need be routinely tested.*

***This frequency presumes availability of Point of Care testing on-site at the nursing home or where off-site testing turnaround time is <48 hours.**

If the 48-hour turn-around time cannot be met due to community testing supply shortages, limited access or inability of laboratories to process tests within 48 hours, the facility should have documentation of its efforts to obtain quick turnaround test results with the identified laboratory or laboratories and contact with the local and state health departments.

The facility should *test* all *unvaccinated* staff at the frequency prescribed in the Routine Testing table based on the county positivity rate reported in the past week. Facilities should monitor their county positivity rate every other week (e.g., first and third Monday of every month) and adjust the frequency of performing staff testing according to the table above.

- If the county positivity rate increases to a higher level of activity, the facility should begin testing staff at the frequency shown in the table above as soon as the criteria for the higher activity are met.
- If the county positivity rate decreases to a lower level of activity, the facility should continue testing staff at the higher frequency level until the county positivity rate has remained at the lower activity level for at least two weeks before reducing testing frequency.

The guidance above represents the minimum testing expected. Facilities may consider other factors, such as the positivity rate in an adjacent (i.e., neighboring) county to test at a frequency that is higher than required. For example, if a facility in a county with low a positivity rate has many staff that live in a county with a medium positivity rate, the facility should consider testing based on the higher positivity rate (in scenario described, weekly staff testing would be indicated).

State and local officials may also direct facilities to monitor other factors that increase the risk for COVID-19 transmission, such as rates of Emergency Department visits of individuals with COVID-19-like symptoms. Facilities should consult with state and local officials on these factors, and the actions that should be taken to reduce the spread of the virus. https://www.cdc.gov/covid-data-tracker/index.html#ed-visits.

NOTE: Routine testing of asymptomatic residents is not recommended unless prompted by a change in circumstances, such as the identification of a confirmed COVID-19 case in the facility. Facilities may consider testing asymptomatic residents who leave the facility frequently, such as for dialysis or chemotherapy. Facilities should inform resident transportation services (such as non-emergency medical transportation) and receiving healthcare providers (such as hospitals) regarding a resident's COVID-19 status to ensure appropriate infection control precautions are followed.

Routine communication between the nursing home and other entities about the resident's status should ideally occur prior to the resident leaving the nursing home for treatment. Coordination between the nursing home and the other healthcare entity is vital to ensure healthcare staff are informed of the most up to date information relating to the resident's health status, including COVID-19 status, and to allow for proper planning of care and operations. Additionally, facilities should maintain communications with the local ambulance and other contracted providers that transport residents between facilities, to ensure appropriate infection control precautions are followed as described by the CDC.

Refusal of Testing

Facilities must have procedures in place to address staff who refuse testing. Procedures should ensure that staff who have signs or symptoms of COVID-19 and refuse testing are prohibited from entering the building until the return to work criteria are met. If outbreak testing has been triggered and a staff member refuses testing, the staff member should be restricted from the building until the procedures for outbreak testing have been completed. The facility should follow its occupational health and local jurisdiction policies with respect to any asymptomatic staff who refuse routine testing.

Residents (or resident representatives) may exercise their right to decline COVID-19 testing in accordance with the requirements under 42 CFR § 483.10(c)(6). In discussing testing with residents, staff should use person-centered approaches when explaining the importance of testing for COVID-19. Facilities must have procedures in place to address residents who refuse testing. Procedures should ensure that residents who have signs or symptoms of COVID-19 and refuse testing are placed on TBP until the criteria for discontinuing TBP have been met. If outbreak testing has been triggered and an asymptomatic resident refuses testing, the facility should be extremely vigilant, such as through additional monitoring, to ensure the resident maintains appropriate distance from other residents, wears a face covering, and practices effective hand hygiene until the procedures for outbreak testing have been completed.

Clinical discussions about testing may include alternative specimen collection sources that may be more acceptable to residents than nasopharyngeal swabs (e.g., anterior nares). Providing information about the method of testing and reason for pursuing testing may facilitate discussions with residents or resident representatives.

If a resident has symptoms consistent with COVID-19 or has been exposed to COVID-19, or if there is a facility outbreak and the resident declines testing, he or she should be placed on or remain on TBP until he or she meets the symptom-based criteria for discontinuation.

Other Testing Considerations

In keeping with current CDC recommendations staff and residents who have recovered from COVID-19 and are asymptomatic do not need to be retested for COVID-19 within 3 months after symptom onset. Until more is known, testing should be encouraged again (e.g., in response to an exposure) 3 months after the date of symptom onset with the prior infection. Facilities should continue to monitor the CDC webpages and FAQs for the latest information. The facility should consult with infectious diseases specialists and public health authorities to review all available information (e.g., medical history, time from initial positive test, Reverse Transcription-Polymerase Chain Reaction Cycle Threshold (RT-PCR Ct) values, and presence of COVID-19 signs or symptoms). Individuals who are determined to be potentially infectious should undergo evaluation and remain isolated until they meet criteria for discontinuation of isolation or discontinuation of transmission-based precautions, depending on their circumstances.

For residents or staff who test positive, facilities should contact the appropriate state or local entity for contact tracing.

While not required, facilities may test residents' visitors to help facilitate visitation while also preventing the spread of COVID-19. Facilities should prioritize resident and staff testing and have adequate testing supplies to meet required testing, prior to testing resident visitors.

Conducting Testing

In accordance with 42 CFR § 483.50(a)(2)(i), the facility must obtain an order from a physician, physician assistant, nurse practitioner, or clinical nurse specialist in accordance with State law, including scope of practice laws to provide or obtain laboratory services for a resident, which includes COVID-19 testing (see F773). This may be accomplished through the use of physician approved policies (e.g., standing orders), or other means as specified by scope of practice laws and facility policy.

NOTE: Concerns related to orders for laboratory and/or POC testing should be investigated under F773.

Rapid POC Testing devices are prescription use tests under the Emergency Use Authorization and must be ordered by a healthcare professional licensed under the applicable state law or a pharmacist under HHS guidance. Accordingly, the facility must have an order from a healthcare professional or pharmacist, as previously described, to perform a rapid POC COVID-19 test on an individual.

Facilities must conduct testing according to nationally recognized guidelines, outlined by the Centers for Disease Control and Prevention (CDC). This would include the following guidelines:

- Interim Infection Prevention and Control Recommendations to Prevent SARS-CoV-2 Spread in Nursing Homes: https://www.cdc.gov/coronavirus/2019-ncov/hcp/long-term-care.html.
- Testing Guidelines for Nursing Homes: https://www.cdc.gov/coronavirus/2019-ncov/hcp/nursing-homes-testing.html.

- Interim Guidance on Testing Healthcare Personnel for SARS-CoV-2: https://www.cdc.gov/coronavirus/2019-ncov/hcp/testing-healthcare-personnel.html.

A diagnostic test shows if a patient has an active coronavirus infection. As of the date of this guidance, there are two types of diagnostic tests which detect the active virus – molecular tests, such as RT-PCR tests, that detect the virus's genetic material, and antigen tests that detect specific proteins on the surface of the virus. An antibody test looks for antibodies that are made by the immune system in response to a threat, such as a specific virus. An antibody test does not identify an active coronavirus infection; therefore, conducting an antibody test on a staff or resident would not meet the requirements under this regulation.

Frequently asked questions related to the use of these testing devices in high-risk congregate settings such as nursing homes can be found here. In addition, when testing residents, a facility's selection of a test should be person-centered.

Collecting and handling specimens correctly and safely is imperative to ensure the accuracy of test results and prevent any unnecessary exposures. The specimen should be collected and, if necessary, stored in accordance with the manufacturer's instructions for use for the test and CDC guidelines.

During specimen collection, facilities must maintain proper infection control and use recommended personal protective equipment (PPE), which includes an N95 or higher-level respirator (or facemask if a respirator is not available), eye protection, gloves, and a gown, when collecting specimens.

The CDC has provided guidance on proper specimen collection:

- Influenza Specimen Collection: https://www.cdc.gov/flu/pdf/professionals/flu-specimen-collection-poster.pdf.
- Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens from Persons for Coronavirus Disease 2019 (COVID-19): (https://www.cdc.gov/coronavirus/2019-ncov/lab/guidelines-clinical-specimens.html).
- CDC's Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with Coronavirus Disease 2019 (COVID-19): https://www.cdc.gov/coronavirus/2019-ncov/lab/lab-biosafety-guidelines.html.

For additional considerations for antigen testing, see CDC's Interim Guidance for Rapid Antigen Testing for SARS-CoV-2.

As a reminder, per 42 CFR § 483.50(a), the facility must provide or obtain laboratory services to meet the needs of its residents. If a facility provides its own laboratory services or performs any laboratory tests directly (e.g., SARS-CoV-2 point-of-care test) the provisions of 42 CFR Part 493 apply and the facility must have a current CLIA certificate appropriate for the level of testing performed within the facility. Surveyors should only verify that the facility has a current CLIA certificate and not attempt to determine compliance with the requirements in 42 CFR Part 493.

Reporting Test Results

Facilities conducting tests under a CLIA certificate of waiver are subject to regulations that require laboratories to report data for all testing completed, for each individual tested. For additional information on reporting requirements see:

- Frequently Asked Questions: COVID-19 Testing at Skilled Nursing Facilities/Nursing Homes
- CMS memorandum: Interim Final Rule (IFC). CMS-3401-IFC, Updating Requirements for Reporting of SARS-CoV-2 Test Results by Clinical Laboratory Improvement Amendments of 1988 (CLIA) Laboratories, and Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency

Surveyors should report concerns related to CLIA certificates or laboratory reporting requirements to the CMS Division of Clinical Laboratory Improvement and Quality at LabExcellence@cms.hhs.gov. When reporting concerns include the CLIA number; name and address of laboratory (facility); number of days that results were not reported, if known; and number of results not reported, if known.

In addition to reporting in accordance with CLIA requirements, facilities must continue to report COVID-19 information to the CDC's National Healthcare Safety Network (NHSN), in accordance with 42 CFR § 483.80(g)(1)-(2). See "Interim Final Rule Updating Requirements for Notification of Confirmed and Suspected COVID-19 Cases Among Residents and Staff in Nursing Homes," CMS Memorandum QSO-20-29-NH (May 6, 2020).

NOTE: Concerns related to informing residents, their representatives and families of new or suspected cases of COVID-19 should be investigated under F885.

NOTE: Concerns related to the reporting to state and local public health authority of communicable diseases and outbreaks, including for purposes such as contact tracing, should be investigated under F880.

Documentation of Testing

Facilities must demonstrate compliance with the testing requirements. To do so, facilities should do the following:

- For symptomatic residents and staff, document the date(s) and time(s) of the identification of signs or symptoms, when testing was conducted, when results were obtained, and the actions the facility took based on the results.
- Upon identification of a new COVID-19 case in the facility (i.e., outbreak), document the date the case was identified, the date that all other residents and staff are tested, the dates that staff and residents who tested negative are retested, and the results of all tests. All residents and staff that tested negative are expected to be retested until testing identifies no new cases of COVID-19 infection among staff or residents for a period of at least 14 days since the most recent positive result (see section Testing of Staff and Residents in response to an outbreak above).
- For staff routine testing, document the facility's county positivity rate, the corresponding testing frequency indicated (e.g., every other week), and the date each positivity rate was collected. Also, document the date(s) that testing was performed for all staff, and the results of each test.
- Document the facility's procedures for addressing residents and staff that refuse testing or are unable to be tested, and document any staff or residents who refused or were unable to be tested and how the facility addressed those cases.

- When necessary, such as in emergencies due to testing supply shortages, document that the facility contacted state and local health departments to assist in testing efforts, such as obtaining testing supplies or processing test results.

Facilities may document the conducting of tests in a variety of ways, such as a log of county positivity rates, schedules of completed testing, and/or staff and resident records. However, the results of tests must be done in accordance with standards for protected health information. For residents, the facility must document testing results in the medical record. For staff, including individuals providing services under arrangement and volunteers, the facility must document testing results in a secure manner consistent with requirements specified in 483.80(h)(3).

Surveying for Compliance

Compliance will be assessed through the following process using the COVID-19 Focused Survey for Nursing Homes:

1. Surveyors will ask for the facility's documentation noted in the "Documentation of Testing" section above, and review the documentation for compliance.
2. Surveyors will also review records of those residents and staff selected as a sample as part of the survey process.
3. If possible, surveyors should observe how the facility conducts testing in real-time. In this process, surveyors will assess if the facility is conducting testing and specimen collection in a manner that is consistent with current standards of practice for conducting COVID-19 tests, such as ensuring PPE is used correctly to prevent the transmission of the virus. If observation is not possible, surveyors should interview an individual responsible for testing and inquire on how testing is conducted (e.g., "what are the steps taken to conduct each test?").
4. If the facility has a shortage of testing supplies, or cannot obtain test results within 48 hours, the surveyor should ask for documentation that the facility contacted state and local health departments to assist with these issues.

Facilities that do not comply with the testing requirements in § 483.80(h) will be cited for noncompliance at F886. Additionally, enforcement remedies (such as civil money penalties) will be imposed based on the resident outcome (i.e., the scope and severity of the noncompliance), in accordance with Chapter 7 of the State Operations Manual.

If the facility has documentation that demonstrates their attempts to perform and/or obtain testing in accordance with these guidelines (e.g., timely contacting state officials, multiple attempts to identify a laboratory that can provide testing results within 48 hours), surveyors should not cite the facility for noncompliance. Surveyors should also inform the state or local health authority of the facility's lack of resources.

CMS is also continuing to assess automated methods for determining compliance with the testing requirements, which may augment the assessment of compliance through onsite surveys.

Additional Resource Links:

- Clinical Questions about COVID-19: Questions and Answers-Testing in Nursing Homes https://www.cdc.gov/coronavirus/2019-ncov/hcp/faq.html#Testing-in-Nursing-Homes
- Nursing Home Reopening Recommendations for State and Local Officials https://www.cms.gov/files/document/qso-20-30-nh.pdf-0

- Discontinuation of Transmission-Based Precautions and Disposition of Patients with COVID-19 in Healthcare Settings
  https://www.cdc.gov/coronavirus/2019-ncov/hcp/disposition-hospitalized-patients.html

COVID-19 Focused Survey for Nursing Homes

CMS revised the COVID-19 Focused Survey for Nursing Homes tool to reflect the new testing requirements implemented in the IFC. *The current Survey/Infection Prevention, Control & Immunization Pathway (CMS-20054) can be found in the LTC Survey Pathways zipfile located at https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/GuidanceforLawsAndRegulations/Downloads/LTC-Survey-Pathways.zip.*

Contact: Questions related to the nursing home testing requirement may be submitted to: DNH_TriageTeam@cms.hhs.gov.

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

/s/
David R. Wright

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Center for Clinical Standards and Quality/Survey & Certification Group

Ref: QSO-20-39-NH

DATE: **September 17, 2020** ***REVISED 04/27/2021***

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Nursing Home Visitation - COVID-19 *(REVISED)*

Memorandum Summary

- CMS is committed to continuing to take critical steps to ensure America's healthcare facilities are prepared to respond to the Coronavirus Disease 2019 (COVID-19) Public Health Emergency (PHE).
- **Visitation Guidance:** CMS is issuing new guidance for visitation in nursing homes during the COVID-19 PHE, including the impact of COVID-19 vaccination.

Background

Nursing homes have been severely impacted by COVID-19, with outbreaks causing high rates of infection, morbidity, and mortality.[1] The vulnerable nature of the nursing home population combined with the inherent risks of congregate living in a healthcare setting have required aggressive efforts to limit COVID-19 exposure and to prevent the spread of COVID-19 within nursing homes.

In March 2020, CMS issued memorandum QSO-20-14-NH providing guidance to facilities on restricting visitation of all visitors and non-essential health care personnel, except for certain compassionate care situations, such as an end-of-life situation. In May 2020, CMS released Nursing Home Reopening Recommendations, which provided additional guidance on visitation for nursing homes as their states and local communities progress through the phases of reopening.

While CMS guidance has focused on protecting nursing home residents from COVID-19, we recognize that physical separation from family and other loved ones has taken a physical and emotional toll on residents and their loved ones. Residents may feel socially isolated, leading to increased risk for depression, anxiety, and other expressions of distress. Residents living with cognitive impairment or other disabilities may find visitor restrictions and other ongoing changes related to COVID-19 confusing or upsetting. CMS understands that nursing home residents derive

[1] Information on outbreaks and deaths in nursing homes may be found at https://data.cms.gov/stories/s/COVID-19-Nursing-Home-Data/bkwz-xpvg.

value from the physical, emotional, and spiritual support they receive through visitation from family and friends. In light of this, CMS is revising the guidance regarding visitation in nursing homes during the COVID-19 PHE. The information contained in this memorandum supersedes and replaces previously issued guidance and recommendations regarding visitation.

Since the release of QSO memorandum 20-39-NH on September 17, 2020, COVID-19 vaccines have received Emergency Use Authorization from the Food and Drug Administration. Millions of vaccinations have since been administered to nursing home residents and staff, and these vaccines have been shown to help prevent symptomatic SARS-CoV-2 infection (i.e., COVID-19). **Therefore, CMS, in conjunction with the Centers for Disease Control and Prevention (CDC), is updating its visitation guidance accordingly, but emphasizing the importance of maintaining infection prevention practices, given the continued risk of COVID-19 transmission.**

Guidance

Visitation can be conducted through different means based on a facility's structure and residents' needs, such as in resident rooms, dedicated visitation spaces, outdoors, and for circumstances beyond compassionate care situations. Regardless of how visits are conducted, there are certain core principles and best practices that reduce the risk of COVID-19 transmission:

Core Principles of COVID-19 Infection Prevention

- Screening ~~of all who enter the facility for signs and symptoms~~ of COVID-19 (e.g., temperature checks, questions about and observations of signs or symptoms), and denial of entry of those with signs or symptoms or those who have had close contact with someone with COVID-19 infection in the prior 14 days (regardless of the visitor's vaccination status)
- Hand hygiene (use of alcohol-based hand rub is preferred)
- Face covering or mask (covering mouth and nose) and social distancing at least six feet between persons, *in accordance with CDC guidance*
- Instructional signage throughout the facility and proper visitor education on COVID-19 signs and symptoms, infection control precautions, other applicable facility practices (e.g., use of face covering or mask, specified entries, exits and routes to designated areas, hand hygiene)
- Cleaning and disinfecting high-frequency touched surfaces in the facility often, and designated visitation areas after each visit
- Appropriate staff use of Personal Protective Equipment (PPE)
- Effective cohorting of residents (e.g., separate areas dedicated to COVID-19 care)
- Resident and staff testing conducted as required at 42 CFR § 483.80(h) (see QSO-20-38-NH Revised)

These core principles are consistent with the Centers for Disease Control and Prevention (CDC) guidance for nursing homes, and should be **adhered to at all times.** Additionally, visitation should be person-centered, consider the residents' physical, mental, and psychosocial well-being, and support their quality of life. The risk of transmission can be further reduced through the use of physical barriers (e.g., clear Plexiglass dividers, curtains). Also, nursing homes should enable visits to be conducted with an adequate degree of privacy. Visitors who are unable to adhere to the core principles of COVID-19 infection prevention should not be permitted to visit or should be asked to leave. By following a person-centered approach and adhering to these core principles,

visitation can occur safely based on the below guidance.

Outdoor Visitation

While taking a person-centered approach and adhering to the core principles of COVID-19 infection prevention, outdoor visitation is preferred even when the resident and visitor are fully vaccinated* against COVID-19. Outdoor visits generally pose a lower risk of transmission due to increased space and airflow. Therefore, visits should be held outdoors whenever practicable. However, weather considerations (e.g., inclement weather, excessively hot or cold temperatures, poor air quality) or an individual resident's health status (e.g., medical condition(s), COVID-19 status, *quarantine status*) may hinder outdoor visits. For outdoor visits, facilities should create accessible and safe outdoor spaces for visitation, such as in courtyards, patios, or parking lots, including the use of tents, if available. When conducting outdoor visitation, all appropriate infection control and prevention practices should be adhered to.

*Fully vaccinated refers to a person who is ≥2 weeks following receipt of the second dose in a 2-dose series, or ≥2 weeks following receipt of one dose of a single-dose vaccine, per the CDC's Public Health Recommendations for Vaccinated Persons.

Indoor Visitation

See the current CDC guidance at Updated Healthcare Infection Prevention and Control Recommendations in Response to COVID-19 Vaccination for information on indoor visitation.

Facilities should allow indoor visitation at all times and for all residents (regardless of vaccination status), except for a few circumstances when visitation should be limited due to a high risk of COVID-19 transmission (note: compassionate care visits should be permitted at all times). These scenarios include limiting indoor visitation for:

- Unvaccinated residents, if the nursing home's COVID-19 county positivity rate is >10% **and** <70% of residents in the facility are fully vaccinated;[2]
- Residents with confirmed COVID-19 infection, whether vaccinated or unvaccinated until they have met the criteria to discontinue Transmission-Based Precautions; *or*
- Residents in quarantine, whether vaccinated or unvaccinated, until they have met criteria for release from quarantine.

Facilities should consider how the number of visitors per resident at one time and the total number of visitors in the facility at one time (based on the size of the building and physical space) may affect the ability to maintain the core principles of infection prevention. If necessary, facilities should consider scheduling visits for a specified length of time to help ensure all residents are able to receive visitors. During indoor visitation, facilities should limit visitor movement in the facility. For example, visitors should not walk around different halls of the facility. Rather, they should go directly to the resident's room or designated visitation area. Visits for residents who share a room should not be conducted in the resident's room, if possible. For situations where there is a roommate and the health status of the resident prevents leaving the room, facilities should attempt to enable in-room visitation while adhering to the core principles of COVID-19 infection prevention.

[2] The county positivity rate refers to the color-coded positivity classification, which can be found on the *COVID-19 Nursing Home Data site*.

NOTE: CMS and CDC continue to recommend facilities, residents, and families adhere to the core principles of COVID-19 infection, including physical distancing (maintaining at least 6 feet between people). This continues to be the safest way to prevent the spread of COVID-19, particularly if either party has not been fully vaccinated. However, we acknowledge the toll that separation and isolation has taken. We also acknowledge that there is no substitute for physical contact, such as the warm embrace between a resident and their loved one. Therefore, if the resident is fully vaccinated, they can choose to have close contact (including touch) with their visitor *in accordance with the CDC's Updated Healthcare Infection Prevention and Control Recommendations in Response to COVID-19 Vaccination. Visitors* should physically distance from other residents and staff in the facility.

Indoor Visitation during an Outbreak

An outbreak exists when a new nursing home onset of COVID-19 occurs (i.e., a new COVID-19 case among residents or staff). This guidance is intended to describe how visitation can still occur when there is an outbreak, but there is evidence that the transmission of COVID-19 is contained to a single area (e.g., unit) of the facility. To swiftly detect cases, we remind facilities to adhere to CMS regulations and guidance for COVID-19 testing, including routine staff testing, testing of individuals with symptoms, and outbreak testing.

When a new case of COVID-19 among residents or staff is identified, a facility should immediately begin outbreak testing and suspend all visitation (except that required under federal disability rights law), until at least one round of facility-wide testing is completed. Visitation can resume based on the following criteria:

- If the first round of outbreak testing reveals **no additional COVID-19 cases in other areas (e.g., units) of the facility**, then visitation can resume for residents in areas/units with no COVID-19 cases. However, the facility should suspend visitation on the affected unit until the facility meets the criteria to discontinue outbreak testing.[3]
    - For example, if the first round of outbreak testing reveals two more COVID-19 cases in the same unit as the original case, but not in other units, visitation can resume for residents in areas/units with no COVID-19 cases.
- If the first round of outbreak testing **reveals one or more additional COVID-19 cases in other areas/units of the facility** (e.g., new cases in two or more units), then facilities should suspend visitation for all residents (vaccinated and unvaccinated), until the facility meets the criteria to discontinue outbreak testing.

While the above scenarios describe how visitation can continue after one round of outbreak testing, facilities should continue all necessary rounds of outbreak testing. In other words, this guidance provides information on how visitation can occur during an outbreak, but does not change any expectations for testing and adherence to infection prevention and control practices. If subsequent rounds of outbreak testing identify **one or more additional COVID-19 cases in other areas/units of the facility**, then facilities should suspend visitation for all residents (vaccinated and unvaccinated), until the facility meets the criteria to discontinue outbreak testing.

NOTE: In all cases, visitors should be notified about the potential for COVID-19 exposure in the facility (e.g., appropriate signage regarding current outbreaks), and adhere to the core principles of

[3] *Outbreak testing is discontinued when testing identifies no new cases of COVID-19 infection among staff or residents for at least 14 days since the most recent positive result. For more information see CMS Memorandum QSO-20-38-NH.*

COVID-19 infection prevention, including effective hand hygiene and use of face-coverings.

We note that compassionate care visits and visits required under federal disability rights law should be **allowed at all times**, for any resident (vaccinated or unvaccinated) regardless of the above scenarios. Lastly, facilities should continue to consult with their state or local health departments when an outbreak is identified to ensure adherence to infection control precautions, and for recommendations to reduce the risk of COVID-19 transmission.

Visitor Testing and Vaccination

While not required, we encourage facilities in medium- or high-positivity counties to offer testing to visitors, if feasible. If so, facilities should prioritize visitors that visit regularly (e.g., weekly), although any visitor can be tested. Facilities may also encourage visitors to be tested on their own prior to coming to the facility (e.g., within 2–3 days). Similarly, we encourage visitors to become vaccinated when they have the opportunity. While visitor testing and vaccination can help prevent the spread of COVID-19, visitors should not be required to be tested or vaccinated (or show proof of such) as a condition of visitation. This also applies to representatives of the Office of the State Long-Term Care Ombudsman and protection and advocacy systems, as described below.

Compassionate Care Visits

While end-of-life situations have been used as examples of compassionate care situations, the term "compassionate care situations" does not exclusively refer to end-of-life situations. Examples of other types of compassionate care situations include, but are not limited to:

- A resident, who was living with their family before recently being admitted to a nursing home, is struggling with the change in environment and lack of physical family support.
- A resident who is grieving after a friend or family member recently passed away.
- A resident who needs cueing and encouragement with eating or drinking, previously provided by family and/or caregiver(s), is experiencing weight loss or dehydration.
- A resident, who used to talk and interact with others, is experiencing emotional distress, seldom speaking, or crying more frequently (when the resident had rarely cried in the past).

Allowing a visit in these situations would be consistent with the intent of, "compassionate care situations." Also, in addition to family members, compassionate care visits can be conducted by any individual that can meet the resident's needs, such as clergy or lay persons offering religious and spiritual support. Furthermore, the above list is not an exhaustive list as there may be other compassionate care situations not included. Compassionate care visits, and visits required under federal disability rights law, should be allowed at all times, regardless of a resident's vaccination status, the county's COVID-19 positivity rate, or an outbreak.

Lastly, visits should be conducted using social distancing; however, if during a compassionate care visit, a visitor and facility identify a way to allow for personal contact, it should only be done following appropriate infection prevention guidelines, and for a limited amount of time. Also, as noted above, if the resident is fully vaccinated, they can choose to have close contact (including touch) with their visitor while wearing a well-fitting face mask and performing hand-hygiene before and after. Regardless, visitors should physically distance from other residents and staff in the facility. Through a person-centered approach, facilities should work with residents, families, caregivers, resident representatives, and the Ombudsman program to identify the need for compassionate care visits.

Required Visitation

Facilities shall not restrict visitation without a reasonable clinical or safety cause, consistent with 42 CFR § 483.10(f) (4) (v). A nursing home **must** facilitate in-person visitation consistent with the applicable CMS regulations, which can be done by applying the guidance stated above. Failure to facilitate visitation, without adequate reason related to clinical necessity or resident safety, would constitute a potential violation of 42 CFR § 483.10(f) (4), and the facility would be subject to citation and enforcement actions.

Residents who are on transmission-based precautions for COVID-19 should only receive visits that are virtual, through windows, or in-person for compassionate care situations, with adherence to transmission-based precautions. However, this restriction should be lifted once transmission-based precautions are no longer required per CDC guidelines, and other visits may be conducted as described above.

Access to the Long-Term Care Ombudsman

As stated in previous CMS guidance QSO-20-28-NH (revised), regulations at 42 CFR § 483.10(f)(4)(i)(C) require that a Medicare and Medicaid- certified nursing home provide representatives of the Office of the State Long-Term Care Ombudsman with immediate access to any resident. During this PHE, in-person access may be limited due to infection control concerns and/or transmission of COVID-19, such as the scenarios stated above for limiting indoor visitation; however, in-person access may not be limited without reasonable cause. We note that representatives of the Office of the Ombudsman should adhere to the core principles of COVID-19 infection prevention as described above. If in-person access is deemed inadvisable (e.g., the Ombudsman has signs or symptoms of COVID-19), facilities must, at a minimum, facilitate alternative resident communication with the ombudsman, such as by phone or through use of other technology. Nursing homes are also required under 42 CFR § 483.10(h)(3)(ii) to allow the Ombudsman to examine the resident's medical, social, and administrative records as otherwise authorized by State law.

Federal Disability Rights Laws and Protection & Advocacy (P&A) Programs

Section 483.10(f)(4)(i)(E) and (F) requires the facility to allow immediate access to a resident by any representative of the protection and advocacy systems, as designated by the state, and as established under the Developmental Disabilities Assistance and Bill of Rights Act of 2000 (DD Act), and of the agency responsible for the protection and advocacy system for individuals with a mental disorder (established under the Protection and Advocacy for Mentally Ill Individuals Act of 2000). P&A programs authorized under the DD Act protect the rights of individuals with developmental and other disabilities and are authorized to "investigate incidents of abuse and neglect of individuals with developmental disabilities if the incidents are reported to the system or if there is probable cause to believe the incidents occurred." 42 U.S.C. § 15043(a)(2)(B). Under its federal authorities, representatives of P&A programs are permitted access to all facility residents, which includes "the opportunity to meet and communicate privately with such individuals regularly, both formally and informally, by telephone, mail and in person." 42 CFR § 51.42(c); 45 CFR § 1326.27.

Additionally, each facility must comply with federal disability rights laws such as Section 504 of the Rehabilitation Act and the Americans with Disabilities Act (ADA).

For example, if a resident requires assistance to ensure effective communication (e.g., a qualified interpreter or someone to facilitate communication) and the assistance is not available by onsite staff or effective communication cannot be provided without such entry (e.g., video remote interpreting), the facility must allow the individual entry into the nursing home to interpret or facilitate, with some exceptions. This would not preclude nursing homes from imposing legitimate safety measures that are necessary for safe operations, such as requiring such individuals to adhere to the core principles of COVID-19 infection prevention. Any questions about or issues related to enforcement or oversight of the non-CMS requirements and citations referenced above under this section subject heading should be referred to the HHS Office for Civil Rights, the Administration for Community Living, or other appropriate oversight agency.

Entry of Healthcare Workers and Other Providers of Services

Health care workers who are not employees of the facility but provide direct care to the facility's residents, such as hospice workers, Emergency Medical Services (EMS) personnel, dialysis technicians, laboratory technicians, radiology technicians, social workers, clergy, etc., must be permitted to come into the facility as long as they are not subject to a work exclusion due to an exposure to COVID-19 or showing signs or symptoms of COVID-19 after being screened. We note that EMS personnel do not need to be screened, so they can attend to an emergency without delay. We remind facilities that all staff, including individuals providing services under arrangement as well as volunteers, should adhere to the core principles of COVID-19 infection prevention and must comply with COVID-19 testing requirements.

We understand that some states or facilities have designated categories of visitors, such as "essential caregivers," based on their visit history or resident designation. CMS does not distinguish between these types of visitors and other visitors. Using a person-centered approach when applying this guidance should cover all types of visitors, including those who have been categorized as "essential caregivers."

Communal Activities and Dining

While adhering to the core principles of COVID-19 infection prevention, communal activities and dining may occur. Book clubs, crafts, movies, exercise, and bingo are all activities that can be facilitated with alterations to adhere to the guidelines for preventing transmission. *The CDC has provided additional guidance on activities and dining based on resident vaccination status. For example, residents who are fully vaccinated may dine and participate in activities without face coverings or social distancing if all participating residents are fully vaccinated; if unvaccinated residents are present during communal dining or activities, then all residents should use face coverings when not eating and unvaccinated residents should physically distance from others. See the CDC guidance Updated Healthcare Infection Prevention and Control Recommendations in Response to COVID-19 Vaccination for information on communal dining and activities.*

Survey Considerations

Federal and state surveyors are not required to be vaccinated and must be permitted entry into facilities unless they exhibit signs or symptoms of COVID-19. Surveyors should also adhere to the core principles of COVID-19 infection prevention, and adhere to any COVID-19 infection prevention requirements set by state law.

- For concerns related to resident communication with and access to persons and services inside and outside the facility, surveyors should investigate for non-compliance at 42

CFR § 483.10(b), F550.

- For concerns related to a facility limiting visitors without a reasonable clinical and safety cause, surveyors should investigate for non-compliance at 42 CFR § 483.10(f)(4), F563.
- For concerns related to ombudsman access to the resident and the resident's medical record, surveyors should investigate for non-compliance at 42 CFR §§ 483.10(f)(4)(i)(C), F562 and 483.10(h)(3)(ii), F583.
- For concerns related to lack of adherence to infection control practices ***including practices for residents and staff based on COVID-19 vaccination status***, surveyors should investigate for non-compliance at 42 CFR § 483.80(a), F880.

Contact: Questions related to this memorandum may be submitted to: DNH_TriageTeam@cms.hhs.gov.

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

/s/
David R. Wright

cc: Survey Operations Group

EXHIBIT
sheet Attachment B
3/17/2020

Health

COVID-19 FACILITY REQUIRMENTS
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 111.1

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 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 Ft^2 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]

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 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	Ft² per person
Inpatient treatment departments	240
Sleeping Departments	120

EXHIBIT
Attachment A

RECEIVED
MAR 12 2020
Secretary of State
Tre Hargett

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

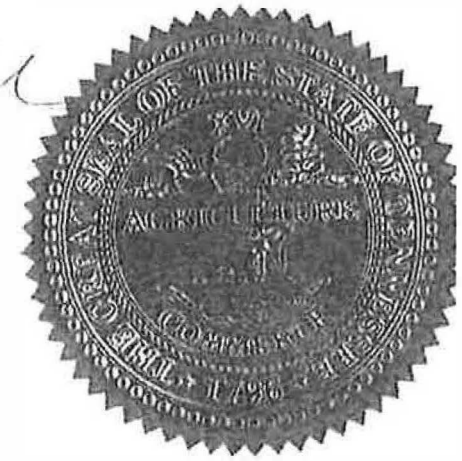

EXHIBIT
Attachment E

TN Health

COVID-19 FACILITY REQUIRMENTS
Temporary Structures

3/17/2020

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 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 Ft^2 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]

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 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	Ft² per person
Inpatient treatment departments	240
Sleeping Departments	120

EXHIBIT
Attachment C

TN Health

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-certificationsurveycertificationgeninfopolicy-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.

Commissioner's Office • Andrew Johnson Tower, 5th Floor • 710 James Robertson Parkway•
Nashville, TN 37243 • Tel: 615-741-3111 • Fax: 615-741-2491 • tn.gov/health

EXHIBIT

Attachment D

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop C2-21-16
Baltimore, Maryland 21244-1850

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

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

Ref: QSO-20-12-All

DATE: **March 4, 2020**

TO: State Survey Agency Directors

FROM: Director
Quality, Safety & Oversight Group

SUBJECT: Suspension of Survey Activities

Memorandum Summary

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

Background

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

Discussion

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

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

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

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

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

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

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

/s/
David R. Wright

Attachment A- Survey Planning in Facilities with Active or Suspected Cases of COVID-19 Cases
Attachment B- Infection Prevention, Control & Immunizations

cc: Survey and Operations Group Management

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

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

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

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

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

II. Focused Surveying – Prioritizing Threats

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

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

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

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

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

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

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

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

I. Before Survey Entry

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

A. Personal Protective Equipment Considerations

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

This guidance indicates, "Respirator use must be in the context of a complete respiratory protection program in accordance with Occupational Safety and Health Administration (OSHA) Respiratory Protection standard 29 CFR 1910.134). Staff should be medically cleared and 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/respiratoryprotection/respirator_basics.html

B. Offsite Planning Considerations

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

II. Onsite Survey Activities

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

Coordinate with the facility on how to gather medical record information, with the goal to conduct as much record review offsite as possible. If the facility has an electronic health record (EHR) system that may be accessed remotely, request remote access to the EHR to review needed records for a limited period of time. If this is not an option, discuss with the facility the best options to get needed medical record information, such as fax, secure website, encrypted email, etc.

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

During onsite observation and investigation, focus on concerns with:

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

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

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

III. Complete Survey Offsite

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

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

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

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

III: Enforcement Activities

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

Infection Prevention, Control & Immunizations

Infection Control: *This facility task must be used to investigate compliance at F880, F881, and F883. For the purpose of this task, "staff" includes employees, consultants, contractors, volunteers, and others who provide care and services to residents on behalf of the facility. The Infection Prevention and Control Program (IPCP) program must be facility-wide and include all departments and contracted services. If a specific care area concern is identified, it should be evaluated under the specific care area, such as for pressure ulcers, respiratory care, catheter care, and medication pass observations which include central lines, peripheral IVs, and oral/IM respiratory medications.*

Coordination:

☐ One surveyor coordinates the facility task to review for:

- The overall Infection Prevention and Control Program (IPCP);
- The annual review of the IPCP policies and practices;
- The review of the surveillance and antibiotic stewardship programs; and
- Tracking influenza/pneumococcal immunization of residents.

☐ Team assignments must be made to include the review of:

- Laundry services;
- A resident on transmission-based precautions, if any;
- Five sampled residents for influenza/pneumococcal immunizations; and
- Other care-specific observations if concerns are identified.

☐ Every surveyor assesses IPCP compliance throughout the survey and communicates any concerns to the team.

Hand Hygiene:

☐ Staff implement standard precautions (e.g., hand hygiene and the appropriate use of personal protective equipment (PPE)).

☐ Appropriate hand hygiene practices are followed.

☐ Alcohol-based hand rub (ABHR) is readily accessible and placed in appropriate locations. These may include:

- Entrances to resident rooms;
- At the bedside (as appropriate for resident population);
- In individual pocket-sized containers by healthcare personnel;
- Staff work stations; and
- Other convenient locations.

☐ Staff wash hands with soap and water when their hands are visibly soiled (e.g., blood, body fluids), or after caring for a resident with known or suspected *C. difficile* infection (CDI) or norovirus during an outbreak, or if endemic rates of CDI are high. ABHR is not appropriate to use under these circumstances.

☐ Staff perform hand hygiene (even if gloves are used) in the following situations:

- Before and after contact with the resident;

- 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;

- 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:

- 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.

Infection Prevention, Control & Immunizations

☐ 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**

EXHIBIT
Attachment E

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop C2-21-16
Baltimore, Maryland 21244-1850

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

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-assesment-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/di-position-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/controrecommendations.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fcoronavirus%2F2019-ncov%2Fhcp%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
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop C2-21-16
Baltimore, Maryland 21244-1850

CENTERS FOR MEDICARE & MEDICAID SERVICES

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 maybe 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

EXHIBIT
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DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
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CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

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 an 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

EXHIBIT
Attachment H

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop C2-21-16
Baltimore, Maryland 21244-1850

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

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/HAN00427.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.

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

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

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) 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.

EXHIBIT
Attachment I

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

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

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-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).

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

EXHIBIT
tabbies Attachment J

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop C2-21-16
Baltimore, Maryland 21244-1850

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

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-assesment-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 maybe 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/hcp/guidance-prevent-spread.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 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

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop C2-21-16
Baltimore, Maryland 21244-1850

CENTERS FOR MEDICARE & MEDICAID SERVICES

Center for Clinical Standards and Quality/Survey & Certification Group

Ref: QSO-20-38-NH

DATE: **August 26, 2020**

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: **Interim Final Rule (IFC), CMS-3401-IFC, Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency related to Long-Term Care (LTC) Facility Testing Requirements and Revised COVID-19 Focused Survey Tool**

Memorandum Summary

- CMS is committed to taking critical steps to ensure America's healthcare facilities continue to respond effectively to the Coronavirus Disease 2019 (COVID-19) Public Health Emergency (PHE).
- On August 25, 2020, CMS published an interim final rule with comment period (IFC). This rule establishes **Long-Term Care (LTC) Facility Testing Requirements for Staff and Residents.** Specifically, facilities are required to test residents and staff, including individuals providing services under arrangement and volunteers, for COVID-19 based on parameters set forth by the HHS Secretary. This memorandum provides guidance for facilities to meet the new requirements.
- **Revised COVID-19 Focused Survey Tool** - To assess compliance with the new testing requirements, CMS has revised the survey tool for surveyors. We are also adding to the survey process the assessment of compliance with the requirements for facilities to designate one or more individual(s) as the infection preventionist(s) (IPs) who are responsible for the facility's infection prevention and control program (IPCP) at 42 CFR § 483.80(b). In addition, we are making a number of revisions to the survey tool to reflect other COVID-19 guidance updates.

On August 25, 2020, CMS published an interim final rule with comment period (IFC), CMS-3401-IFC, entitled "Medicare and Medicaid Programs, Clinical Laboratory Improvement Amendments of 1988 (CLIA), and Patient Protection and Affordable Care Act; Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency". CMS's recommendation below to test with authorized nucleic acid or antigen detection assays is an important addition to other infection prevention and control (IPC) recommendations aimed at preventing COVID-19 from entering nursing homes, detecting cases quickly, and stopping transmission. Swift identification of confirmed COVID-19 cases allows the facility to take immediate action to remove exposure risks to nursing home residents and staff. CMS has added

EXHIBIT
Attachment K

42 CFR § 483.80(h) which requires that the facility test all residents and staff for COVID-19. Guidance related to the requirements is located below. Noncompliance related to this new requirement will be cited at new tag F886.

§ 483.80 Infection control

* * * * *

§ 483.80(h) *COVID-19 Testing.* The LTC facility must test residents and facility staff, including individuals providing services under arrangement and volunteers, for COVID-19. At a minimum, for all residents and facility staff, including individuals providing services under arrangement and volunteers, the LTC facility must:

(1) Conduct testing based on parameters set forth by the Secretary, including but not limited to:

(i) Testing frequency;

(ii) The identification of any individual specified in this paragraph diagnosed with COVID-19 in the facility;

(iii) The identification of any individual specified in this paragraph with symptoms consistent with COVID-19 or with known or suspected exposure to COVID-19;

(iv) The criteria for conducting testing of asymptomatic individuals specified in this paragraph, such as the positivity rate of COVID-19 in a county;

(v) The response time for test results; and

(vi) Other factors specified by the Secretary that help identify and prevent the transmission of COVID-19.

(2) Conduct testing in a manner that is consistent with current standards of practice for conducting COVID-19 tests;

(3) For each instance of testing:

(i) Document that testing was completed and the results of each staff test; and

(ii) Document in the resident records that testing was offered, completed (as appropriate to the resident's testing status), and the results of each test.

(4) Upon the identification of an individual specified in this paragraph with symptoms consistent with COVID-19, or who tests positive for COVID-19, take actions to prevent the transmission of COVID-19.

(5) Have procedures for addressing residents and staff, including individuals providing services under arrangement and volunteers, who refuse testing or are unable to be tested.

(6) When necessary, such as in emergencies due to testing supply shortages, contact state and local health departments to assist in testing efforts, such as obtaining testing supplies or processing test results.

GUIDANCE FOR F886

Testing of Nursing Home Staff and Residents

To enhance efforts to keep COVID-19 from entering and spreading through nursing homes, facilities are required to test residents and staff based on parameters and a frequency set forth by the HHS Secretary.

Facilities can meet the testing requirements through the use of rapid point-of-care (POC) diagnostic testing devices or through an arrangement with an offsite laboratory. POC Testing is diagnostic testing that is performed at or near the site of resident care. For a facility to conduct these tests with their own staff and equipment (including POC devices provided by the Department of Health and Human Services), the facility must have a CLIA Certificate of Waiver. Information on obtaining a CLIA Certificate of Waiver can be found here.

Facilities without the ability to conduct COVID-19 POC testing should have arrangements with a laboratory to conduct tests to meet these requirements. Laboratories that can quickly process large numbers of tests with rapid reporting of results (e.g., within 48 hours) should be selected to rapidly inform infection prevention initiatives to prevent and limit transmission.

"Facility staff" includes employees, consultants, contractors, volunteers, and caregivers who provide care and services to residents on behalf of the facility, and students in the facility's nurse aide training programs or from affiliated academic institutions. For the purpose of testing "individuals providing services under arrangement and volunteers," facilities should prioritize those individuals who are regularly in the facility (e.g., weekly) and have contact with residents or staff. We note that the facility may have a provision under its arrangement with a vendor or volunteer that requires them to be tested from another source (e.g., their employer or on their own). However, the facility is still required to obtain documentation that the required testing was completed during the timeframe that corresponds to the facility's testing frequency, as described in Table 2 below.

Regardless of the frequency of testing being performed or the facility's COVID-19 status, the facility should continue to screen all staff (each shift), each resident (daily), and all persons entering the facility, such as vendors, volunteers, and visitors, for signs and symptoms of COVID-19.

When prioritizing individuals to be tested, facilities should prioritize individuals with signs and symptoms of COVID-19 first, then perform testing triggered by an outbreak (as specified below).

Table 1: Testing Summary

Testing Trigger	Staff	Residents
Symptomatic individual identified	Staff with signs and symptoms must be tested	Residents with signs and symptoms must be tested
Outbreak (Any new case arises in facility)	Test all staff that previously tested negative until no new cases are identified*	Test all residents that previously tested negative untilno new cases are identified*
Routine testing	According to Table 2 below	Not recommended, unless the resident leaves the facility routinely.

*For outbreak testing, all staff and residents should be tested, and all staff and residents that tested negative should be retested every 3 days to 7 days until testing identifies no new cases of

COVID-19 infection among staff or residents for a period of at least 14 days since the most recent positive result. For more information, please review the section below titled, "Testing of Staff and Residents in Response to an Outbreak."

Testing of Staff and Residents with COVID-19 Symptoms or Signs

Staff with symptoms or signs of COVID-19 must be tested and are expected to be restricted from the facility pending the results of COVID-19 testing. If COVID-19 is confirmed, staff should follow Centers for Disease Control and Prevention (CDC) guidelines "Criteria for Return to Work for Healthcare Personnel with SARS-CoV2 Infection." Staff who do not test positive for COVID-19 but have symptoms should follow facility policies to determine when they can return to work.

Residents who have signs or symptoms of COVID-19 must be tested. While test results are pending, residents with signs or symptoms should be placed on transmission-based precautions (TBP) in accordance with CDC guidance. Once test results are obtained, the facility must take the appropriate actions based on the results.

Note: Concerns related to initiating and/or maintaining TBP should be investigated under F880, Infection Control.

Testing of Staff and Residents in Response to an Outbreak

An outbreak is defined as a new COVID-19 infection in any healthcare personnel (HCP) or any nursing home-onset COVID-19 infection in a resident. In an outbreak investigation, rapid identification and isolation of new cases is critical in stopping further viral transmission. A resident who is admitted to the facility with COVID-19 does not constitute a facility outbreak.

Upon identification of a single new case of COVID-19 infection in any staff or residents, all staff and residents should be tested, and all staff and residents that tested negative should be retested every 3 days to 7 days until testing identifies no new cases of COVID-19 infection among staff or residents for a period of at least 14 days since the most recent positive result. See CDC guidance "Testing Guidelines for Nursing Homes" section Non-diagnostic testing of asymptomatic residents without known or suspected exposure to an individual infected with SARS-CoV-2.

For individuals who test positive for COVID-19, repeat testing is not recommended. A symptom-based strategy is intended to replace the need for repeated testing. Facilities should follow the CDC guidance Test-Based Strategy for Discontinuing Transmission-Based PrecautionsDiscontinuing Transmission-Based Precautions for residents and Criteria for Return to Work for Healthcare Personnel with SARS-CoV2 Infection.

Routine Testing of Staff

Routine testing should be based on the extent of the virus in the community, therefore facilities should use their county positivity rate in the prior week as the trigger for staff testing frequency. Reports of COVID-19 county-level positivity rates will be available on the following website by August 28, 2020 (see section titled, "COVID-19 Testing"): https://data.cms.gov/stories/s/COVID-19-Nursing-Home-Data/bkwz-xpvg

Table 2: Routine Testing Intervals Vary by Community COVID-19 Activity Level

Community COVID-19 Activity	County Positivity Rate in the past week	Minimum Testing Frequency
Low	<5%	Once a month
Medium	5% - 10%	Once a week*
High	>10%	Twice a week*

***This frequency presumes availability of Point of Care testing on-site at the nursing home or where off-site testing turnaround time is <48 hours.**

If the 48-hour turn-around time cannot be met due to community testing supply shortages, limited access or inability of laboratories to process tests within 48 hours, the facility should have documentation of its efforts to obtain quick turnaround test results with the identified laboratory or laboratories and contact with the local and state health departments.

The facility should begin testing all staff at the frequency prescribed in the Routine Testing table based on the county positivity rate reported in the past week. Facilities should monitor their county positivity rate every other week (e.g., first and third Monday of every month) and adjust the frequency of performing staff testing according to the table above.

- If the county positivity rate increases to a higher level of activity, the facility should begin testing staff at the frequency shown in the table above as soon as the criteria for the higher activity are met.
- If the county positivity rate decreases to a lower level of activity, the facility should continue testing staff at the higher frequency level until the county positivity rate has remained at the lower activity level for at least two weeks before reducing testing frequency.

The guidance above represents the minimum testing expected. Facilities may consider other factors, such as the positivity rate in an adjacent (i.e., neighboring) county to test at a frequency that is higher than required. For example, if a facility in a county with low a positivity rate has many staff that live in a county with a medium positivity rate, the facility should consider testing based on the higher positivity rate (in scenario described, weekly staff testing would be indicated).

State and local officials may also direct facilities to monitor other factors that increase the risk for COVID-19 transmission, such as rates of Emergency Department visits of individuals with COVID-19-like symptoms. Facilities should consult with state and local officials on these factors, and the actions that should be taken to reduce the spread of the virus. https://www.cdc.gov/covid-data-tracker/index.html#ed-visits.

NOTE: Routine testing of asymptomatic residents is not recommended unless prompted by a change in circumstances, such as the identification of a confirmed COVID-19 case in the facility. Facilities may consider testing asymptomatic residents who leave the facility frequently, such as for dialysis or chemotherapy. Facilities should inform resident transportation services (such as non-emergency medical transportation) and receiving healthcare providers (such as hospitals) regarding a resident's COVID-19 status to ensure appropriate infection control precautions are followed.

Routine communication between the nursing home and other entities about the resident's status should ideally occur prior to the resident leaving the nursing home for treatment. Coordination between the nursing home and the other healthcare entity is vital to ensure healthcare staff are informed of the most up to date information relating to the resident's health status, including COVID-19 status, and to allow for proper planning of care and operations. Additionally, facilities should maintain communications with the local ambulance and other contracted providers that transport residents between facilities, to ensure appropriate infection control precautions are followed as described by the CDC.

Refusal of Testing

Facilities must have procedures in place to address staff who refuse testing. Procedures should ensure that staff who have signs or symptoms of COVID-19 and refuse testing are prohibited from entering the building until the return to work criteria are met. If outbreak testing has been triggered and a staff member refuses testing, the staff member should be restricted from the building until the procedures for outbreak testing have been completed. The facility should follow its occupational health and local jurisdiction policies with respect to any asymptomatic staff who refuse routine testing.

Residents (or resident representatives) may exercise their right to decline COVID-19 testing in accordance with the requirements under 42 CFR § 483.10(c)(6). In discussing testing with residents, staff should use person-centered approaches when explaining the importance of testing for COVID-19. Facilities must have procedures in place to address residents who refuse testing. Procedures should ensure that residents who have signs or symptoms of COVID-19 and refuse testing are placed on TBP until the criteria for discontinuing TBP have been met. If outbreak testing has been triggered and an asymptomatic resident refuses testing, the facility should be extremely vigilant, such as through additional monitoring, to ensure the resident maintains appropriate distance from other residents, wears a face covering, and practices effective hand hygiene until the procedures for outbreak testing have been completed.

Clinical discussions about testing may include alternative specimen collection sources that may be more acceptable to residents than nasopharyngeal swabs (e.g., anterior nares). Providing information about the method of testing and reason for pursuing testing may facilitate discussions with residents or resident representatives.

If a resident has symptoms consistent with COVID-19 or has been exposed to COVID-19, or if there is a facility outbreak and the resident declines testing, he or she should be placed on or remain on TBP until he or she meets the symptom-based criteria for discontinuation.

Other Testing Considerations

In keeping with current CDC recommendations staff and residents who have recovered from COVID-19 and are asymptomatic do not need to be retested for COVID-19 within 3 months after symptom onset. Until more is known, testing should be encouraged again (e.g., in response to an exposure) 3 months after the date of symptom onset with the prior infection. Facilities should continue to monitor the CDC webpages and FAQs for the latest information. The facility should consult with infectious diseases specialists and public health authorities to review all available information (e.g., medical history, time from initial positive test, Reverse Transcription-Polymerase Chain Reaction Cycle Threshold (RT-PCR Ct) values, and presence of COVID-19 signs or symptoms). Individuals who are determined to be potentially infectious

should undergo evaluation and remain isolated until they meet criteria for discontinuation of isolation or discontinuation of transmission-based precautions, depending on their circumstances.

For residents or staff who test positive, facilities should contact the appropriate state or local entity for contact tracing.

While not required, facilities may test residents' visitors to help facilitate visitation while also preventing the spread of COVID-19. Facilities should prioritize resident and staff testing and have adequate testing supplies to meet required testing, prior to testing resident visitors.

Conducting Testing

In accordance with 42 CFR § 483.50(a)(2)(i), the facility must obtain an order from a physician, physician assistant, nurse practitioner, or clinical nurse specialist in accordance with State law, including scope of practice laws to provide or obtain laboratory services for a resident, which includes COVID-19 testing (see F773). This may be accomplished through the use of physician approved policies (e.g., standing orders), or other means as specified by scope of practice laws and facility policy.

NOTE: Concerns related to orders for laboratory and/or POC testing should be investigated under F773.

Rapid POC Testing devices are prescription use tests under the Emergency Use Authorization and must be ordered by a healthcare professional licensed under the applicable state law or a pharmacist under HHS guidance. Accordingly, the facility must have an order from a healthcare professional or pharmacist, as previously described, to perform a rapid POC COVID-19 test on an individual.

Facilities must conduct testing according to nationally recognized guidelines, outlined by the Centers for Disease Control and Prevention (CDC). This would include the following guidelines:

- Preparing for COVID-19 in Nursing Homes: https://www.cdc.gov/coronavirus/2019-ncov/hcp/long-term-care.html.
- Testing Guidelines for Nursing Homes: https://www.cdc.gov/coronavirus/2019-ncov/hcp/nursing-homes-testing.html.
- Performing Facility-wide SARS-CoV-2 Testing in Nursing Homes: https://www.cdc.gov/coronavirus/2019-ncov/hcp/nursing-homes-facility-wide-testing.html.
- Interim Guidance on Testing Healthcare Personnel for SARS-CoV-2: https://www.cdc.gov/coronavirus/2019-ncov/hcp/testing-healthcare-personnel.html.

A diagnostic test shows if a patient has an active coronavirus infection. As of the date of this guidance, there are two types of diagnostic tests which detect the active virus – molecular tests, such as RT-PCR tests, that detect the virus's genetic material, and antigen tests that detect specific proteins on the surface of the virus. An antibody test looks for antibodies that are made by the immune system in response to a threat, such as a specific virus. An antibody test does not identify an active coronavirus infection; therefore, conducting an antibody test on a staff or resident would not meet the requirements under this regulation.

Frequently asked questions related to the use of these testing devices in high-risk congregate

settings such as nursing homes can be found here. In addition, when testing residents, a facility's selection of a test should be person-centered.

Collecting and handling specimens correctly and safely is imperative to ensure the accuracy of test results and prevent any unnecessary exposures. The specimen should be collected and, if necessary, stored in accordance with the manufacturer's instructions for use for the test and CDC guidelines.

During specimen collection, facilities must maintain proper infection control and use recommended personal protective equipment (PPE), which includes an N95 or higher-level respirator (or facemask if a respirator is not available), eye protection, gloves, and a gown, when collecting specimens.

The CDC has provided guidance on proper specimen collection:

- See section "Recommendations for conducting swabbing" under CDC's "Considerations for Performing Facility-wide SARS-CoV-2 Testing in Nursing Homes": https://www.cdc.gov/coronavirus/2019-ncov/hcp/nursing-homes-facility-wide-testing.html.
- Influenza Specimen Collection: https://www.cdc.gov/flu/pdf/professionals/flu-specimen-collection-poster.pdf.
- Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens from Persons for Coronavirus Disease 2019 (COVID-19): (https://www.cdc.gov/coronavirus/2019-ncov/lab/guidelines-clinical-specimens.html).
- CDC's Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with Coronavirus Disease 2019 (COVID-19): https://www.cdc.gov/coronavirus/2019-ncov/lab/lab-biosafety-guidelines.html#decentralized.
- Guidelines for Safe Work Practices in Human and Animal Medical Diagnostic Laboratories: https://www.cdc.gov/coronavirus/2019-ncov/lab/lab-biosafety-guidelines.html.

For additional considerations for antigen testing, see CDC's Interim Guidance for Rapid Antigen Testing for SARS-CoV-2.

As a reminder, per 42 CFR § 483.50(a), the facility must provide or obtain laboratory services to meet the needs of its residents. If a facility provides its own laboratory services or performs any laboratory tests directly (e.g., SARS-CoV-2 point-of-care test) the provisions of 42 CFR Part 493 apply and the facility must have a current CLIA certificate appropriate for the level of testing performed within the facility. Surveyors should only verify that the facility has a current CLIA certificate and not attempt to determine compliance with the requirements in 42 CFR Part 493.

Reporting Test Results

Facilities conducting tests under a CLIA certificate of waiver are subject to regulations that require laboratories to report data for all testing completed, for each individual tested. For additional information on reporting requirements see:

- Frequently Asked Questions: COVID-19 Testing at Skilled Nursing Facilities/Nursing Homes

- CMS memorandum: Interim Final Rule (IFC), CMS-3401-IFC, Updating Requirements for Reporting of SARS-CoV-2 Test Results by Clinical Laboratory Improvement Amendments of 1988 (CLIA) Laboratories, and Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency

Surveyors should report concerns related to CLIA certificates or laboratory reporting requirements to the CMS Division of Clinical Laboratory Improvement and Quality at LabExcellence@cms.hhs.gov. When reporting concerns include the CLIA number; name and address of laboratory (facility); number of days that results were not reported, if known; and number of results not reported, if known.

In addition to reporting in accordance with CLIA requirements, facilities must continue to report COVID-19 information to the CDC's National Healthcare Safety Network (NHSN), in accordance with 42 CFR § 483.80(g)(1)–(2). See "Interim Final Rule Updating Requirements for Notification of Confirmed and Suspected COVID-19 Cases Among Residents and Staff in Nursing Homes," CMS Memorandum QSO-20-29-NH (May 6, 2020).

NOTE: Concerns related to informing residents, their representatives and families of new or suspected cases of COVID-19 should be investigated under F885.

NOTE: Concerns related to the reporting to state and local public health authority of communicable diseases and outbreaks, including for purposes such as contact tracing, should be investigated under F880.

Documentation of Testing

Facilities must demonstrate compliance with the testing requirements. To do so, facilities should do the following:

- For symptomatic residents and staff, document the date(s) and time(s) of the identification of signs or symptoms, when testing was conducted, when results were obtained, and the actions the facility took based on the results.
- Upon identification of a new COVID-19 case in the facility (i.e., outbreak), document the date the case was identified, the date that all other residents and staff are tested, the dates that staff and residents who tested negative are retested, and the results of all tests. All residents and staff that tested negative are expected to be retested until testing identifies no new cases of COVID-19 infection among staff or residents for a period of at least 14 days since the most recent positive result (see section Testing of Staff and Residents in response to an outbreak above).
- For staff routine testing, document the facility's county positivity rate, the corresponding testing frequency indicated (e.g., every other week), and the date each positivity rate was collected. Also, document the date(s) that testing was performed for all staff, and the results of each test.
- Document the facility's procedures for addressing residents and staff that refuse testing or are unable to be tested, and document any staff or residents who refused or were unable to be tested and how the facility addressed those cases.
- When necessary, such as in emergencies due to testing supply shortages, document that the facility contacted state and local health departments to assist in testing efforts, such as obtaining testing supplies or processing test results.

Facilities may document the conducting of tests in a variety of ways, such as a log of county positivity rates, schedules of completed testing, and/or staff and resident records. However, the results of tests must be done in accordance with standards for protected health information. For residents, the facility must document testing results in the medical record. For staff, including individuals providing services under arrangement and volunteers, the facility must document testing results in a secure manner consistent with requirements specified in 483.80(h)(3).

Surveying for Compliance

Compliance will be assessed through the following process using the COVID-19 Focused Survey for Nursing Homes:

1. Surveyors will ask for the facility's documentation noted in the "Documentation of Testing" section above, and review the documentation for compliance.
2. Surveyors will also review records of those residents and staff selected as a sample as part of the survey process.
3. If possible, surveyors should observe how the facility conducts testing in real-time. In this process, surveyors will assess if the facility is conducting testing and specimen collection in a manner that is consistent with current standards of practice for conducting COVID-19 tests, such as ensuring PPE is used correctly to prevent the transmission of the virus. If observation is not possible, surveyors should interview an individual responsible for testing and inquire on how testing is conducted (e.g., "what are the steps taken to conduct each test?").
4. If the facility has a shortage of testing supplies, or cannot obtain test results within 48 hours, the surveyor should ask for documentation that the facility contacted state and local health departments to assist with these issues.

Facilities that do not comply with the testing requirements in § 483.80(h) will be cited for noncompliance at F886. Additionally, enforcement remedies (such as civil money penalties) will be imposed based on the resident outcome (i.e., the scope and severity of the noncompliance), in accordance with Chapter 7 of the State Operations Manual.

If the facility has documentation that demonstrates their attempts to perform and/or obtain testing in accordance with these guidelines (e.g., timely contacting state officials, multiple attempts to identify a laboratory that can provide testing results within 48 hours), surveyors should not cite the facility for noncompliance. Surveyors should also inform the state or local health authority of the facility's lack of resources.

CMS is also continuing to assess automated methods for determining compliance with the testing requirements, which may augment the assessment of compliance through onsite surveys.

Additional Resource Links:

- Clinical Questions about COVID-19: Questions and Answers-Testing in Nursing Homes https://www.cdc.gov/coronavirus/2019-ncov/hcp/faq.html#Testing-in-Nursing-Homes
- Nursing Home Reopening Recommendations for State and Local Officials https://www.cms.gov/files/document/qso-20-30-nh.pdf-0
- Discontinuation of Transmission-Based Precautions and Disposition of Patients with COVID-19 in Healthcare Settings https://www.cdc.gov/coronavirus/2019-ncov/hcp/disposition-hospitalized-patients.html

COVID-19 Focused Survey for Nursing Homes

CMS is revising the COVID-19 Focused Survey for Nursing Homes tool to reflect the new testing requirements implemented in the IFC, as well as other updates to help ensure an effective assessment of the facility's compliance, such as selecting a number of residents as a sample to review the facility's application of the standards on that sample, and that a facility is implementing the appropriate infection prevention standards (e.g., transmission-based precautions, face coverings, etc.). We are also revising the survey process to include the assessment of compliance with the requirements for facilities to designate one or more individuals as the infection preventionist(s) (IPs) who are responsible for the facility's infection prevention and control program at 42 CFR § 483.80(b). Noncompliance related to this requirement will be cited at tag F882.

Contact: Questions related to the nursing home testing requirement may be submitted to: DNH_TriageTeam@cms.hhs.gov.

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

/s/
David R. Wright

Attachments:

COVID-19 Focused Survey for Nursing Homes

COVID-19 Focused Survey for Nursing Homes

Infection Control

This survey tool must be used to investigate compliance at F880, *F882*, F884 (CMS Federal surveyors only), F885, *F886*, and E0024. Surveyors must determine whether the facility is implementing proper infection prevention and control practices to prevent the development and transmission of COVID-19 and other communicable diseases and infections. Entry and screening procedures as well as resident care guidance has varied over the progression of COVID-19 transmission in facilities. Facilities are expected to be in compliance with CMS requirements and surveyors will use guidance that is in effect at the time of the survey. Refer to QSO memos released at: https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Policy-and-Memos-to- States-and-Regions.

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

If citing for noncompliance related to COVID-19, the surveyor(s) must include the following language at the beginning of the Deficient Practice Statement or other place determined appropriate on the Form CMS-2567: "Based on [observations/interviews/record review], the facility failed to [properly prevent and/or contain – or other appropriate statement] **COVID-19**."

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

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

Note: It is imperative that surveyors refer to the most recent information for COVID-19 testing parameters and frequency set forth by the Secretary *described in the guidance for F886. County-level data are available on the CDC website: https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/county-map.html.*

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

COVID-19 Focused Survey for Nursing Homes

Surveyor(s) reviews for:

- The overall effectiveness of the Infection Prevention and Control Program (IPCP) including IPCP policies and procedures;
- Standard and Transmission-Based Precautions *(review care of a resident under observation, suspected of, or confirmed to have COVID-19 infection);*
- Quality of resident care practices, including those *under observation, suspected of, and confirmed to have* COVID-19 *infection*, if applicable;
- The surveillance *and testing* process;
- Visitor entry and facility screening practices;
- Education, monitoring, and screening practices of staff;
- *Actions taken to prevent transmission, such as cohorting and managing care for residents suspected of having or confirmed to have COVID-19;*
- Facility policies and procedures to address staffing issues during emergencies, such as transmission of COVID-19;
- How the facility informs residents, their representatives, and families of suspected or confirmed COVID-19 cases in the facility*; and*
- *The infection preventionist role.*

The survey team will select a random sample of three residents, and if not already sampled, add one additional resident who was confirmed COVID-19 positive or had signs or symptoms consistent with COVID-19, for purposes of determining compliance.

The survey team will select a random sample of three staff, and if not already sampled, add one additional staff who was confirmed COVID-19 positive or had signs or symptoms consistent with COVID-19, for purposes of determining compliance.

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1. Standard and Transmission-Based Precautions (TBPs)

CMS is aware that there is a scarcity of some supplies in certain areas of the country. State and Federal surveyors should not cite facilities for not having certain supplies (e.g., PPE such as gowns, N95 respirators, surgical masks) if they are having difficulty obtaining these supplies for reasons outside of their control. However, we do expect facilities to take actions to mitigate any resource shortages and show they are taking all appropriate steps to obtain the necessary supplies as soon as possible. For example, if there is a shortage of PPE (e.g., due to supplier shortage, which may be a regional or national issue), the facility should contact their healthcare coalition for assistance (https://www.phe.gov/Preparedness/planning/hpp/Pages/find-hc-coalition.aspx), follow national and/or local guidelines for optimizing their current supply, or identify the next best option to care for residents. Among other practices, optimizing their current supply may mean prioritizing use of gowns based on risk of exposure to infectious organisms, blood or body fluids, splashes or sprays, high contact procedures, or aerosol generating procedures (AGPs), as well as possibly extending use of PPE (follow national and/or local guidelines). Current CDC

guidance for healthcare professionals is located at: https://www.cdc.gov/coronavirus/2019-nCoV/hcp/index.html and healthcare facilities is located at: *https://www.cdc.gov/coronavirus/2019-ncov/hcp/us-healthcare-facilities.html*. Guidance on strategies for optimizing PPE supply is located at: https://www.cdc.gov/coronavirus/2019-ncov/hcp/ppe-strategy/index.html. If a surveyor believes a facility should be cited for not having or providing the necessary supplies, the State Agency should contact the CMS Regional Location.

General Standard Precautions:

☐ Are staff performing the following appropriately:

- Respiratory hygiene/cough etiquette,
- Environmental cleaning and disinfection, and
- Reprocessing of reusable resident medical equipment (e.g., cleaning and disinfection of glucometers per device and disinfectant manufacturer's instructions for use)?

Hand Hygiene:

☐ Are staff performing hand hygiene when indicated?

☐ If alcohol-based hand rub (ABHR) is available, is it readily accessible and preferentially used by staff for hand hygiene?

☐ If there are shortages of ABHR, are staff performing hand hygiene using soap and water instead?

☐ Are staff washing hands with soap and water when their hands are visibly soiled (e.g., blood, body fluids)?

☐ Do staff perform hand hygiene (even if gloves are used) in the following situations:

- Before and after contact with the resident;
- After contact with blood, body fluids, or visibly contaminated surfaces;
- After contact with objects and surfaces in the resident's environment;
- After removing personal protective equipment (e.g., gloves, gown, facemask); and
- Before performing a procedure such as an aseptic task (e.g., insertion of an invasive device such as a urinary catheter, manipulation of a central venous catheter, and/or dressing care)?

☐ When being assisted by staff, is resident hand hygiene performed after toileting and before meals? *How are residents reminded to perform hand hygiene?*

☐ Interview appropriate staff to determine if hand hygiene supplies (e.g., ABHR, soap, paper towels) are readily available and who they contact for replacement supplies.

Personal Protective Equipment (PPE):

☐ Determine if staff appropriately use PPE including, but not limited to, the following:

- Gloves are worn if potential contact with blood or body fluid, mucous membranes, or non-intact skin;
- Gloves are removed after contact with blood or body fluids, mucous membranes, or non-intact skin;
- Gloves are changed and hand hygiene is performed before moving from a contaminated body site to a clean body site during resident care; and
- An isolation gown, *eye protection (e.g. goggles or face shield), and an N95 or equivalent or higher-level respirator are* worn for direct resident contact if the resident has uncontained secretions or excretions *including splashes or sprays.*

☐ Is PPE appropriately removed and discarded after resident care, prior to leaving room (except in the case of extended use of PPE per national/local recommendations), followed by hand hygiene?

☐ If PPE use is extended/reused, is it done according to national and/or local guidelines? If it is reused, is it cleaned/decontaminated/maintained after and/or between uses?

☐ Interview appropriate staff to determine if PPE is available, accessible, and used by staff.

- Are there sufficient PPE supplies available to follow infection prevention and control guidelines? In the event of PPE shortages, what actions is the facility taking to address this issue?
- Do staff know how to obtain PPE supplies before providing care?
- Do they know who to contact for replacement supplies?

☐ *Are all staff wearing a facemask (e.g., a cloth face covering can be used by staff where PPE is not indicated, such as administrative staff who are not at risk of coming in contact with infectious materials)?*

☐ *When COVID-19 is present in the facility, are staff wearing an N95 or equivalent or higher-level respirator, instead of a facemask, for aerosol generating procedures?*

Source Control:

☐ *Are residents, visitors, and others at the facility donning a cloth face covering or facemask while in the facility or while around others outside?*

Transmission-Based Precautions (Note: PPE use is based on availability and latest CDC guidance. See note on Pages 1-2):

☐ Determine if appropriate Transmission-Based Precautions are implemented:

- For a resident on Contact Precautions: staff don gloves and isolation gown before contact with the resident and/or his/her environment;
- For a resident on Droplet Precautions: staff don a facemask within six feet of a resident;
- For a resident on Airborne Precautions: staff don an N95 or higher-level respirator prior to room entry of a resident;

- For a resident with an undiagnosed respiratory infection: staff follow Standard, Contact, and Droplet Precautions (i.e., facemask, gloves, isolation gown) with eye protection when caring for a resident unless the suspected diagnosis requires Airborne Precautions (e.g., tuberculosis);
- For a resident with known or suspected COVID-19: staff wear gloves, isolation gown, eye protection and an N95 or higher-level respirator if available. A facemask is an acceptable alternative if a respirator is not available. When COVID-19 is identified in the facility, staff wear all recommended PPE (i.e., gloves, gown, eye protection and respirator or facemask) for the care of all residents on the unit (or facility-wide based on the location of affected residents), regardless of symptoms (based on availability).
    - Some procedures performed on residents with known or suspected COVID-19 could generate infectious aerosols (i.e., aerosol-generating procedures (AGPs)). In particular, procedures that are likely to induce coughing (e.g., sputum induction, open suctioning of airways) should be performed cautiously. If performed, the following should occur:
        - Staff in the room should wear an N95 or higher-level respirator, eye protection, gloves, and an isolation gown.
        - The number of staff present during the procedure should be limited to only those essential for resident care and procedure support.
        - AGPs should ideally take place in an airborne infection isolation room (AIIR). If an AIIR is not available and the procedure is medically necessary, then it should take place in a private room with the door closed.
        - Clean and disinfect the room surfaces with *an* appropriate disinfectant. Use disinfectants on List N of the EPA website that have qualified under EPA's emerging viral pathogens program for use against SARS-CoV-2 or other national recommendations.
- Dedicated or disposable noncritical resident-care equipment (e.g., blood pressure cuffs, blood glucose monitor equipment) is used, or if not available, then equipment is cleaned and disinfected according to manufacturers' instructions using an EPA-registered disinfectant for healthcare setting *(effective against the identified organism if known)* prior to use on another resident;
- Objects and environmental surfaces that are touched frequently and in close proximity to the resident (e.g., bed rails, over-bed table, bedside commode, lavatory surfaces in resident bathrooms) are cleaned and disinfected with an EPA-registered disinfectant for healthcare setting (effective against the organism identified if known) at least daily and when visibly soiled; and
- Is signage on the use of specific PPE (for staff) posted in appropriate locations in the facility (e.g., outside of a resident's room, wing, or facility-wide)?

☐ Interview appropriate staff to determine if they are aware of processes/protocols for Transmission-Based Precautions and how staff is monitored for compliance.

☐ *Observe staff to determine if they use appropriate infection control precautions when moving between resident rooms, units and other areas of the facility.*

☐ If concerns are identified, expand the sample to include more residents on Transmission-Based Precautions.

COVID-19 Focused Survey for Nursing Homes

1. Did staff implement appropriate Standard (e.g., hand hygiene, appropriate use of PPE, environmental cleaning and disinfection, and reprocessing of reusable resident medical equipment) and Transmission-Based Precautions (if applicable)? ☐ **Yes** ☐ **No F880**

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2. Resident Care

☐ *Are residents on Transmission-Based Precautions restricted* to their rooms except for medically necessary purposes? If these residents have to leave their room, are they wearing a facemask *or cloth face covering*, performing hand hygiene, limiting their movement in the facility, and performing social distancing (efforts are made to keep them at least 6 feet away from others)?

☐ *When residents not on Transmission-Based Precautions are outside of their room,are they wearing a cloth face covering or facemask as part of source control? If a cloth face covering or facemask is not tolerated, does the resident cover his/her mouth and nose with tissues and is reminded or assisted to perform hand hygiene? Is at least 6 feet maintained between residents?*

☐ *Is* the facility *ensuring only COVID-19 negative residents* and those not suspected or under observation for COVID-19 *are participating in group outings (e.g., if in phase 2 or 3 of CMS' OSO-20-30-NH- "Nursing Home Reopening Recommendations for State and Local Officials"), group activities, and communal dining following State and local official guidance if more restrictive? Is the facility ensuring that residents are maintaining social distancing (e.g., limited number of people in areas and spaced by at least 6 feet), performing hand hygiene, and wearing cloth face coverings?*

☐ *Does the facility have a plan (including appropriate placement and PPE use) to manage residents that are new/readmissions under observation, those exposed to COVID-19, and those suspected of COVID-19? Are these actions based on national (e.g., CDC), state, or local public health authority recommendations?*

☐ *Does* the facility *have a plan to prevent transmission, such as having a dedicated space in the facility for cohorting and managing care for residents with COVID-19? Are these* actions based on national (e.g., CDC), state, or local public health authority recommendations?

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

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

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

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3. IPCP Standards, Policies and Procedures

☐ Did the facility establish a facility-wide IPCP including standards, policies, and procedures that are current and based on national standards for undiagnosed respiratory illness and COVID-19?

☐ Do the facility's policies or procedures include when to notify local/state public health officials if there are clusters of respiratory illness or cases of COVID-19 that are identified or suspected?

☐ Concerns must be corroborated as applicable including the review of pertinent policies/procedures as necessary.

3. Does the facility have a facility-wide IPCP including standards, policies, and procedures that are current and based on national standards for undiagnosed respiratory illness and COVID-19? ☐ Yes ☐ **No F880**

4. Infection Surveillance

☐ How many residents and staff in the facility have fever, respiratory signs/symptoms, or other signs/symptoms related to COVID-19?

☐ How many residents and staff have been diagnosed with COVID-19, and when was the first case confirmed?

☐ How has the facility established/implemented a surveillance plan, based on a facility assessment, for identifying (i.e., screening), tracking, monitoring and/or reporting of fever, respiratory illness, and/or other signs/symptoms of COVID-19, and immediately isolate anyone who is symptomatic?

☐ Does the plan include early detection, management of a potentially infectious, symptomatic resident that requires laboratory testing and/or Transmission-Based Precautions/PPE (the plan may include tracking this information in an infectious disease log)?

☐ Does the facility have a process for communicating diagnosis, treatment, and laboratory test results when transferring a resident to an acute care hospital or other healthcare provider; and obtaining pertinent notes such as discharge summary, lab results, current diagnoses, and infection or multidrug-resistant organism colonization status when residents are transferred back from acute care hospitals?

☐ Can appropriate staff (e.g., nursing and unit managers) identify/describe the communication protocol with local/state public health officials?

☐ Interview appropriate staff to determine if infection control concerns are identified, reported, and acted upon.

4. Did the facility provide appropriate infection surveillance? ☐ Yes ☐ **No F880**

5. Visitor Entry

☐ Review for compliance of:

- Screening processes and criteria (i.e., screening questions and assessment of illness);

- Restricting visitation based on federal or state guidance to ensure visitation does not lead to transmission of COVID-19; and
- Signage posted at facility entrances for screening and restrictions as well as a communication plan to alert visitors of new procedures/restrictions.

☐ For those permitted entry, are they instructed to frequently perform hand hygiene; limit their interactions with others in the facility and surfaces touched; restrict their visit to the resident's room or other location(s) designated by the facility; *maintain at least six feet from others in the facility;* and *wear a cloth face covering or facemask during the duration of their visit*? What is the facility's process for communicating this information?

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

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6. Education, Monitoring, and Screening of Staff

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

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

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

☐ *Are non-essential staff permitted into the facility based on state or federal guidance (e.g., reopening recommendations include phase 1: non-essential staff limited; phase 2: limited numbers of non-essential staff allowed; phase 3: all non-essential staff allowed)?*

☐ If staff develop symptoms at work (as stated above), does the facility:

- Inform the facility's infection preventionist and include information on individuals, equipment, and locations the person came in contact with; and
- Follow current guidance about returning to work (e.g., local health department, CDC: https://www.cdc.gov/coronavirus/2019-ncov/healthcare-facilities/hcp-return-work.html).

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

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7. Reporting to Residents, Representatives, and Families

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

☐ Did the facility inform all residents, their representatives, and families by 5 PM the next calendar day following the occurrence of a single confirmed COVID-19 infection or of three or more residents or staff with new onset of respiratory symptoms that occurred within 72 hours of each other?

☐ Did the information include mitigating actions taken by the facility to prevent or reduce the risk of transmission, including if normal operations in the nursing home will be altered (e.g., restrictions to visitations or group activities)?

☐ Did the information include personally identifiable information?

☐ Is the facility providing cumulative updates to residents, their representatives, and families at least weekly or by 5 PM the next calendar day following the subsequent occurrence of either: each time a confirmed COVID-19 infection is identified, or whenever three or more residents or staff with new onset of respiratory symptoms occurs within 72 hours of each other?

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

7. Did the facility inform residents, their representatives, and families of suspected or confirmed COVID-19 cases in the facility along with mitigating actions in a timely manner? ☐ Yes ☐ **No F885**

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

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

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

8. Did the facility report at least once a week to CDC on all of the data elements required in the NHSN COVID-19 Module?
☐ Yes ☐ **No F884**

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9. Emergency Preparedness – Staffing in Emergencies

☐ Policy development: Does the facility have a policy and procedure for ensuring staffing to meet the needs of the residents when needed during an emergency, such as COVID-19 outbreak?

☐ Policy implementation: In an emergency, did the facility implement its planned strategy for ensuring staffing to meet the needs of the residents? (N/A if an emergency staff was not needed).

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

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10. Infection Preventionist (IP):

During interview with facility administration and Infection Preventionist(s), determine the following:

☐ *Did the facility designate one or more individual(s) as the infection preventionist(s) who are responsible for the facility's IPCP?*

☐ *Does the Infection Preventionist(s) work at least part-time at the facility?*

☐ *Has the Infection Preventionist(s) completed specialized training in infection prevention and control?*

☐ *Does the Infection Preventionist(s) participate in the quality assessment and assurance committee? The individual designated as the IP, or at least one of the individuals if there is more than one IP, must be a member of the facility's quality assessment and assurance committee and report to the committee on the IPCP on a regular basis.*

Note: If no to any of the question above, consider citing F882.

10. Is the facility in compliance with requirements set forth at 483.80(b)?

☐ Yes ☐ **No F882**

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11. Staff and Resident Testing

Review the facility's testing documentation (e.g., logs of county level positivity rate, testing schedules, staff and resident records, other documentation). If possible, observe how the facility conducts testing, including the use of PPE and specimen collection. If such observation is not possible, interview an individual responsible for testing and inquire how testing is conducted (e.g., "what are the steps taken to conduct each test?").

☐ *Did the facility conduct testing of staff based on the county level positivity rate according to the recommended frequency?*

☐ *Based on observation or interview, did the facility conduct testing and specimen collection in a manner that is consistent with current standards of practice for conducting COVID-19 tests?*

☐ *Did the facility's documentation demonstrate the facility conducted testing of residents or staff with signs of symptoms of COVID-19 in a manner that is consistent with current standards of practice for conducting COVID-19 tests?*

☐ *Did the facility's documentation demonstrate the facility conducted testing of residents and staff based on the identification of an individual diagnosed with COVID-19 in the facility in a manner that is consistent with current standards of practice for conducting COVID-19 tests?*

☐ *Did the facility take actions to prevent the transmission of COVID-19 upon the identification of an individual with symptoms consistent with or who tests positive for COVID-19?*

☐ *Did the facility have procedures for addressing residents and staff that refuse testing or are unable to be tested?*

☐ *If there was an issue related to testing supplies or processing tests, did the facility contact the state and local health departments for assistance?*

Note: If no to any of the question above, consider citing F886.

11. Is the facility in compliance with requirements set forth at 483.80(h)?

☐ Yes ☐ No **F886**

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop C2-21-16
Baltimore, Maryland 21244-1850

CENTERS FOR MEDICARE & MEDICAID SERVICES

Center for Clinical Standards and Quality/Survey & Certification Group

Ref: QSO-20-39-NH

DATE: **September 17, 2020**

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Nursing Home Visitation - COVID-19

Memorandum Summary

- CMS is committed to continuing to take critical steps to ensure America's healthcare facilities are prepared to respond to the Coronavirus Disease 2019 (COVID-19) Public Health Emergency (PHE).
- **Visitation Guidance:** CMS is issuing new guidance for visitation in nursing homes during the COVID-19 PHE. The guidance below provides reasonable ways a nursing home can safely facilitate in-person visitation to address the psychosocial needs of residents.
- **Use of Civil Money Penalty (CMP) Funds:** CMS will now approve the use of CMP funds to purchase tents for outdoor visitation and/or clear dividers (e.g., Plexiglas or similar products) to create physical barriers to reduce the risk of transmission during in-person visits.

Background

Nursing homes have been severely impacted by COVID-19, with outbreaks causing high rates of infection, morbidity, and mortality.[1] The vulnerable nature of the nursing home population combined with the inherent risks of congregate living in a healthcare setting have required aggressive efforts to limit COVID-19 exposure and to prevent the spread of COVID-19 within nursing homes.

In March 2020, CMS issued memorandum QSO-20-14-NH providing guidance to facilities on restricting visitation of all visitors and non-essential health care personnel, except for certain compassionate care situations, such as an end-of-life situation. In May 2020, CMS released Nursing Home Reopening Recommendations, which provided additional guidance on visitation for nursing homes as their states and local communities progress through the phases of reopening. In June 2020, CMS also released a Frequently Asked Questions document on visitation, which expanded on previously issued guidance on topics such as outdoor visits, compassionate care situations, and communal activities.

[1] Information on outbreaks and deaths in nursing homes may be found at https://data.cms.gov/stories/s/COVID-19-Nursing-Home-Data/bkwz-xpvg.

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While CMS guidance has focused on protecting nursing home residents from COVID-19, we recognize that physical separation from family and other loved ones has taken a physical and emotional toll on residents. Residents may feel socially isolated, leading to increased risk for depression, anxiety, and other expressions of distress. Residents living with cognitive impairment or other disabilities may find visitor restrictions and other ongoing changes related to COVID-19 confusing or upsetting. CMS understands that nursing home residents derive value from the physical, emotional, and spiritual support they receive through visitation from family and friends. In light of this, CMS is revising the guidance regarding visitation in nursing homes during the COVID-19 PHE. The information contained in this memorandum supersedes and replaces previously issued guidance and recommendations regarding visitation.

Guidance

Visitation can be conducted through different means based on a facility's structure and residents' needs, such as in resident rooms, dedicated visitation spaces, outdoors, and for circumstances beyond compassionate care situations. Regardless of how visits are conducted, there are certain core principles and best practices that reduce the risk of COVID-19 transmission:

Core Principles of COVID-19 Infection Prevention

- Screening of all who enter the facility for signs and symptoms of COVID-19 (e.g., temperature checks, questions or observations about signs or symptoms), and denial of entry of those with signs or symptoms
- Hand hygiene (use of alcohol-based hand rub is preferred)
- Face covering or mask (covering mouth and nose)
- Social distancing at least six feet between persons
- Instructional signage throughout the facility and proper visitor education on COVID-19 signs and symptoms, infection control precautions, other applicable facility practices (e.g., use of face covering or mask, specified entries, exits and routes to designated areas, hand hygiene)
- Cleaning and disinfecting high frequency touched surfaces in the facility often, and designated visitation areas after each visit
- Appropriate staff use of Personal Protective Equipment (PPE)
- Effective cohorting of residents (e.g., separate areas dedicated COVID-19 care)
- Resident and staff testing conducted as required at 42 CFR 483.80(h) (see QSO-20-38-NH)

These core principles are consistent with the Centers for Disease Control and Prevention (CDC) guidance for nursing homes, and should be adhered to at all times. Additionally, visitation should be person-centered, consider the residents' physical, mental, and psychosocial well-being, and support their quality of life. The risk of transmission can be further reduced through the use of physical barriers (e.g., clear Plexiglas dividers, curtains). Also, nursing homes should enable visits to be conducted with an adequate degree of privacy. Visitors who are unable to adhere to the core principles of COVID-19 infection prevention should not be permitted to visit or should be asked to leave. By following a person-centered approach and adhering to these core principles, visitation can occur safely based on the below guidance.

Outdoor Visitation

While taking a person-centered approach and adhering to the core principles of COVID-19 infection prevention, outdoor visitation is preferred and can also be conducted in a manner that reduces the risk of transmission. Outdoor visits pose a lower risk of transmission due to increased space and airflow. Therefore, all visits should be held outdoors whenever practicable. Aside from weather considerations (e.g., inclement weather, excessively hot or cold temperatures, poor air quality), an individual resident's health status (e.g., medical condition(s), COVID-19 status), or a facility's outbreak status, outdoor visitation should be facilitated routinely. Facilities should create accessible and safe outdoor spaces for visitation, such as in courtyards, patios, or parking lots, including the use of tents, if available. When conducting outdoor visitation, facilities should have a process to limit the number and size of visits occurring simultaneously to support safe infection prevention actions (e.g., maintaining social distancing). We also recommend reasonable limits on the number of individuals visiting with any one resident at the same time.

Indoor Visitation

Facilities should accommodate and support indoor visitation, including visits for reasons beyond compassionate care situations, based on the following guidelines:

a) There has been no new onset of COVID-19 cases in the last 14 days and the facility is not currently conducting outbreak testing;
b) Visitors should be able to adhere to the core principles and staff should provide monitoring for those who may have difficulty adhering to core principles, such as children;
c) Facilities should limit the number of visitors per resident at one time and limit the total number of visitors in the facility at one time (based on the size of the building and physical space). Facilities should consider scheduling visits for a specified length of time to help ensure all residents are able to receive visitors; and
d) Facilities should limit movement in the facility. For example, visitors should not walk around different halls of the facility. Rather, they should go directly to the resident's room or designated visitation area. Visits for residents who share a room should not be conducted in the resident's room.

NOTE: For situations where there is a roommate and the health status of the resident prevents leaving the room, facilities should attempt to enable in-room visitation while adhering to the core principles of COVID-19 infection prevention.

Facilities should use the COVID-19 county positivity rate, found on the COVID-19 Nursing Home Data site as additional information to determine how to facilitate indoor visitation:

- Low (<5%) = Visitation should occur according to the core principles of COVID-19 infection prevention and facility policies (beyond compassionate care visits)
- Medium (5% – 10%) = Visitation should occur according to the core principles of COVID-19 infection prevention and facility policies (beyond compassionate care visits)
- High (>10%) = Visitation should only occur for compassionate care situations according to the core principles of COVID-19 infection prevention and facility policies

Facilities may also monitor other factors to understand the level of COVID-19 risk, such as rates of COVID-19-Like Illness[2] visits to the emergency department or the positivity rate of a county adjacent to the county where the nursing home is located. We note that county positivity rate does not need to be considered for outdoor visitation.

We understand that some states or facilities have designated categories of visitors, such as "essential caregivers," based on their visit history or resident designation. CMS does not distinguish between these types of visitors and other visitors. Using a person-centered approach when applying this guidance should cover all types of visitors, including those who have been categorized as "essential caregivers."

Visitor Testing

While not required, we encourage facilities in medium or high-positivity counties to test visitors, if feasible. If so, facilities should prioritize visitors that visit regularly (e.g., weekly), although any visitor can be tested. Facilities may also encourage visitors to be tested on their own prior to coming to the facility (e.g., within 2–3 days) with proof of negative test results and date of test.

Compassionate Care Visits

While end-of-life situations have been used as examples of compassionate care situations, the term "compassionate care situations" does not exclusively refer to end-of-life situations. Examples of other types of compassionate care situations include, but are not limited to:

- A resident, who was living with their family before recently being admitted to a nursing home, is struggling with the change in environment and lack of physical family support.
- A resident who is grieving after a friend or family member recently passed away.
- A resident who needs cueing and encouragement with eating or drinking, previously provided by family and/or caregiver(s), is experiencing weight loss or dehydration.
- A resident, who used to talk and interact with others, is experiencing emotional distress, seldom speaking, or crying more frequently (when the resident had rarely cried in the past).

Allowing a visit in these situations would be consistent with the intent of, "compassionate care situations." Also, in addition to family members, compassionate care visits can be conducted by any individual that can meet the resident's needs, such as clergy or lay persons offering religious and spiritual support. Furthermore, the above list is not an exhaustive list as there may be other compassionate care situations not included.

Lastly, at all times, visits should be conducted using social distancing; however, if during a compassionate care visit, a visitor and facility identify a way to allow for personal contact, it should only be done following all appropriate infection prevention guidelines, and for a limited amount of time. Through a person-centered approach, facilities should work with residents, families, caregivers, resident representatives, and the Ombudsman program to identify the need for compassionate care visits.

[2] For information on COVID-19-Like Illness refer to https://www.cdc.gov/coronavirus/2019-ncov/covid-data/covidview/07102020/covid-like-illness.html.

Required Visitation

We believe the guidance above represents reasonable ways a nursing home can facilitate in-person visitation. Except for on-going use of virtual visits, facilities may still restrict visitation due to the COVID-19 county positivity rate, the facility's COVID-19 status, a resident's COVID-19 status, visitor symptoms, lack of adherence to proper infection control practices, or other relevant factor related to the COVID-19 PHE. However, facilities may not restrict visitation without a reasonable clinical or safety cause, consistent with §483.10(f)(4)(v). For example, if a facility has had no COVID-19 cases in the last 14 days and its county positivity rate is low or medium, a nursing home **must** facilitate in-person visitation consistent with the regulations, which can be done by applying the guidance stated above. Failure to facilitate visitation, without adequate reason related to clinical necessity or resident safety, would constitute a potential violation of 42 CFR 483.10(f)(4), and the facility would be subject to citation and enforcement actions.

Residents who are on transmission-based precautions for COVID-19 should only receive visits that are virtual, through windows, or in-person for compassionate care situations, with adherence to transmission-based precautions. However, this restriction should be lifted once transmission-based precautions are no longer required per CDC guidelines, and other visits may be conducted as described above.

Access to the Long-Term Care Ombudsman

As stated in previous CMS guidance QSO-20-28-NH (revised), regulations at 42 CFR 483.10(f)(4)(i)(C) require that a Medicare and Medicaid certified nursing home provide representatives of the Office of the State Long-Term Care Ombudsman with immediate access to any resident. During this PHE, in-person access may be limited due to infection control concerns and/or transmission of COVID-19; however, in-person access may not be limited without reasonable cause. We note that representatives of the Office of the Ombudsman should adhere to the core principles of COVID-19 infection prevention. If in-person access is not advisable, such as the Ombudsman having signs or symptoms of COVID-19, facilities must, at a minimum, facilitate alternative resident communication with the ombudsman, such as by phone or through use of other technology. Nursing homes are also required under 42 CFR 483.10(h)(3)(ii) to allow the Ombudsman to examine the resident's medical, social, and administrative records as otherwise authorized by State law.

Federal Disability Rights Laws and Protection & Advocacy (P&A) Programs

Section 483.10(f)(4)(i)(E) and (F) requires the facility to allow immediate access to a resident by any representative of the protection and advocacy systems, as designated by the state, and as established under the Developmental Disabilities Assistance and Bill of Rights Act of 2000 (DD Act), and of the agency responsible for the protection and advocacy system for individuals with a mental disorder (established under the Protection and Advocacy for Mentally Ill Individuals Act of 2000). P&A programs authorized under the DD Act protect the rights of individuals with developmental and other disabilities and are authorized to "investigate incidents of abuse and neglect of individuals with developmental disabilities if the incidents are reported or if there is probably cause to believe the incidents occurred." 42 U.S.C. § 15043(a)(2)(B). Under its federal authorities, representatives of P&A programs are permitted access to all facility residents, which includes "the opportunity to meet and communicate privately with such individuals regularly,

both formally and informally, by telephone, mail and in person." 42 CFR 51.42(c); 45 CFR 1326.27.

Additionally, each facility must comply with federal disability rights laws such as Section 504 of the Rehabilitation Act and the Americans with Disabilities Act (ADA). For example, if a resident requires assistance to ensure effective communication (e.g., a qualified interpreter or someone to facilitate communication) and the assistance is not available by onsite staff or effective communication cannot be provided without such entry (e.g., video remote interpreting), the facility must allow the individual entry into the nursing home to interpret or facilitate, with some exceptions. This would not preclude nursing homes from imposing legitimate safety measures that are necessary for safe operations, such as requiring such individuals to adhere to the core principles of COVID-19 infection prevention.

Entry of Health Care Workers and Other Providers of Services

Health care workers who are not employees of the facility but provide direct care to the facility's residents, such as hospice workers, Emergency Medical Services (EMS) personnel, dialysis technicians, laboratory technicians, radiology technicians, social workers, clergy etc., must be permitted to come into the facility as long as they are not subject to a work exclusion due to an exposure to COVID-19 or show signs or symptoms of COVID-19 after being screened. We note that EMS personnel do not need to be screened so they can attend to an emergency without delay. We remind facilities that all staff, including individuals providing services under arrangement as well as volunteers, should adhere to the core principles of COVID-19 infection prevention and must comply with COVID-19 testing requirements.

Communal Activities and Dining

While adhering to the core principles of COVID-19 infection prevention, communal activities and dining may occur. Residents may eat in the same room with social distancing (e.g., limited number of people at each table and with at least six feet between each person). Facilities should consider additional limitations based on status of COVID-19 infections in the facility. Additionally, group activities may also be facilitated (for residents who have fully recovered from COVID-19, and for those not in isolation for observation, or with suspected or confirmed COVID-19 status) with social distancing among residents, appropriate hand hygiene, and use of a face covering. Facilities may be able to offer a variety of activities while also taking necessary precautions. For example, book clubs, crafts, movies, exercise, and bingo are all activities that can be facilitated with alterations to adhere to the guidelines for preventing transmission.

Survey Considerations

- For concerns related to resident communication with and access to persons and services inside and outside the facility, surveyors should investigate for non-compliance at 42 CFR 483.10(b), F550.
- For concerns related to a facility limiting visitors without a reasonable clinical and safety cause, surveyors should investigate for non-compliance at 42 CFR 483.10(f)(4), F563.
- For concerns related to ombudsman access to the resident and the resident's medical record, surveyors should investigate for non-compliance at 42 CFR 483.10(f)(4)(i)(C), F562 and 483.10(h)(3)(ii), F583.
- For concerns related to lack of adherence to infection control practices, surveyors should investigate for non-compliance at 42 CFR 483.80(a), F880.

Use of CMP Funds to Aid in Visitation

Technology can help improve social connections for some residents by helping to support and maintain relationships with loved ones. CMS has previously approved the use of CMP funds (See QSO-20-28-NH) to purchase communicative devices, such as tablets or webcams, to increase the ability for nursing homes to help residents stay connected with their loved ones. To ensure a balanced distribution of funds, facilities are limited to purchase one communicative device per 7–10 residents, up to a maximum of $3,000 per facility.

Additionally, facilities may apply to use CMP funds to help facilitate in-person visits. CMS will now approve the use of CMP funds to purchase tents for outdoor visitation and/or clear dividers (e.g., Plexiglas or similar product) to create a physical barrier to reduce the risk of transmission during in-person visits. Funding for tents and clear dividers is also limited to a maximum of $3,000 per facility. NOTE: When installing tents, facilities need to ensure appropriate life safety code requirements found at 42 CFR 483.90 are met, unless waived under the PHE declaration.

To apply to receive CMP funds for communicative devices, tents, or clear dividers, please contact your state agency's CMP contact.

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

/s/
David R. Wright

cc: Survey Operations Group

Increased Visitation in Long Term Care Facilities

Tennessee Department of Health (TDH) recognizes the difficult challenges long term care facilities have faced in protecting vulnerable residents during the COVID-19 response. This document provides guidance for Tennessee Long Term Care Facilities (skilled nursing facilities, assisted living care facilities, and residential homes for the aged) when establishing steps to gradually "re-open" after closures to visitors due to COVID-19 restrictions. Beginning October 1, 2020, these guidelines will remain in effect until replaced or amended with additional guidance.

Facilities will continue to monitor for COVID-19 cases in residents and staff, through appropriate screening and testing. Facilities should be prepared to discontinue visitation and activities if the facility develops one or more new cases amongst residents or staff.

EXHIBIT
M

Resuming Visitation

Visitation Opportunities Always Allowed

The following visits are always allowed:

- Accommodations or support for residents with disabilities;
- Critical assistance;
- Compassionate care/end-of-life situations; or
- Involvement in a religious exercise.

Visitors must make arrangements with the facility, practice proper social distancing and hand hygiene, and wear a face covering for the duration of their visit.

Visitation Opportunities Allowed After 14 Days of no new COVID-19 cases

Other than in a dedicated wing or unit that accepts COVID-19 cases from the community, facilities that have had no new COVID-19 cases (residents and/or staff) in the previous fourteen (14) days may permit outdoor and limited indoor visitation.

Outdoor Visitation

Outdoor visits on the facility grounds may be conducted as allowed by the following:

- Safe and appropriate outdoor space has been identified on the facility's campus to provide for seating spaced at least six (6) feet apart.
- Program area is only used when weather permits.
- Visits are scheduled in advance;
- Last no more than forty-five (45) minutes.
- Prior to visitation, requirements are acknowledged and agreed upon by the visitors.
- Outdoor visits are limited to not more than two (2) persons (not including the resident) and no children under the age of eighteen (18).
- Visitors are screened before entry into the outdoor visitation area including temperature checks and hand sanitization.
- Residents and visitors wear a face covering and maintain physical distancing.
- Facility establishes sufficient space between individual group seating arrangements, so six (6) feet of physical distancing can be maintained

between the groups. Capacity should be based on physical space and ability to staff the area.
- Seating accommodations are sanitized by staff between uses. Staff should remain in sight of the visiting group, in order to encourage safety precautions are followed.
- Visitors unable to pass the screening or comply with infection control practices should be prohibited from visiting.
- Visitors should be asked to self-monitor for symptoms of COVID-19 for fourteen (14) days and immediately report any symptoms or positive COVID-19 test to the local health department and the facility.

Limited Indoor Visitation

Indoor visitation should be limited to designated common spaces that allow for appropriate social distancing and cleaning/disinfection between visitors. Visits in designated indoor spaces should include:

- Safe and appropriate indoor space has been identified in the facility to provide for seating spaced at least six (6) feet apart.
- Visits are scheduled in advance.
- Last no more than forty-five (45) minutes.
- Prior to visitation, requirements should be acknowledged and agreed upon by the visitors.
- Indoor visits should be limited to not more than two (2) persons (not including the resident) and no children under the age of eighteen (18).
- Visitors should be screened before entry into the designated indoor area including temperature checks and proper hand sanitization.
- Residents and visitors should always wear a face covering and maintain physical distancing during the visit.
- Facility should establish sufficient space between individual group seating arrangements, so six (6) feet of physical distancing can be maintained between the groups. Capacity is based on physical space and ability to staff the area.
- Seating accommodations should be sanitized by staff between uses. Indoor visitation rooms must follow all applicable life safety guidance.
- Visitors unable to pass the screening or comply with infection control practices should be prohibited from visiting.
- Visitors should be asked to self-monitor for symptoms of COVID-19 for fourteen (14) days and immediately report any symptoms or positive COVID-19 test to the local health department and the facility.

Resident rooms should only be used for visitation as an accommodation for residents who cannot access the designated common area for indoor visitation.

Indoor visitation is allowed in a resident's room when:

- Resident is unable to leave the room **AND**
- Visitor has had negative PCR test collected within previous 72 hours **OR**
- Visitor has negative onsite point-of-care-test at the facility.

Visitation Opportunities Allowed After 28 Days of no new COVID-19 cases

In addition to outdoor and limited indoor visitation, once there have been no new COVID-19 cases in the facility's residents or staff for at least twenty-eight (28) days, facilities may also allow for indoor visits by essential caregivers.

Essential Caregivers

Essential caregivers (EC) are defined by designating a family member or guardian who, prior to visitation restrictions, was regularly engaged with the resident in activities of daily living (bathing, feeding, clothing, etc.) Essential caregiving visitation includes the following:

- Visitation should be scheduled with time restrictions.
- Each resident may have **up to** five (5) individuals designated as an EC although no more than two (2) at a time can visit per resident.
- ECs should be screened before entry into the facility including temperature checks and proper hand sanitization.
- Residents and ECs should wear a face covering and maintain physical distancing from other residents and staff.
- ECs are subject to the regular testing required of the staff (see testing frequency table below as established by CMS Rules). This could be accomplished by:
  - EC has negative PCR test collected within previous 72 hours **OR**
  - EC has negative onsite point-of-care test at the facility.

Table 2: Routine Testing Intervals Vary by Community COVID-19 Activity Level

Community COVID-19 Activity	County Positivity Rate in the past week	Minimum Testing Frequency
Low	<5%	Once a month
Medium	5% - 10%	Once a week*
High	>10%	Twice a week*

*This frequency presumes availability of Point of Care testing on-site at the nursing home or where off-site testing turnaround time is <48 hours.

EXHIBIT 4

Resuming Activities in Long Term Care Facilities

Tennessee Department of Health (TDH) recognizes the difficult challenges long term care facilities have faced in protecting vulnerable residents during the COVID-19 response. This document provides guidance for Tennessee Long Term Care Facilities (skilled nursing facilities, assisted living care facilities, and residential homes for the aged) when establishing steps to gradually resume activities, following COVID-19 restrictions. Beginning October 1, 2020, these guidelines will remain in effect until replaced or amended with additional guidance.

Facilities should continue to monitor for COVID-19 cases in residents and staff, through appropriate screening and testing. Facilities should be prepared to discontinue visitation and activities if the facility develops one or more new cases amongst residents or staff.

Resuming Facility Activities and Communal Dining

Limitations on Activities and Communal Dining

Until a facility has gone fourteen (14) days without a new COVID-19 case in residents or staff, there should be limitations in place regarding activities and communal dining. Until fourteen (14) days with no new COVID-19 cases, group activities in common areas should not take place, and meal service should be limited to in-room dining.

Activities and Communal Dining Allowed After 14 Days of no new COVID-19 cases

Facilities may resume resident activities (barber/beautician visits, communal dining, small group social activities, etc.) once there have been no new COVID-19 cases in residents or staff in the facility for fourteen (14) days. Facilities should take into consideration set hours and/or timed entry to ensure proper staffing and cleaning of areas.

- Barbers and beauticians may work in the facility with the following considerations:
  - Barbers and beauticians should wear a face covering for the duration of time in the facility.
  - Barbers and beauticians should remain in the salon area and avoid common areas of the facility.
  - The salon area should utilize staged appointments to maintain distancing of at least six (6) feet apart and not to exceed fifty percent (50%) of capacity.
  - Barbers and beauticians must properly sanitize equipment and salon chairs between each resident, and the barber and beautician must perform proper hand hygiene.
  - Barbers and beauticians must routinely sanitize high-touch areas.
  - Residents must wear a face covering during their visit.

- Volunteer staff may work in the facility with following considerations:
  - Volunteers must follow the same infection control requirements as employed staff, including, but not limited to, universal masking, screening before each shift, and routine testing consistent with CMS guidelines.

Communal Dining

- Residents may eat in the dining area maintaining social distancing of at least six (6) feet between tables and no more than two (2) people at a table in order to maintain adequate physical distance between persons.
- A limited number of individuals in a dining area at one time, not to exceed fifty percent (50%) of capacity unless that would be less than ten (10) people.

Group Activities

- Small group activities may occur with at least six (6) feet of distancing, proper hand hygiene, and face coverings.
- A limited number of individuals in a common area at one time, not to exceed fifty percent (50%) of capacity, no more than ten (10) people.
- Facilities should restrict activities that encourage multiple residents to handle the same object(s) (e.g., ball toss).

Therapeutic and Rehabilitation Services

- A limited number of individuals may be in a therapy and rehabilitation area at one time, not to exceed fifty percent (50%) of capacity, no more than ten (10) people.
- Therapeutic and rehabilitation services may occur in a small group setting (therapy gym) with at least six (6) feet of distancing, proper hand hygiene, and face coverings.
- Equipment is sanitized between uses in accordance with facility policies.

Accessing the Community: Medically Necessary Trips

- Telemedicine should be utilized whenever possible.
- Non-medically necessary trips outside the building should be avoided.
- For medically necessary trips:
    - The resident should wear a face covering.
    - The facility must share the resident's COVID-19 status with the transportation service and health care provider with whom the resident has the appointment.
    - Transportation staff, at a minimum, should wear a face covering. Additional PPE may be required.
    - Transportation equipment shall be sanitized between transports.

Activities Allowed After 28 Days of no new COVID-19 cases

There are no additional allowances regarding activities at this time.

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PM 83 AMENDED

Board for Licensing Health Care Facilities

Policy Memorandum

SUBJECT: Extension of Trauma Center Designation Amid COVID-19

DATE: April 1, 2020
*June 3, 2020

POLICY: Extend trauma center designation for those trauma centers due re-designation surveys in the month of May for an additional six (6) months.

*Extends this Board Policy until May 2021 for an additional one (1) year.

EFFECTIVE: April 1, 2020
*June 3, 2020

APPROVED: April 1, 2020
*June 3, 2020

René 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

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PM 83

Board for Licensing Health Care Facilities

Policy Memorandum

SUBJECT: Extension of Trauma Center Designation Amid COVID-19

DATE: April 1, 2020

POLICY: Extend trauma center designation for those trauma centers due re-designation surveys in the month of May for an additional six (6) months.

EFFECTIVE: April 1, 2020

APPROVED: April 1, 2020

René Saunders MD

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

Ann R. Reed

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PM 84

Board for Licensing Health Care Facilities

Policy Memorandum

SUBJECT: Hospital 10% Increase in Licensed Beds

DATE: December 17, 2020

POLICY: The Board hereby adopts HSDA's interpretation that CON holders may request an additional 10% bed increase every three (3) years after the date on which the Health Services and Development Agency (HSDA) has approved any previous 10% bed increase request, pursuant to Tenn. Code Ann. §68-11-1607(g). HSDA shall provide written notification to the Board for Licensing Health Care Facility's administrative staff of its approval of a hospital's licensed bed capacity. Once the written approval is received by HSDA, notification will be made by Board staff to the Board of the HSDA approved bed increase at the Board's regularly scheduled meeting. Facilities will no longer be required to petition the Board for a 10% bed increase, if the action has already been approved by HSDA.

EFFECTIVE: December 17, 2020

APPROVED: December 17, 2020

René Saunders MD

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

Ann R Reed

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

HFC

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Logan Grant
Executive Director

Caroline Tippens
Director, Licensure and Regulation

PM 85

Board for Licensing Health Care Facilities

Policy Memorandum

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

DATE: **NOVEMBER 22, 2022**

POLICY: **85**

EFFECTIVE: **NOVEMBER 22, 2022**

APPROVED: **NOVEMBER 22, 2022**

The Board issues this policy to facilitate the treatment and containment of COVID-19. This policy supersedes Policy 82 Amended.

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 Interim Infection Prevention and Control Recommendations for Healthcare Personnel During the Coronavirus Disease 2019 (COVID-19) Pandemic shall be followed for patient/residents, staff, and visitors in healthcare facilities. See Attachment A.

On August 25, 2020, the Centers for Medicare and Medicaid Services (CMS) published an interim final rule entitled "Medicare and Medicaid Programs, Clinical Laboratory Improvement Amendments of 1988 and Patient Protection and Affordable Care Act; Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency." On August 26, 2020, CMS published a policy memo entitled "Interim Final Rule (IFC), CMS-3401-IFC, Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency Related to Long Term Care (LTC) Facility Requirements and COVID-19 Focused Survey Tool", QSO-20-38-NH, implementing the testing rule. On September 23, 2022, CMS revised the policy memo. https://www.cms.gov/files/document/qso-20-38-nh-revised.pdf

The revised QSO provides updated regulatory guidance on the requirements of the CMS rule, including frequency of the testing, testing in light of community spread, testing for outbreaks, and testing of symptomatic individuals. CMS QSO-20-38-NH shall be followed regarding testing of patients/residents for COVID-19 in CMS skilled nursing facilities/nursing facilities. See Attachment B.

On or about September 17, 2020, CMS published a policy memo entitled "Nursing Home Visitation – COVID-19," QSO-20-39-NH, implementing visitation guidance in CMS skilled nursing facilities/nursing facilities. On September 23, 2022, CMS revised the policy memo. CMS QSO-20-39 NH shall be followed regarding visitation of patients/residents during the COVID-19 pandemic in CMS skilled nursing facilities/nursing facilities. See Attachment C.

All federally certified facility types are to follow CMS guidance.

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 COVID-19 Licensed Hospital Facility Requirements – Temporary Structures. See Attachment D.

On or about April 7, 2022, CMS published a policy memo entitled "Update to COVID-19 Emergency Declaration Blanket Waivers for Specific Providers," QSO-22-15-NH & NLTC & LSC", which ends specific emergency declaration blanket waivers for SNFs/NFs, inpatient hospices, ICF/IIDs and ESRD facilities; blanket waivers remain for hospitals and CAHs. See Attachment E.

This policy shall remain in effect until rescinded by the Board.

Chair, Board for Licensing Health Care Facilities

Caroline Tippens, Esq., CHC
Director, Licensure and Regulation
Health Facilities Commission

Attachments:

Attachment 1	Interim Infection Prevention and Control Recommendations for Healthcare Personnel During the Coronavirus Disease 2019 (COVID-19) Pandemic
Attachment 2	CMS QSO-20-38-NH - Interim Final Rule (IFC), CMS-3401-IFC, Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency related to Long Term Care (LTC) Facility requirements and COVID-19 Focused Survey Tool.
Attachment 3	CMS QSO-20-39 NH – Nursing Home Visitation – COVID-19
Attachment 4	COVID-19 Facility Requirements – Temporary Structures
Attachment 5	QSO-22-15-NH & NLTC & LSC- Update to COVID-19 Emergency Declaration Blanket Waivers for Specific Providers

COVID-19

Interim Infection Prevention and Control Recommendations for Healthcare Personnel During the Coronavirus Disease 2019 (COVID-19) Pandemic

Updated Sept. 23, 2022

For healthcare personnel, see Isolation and work restriction guidance. For strategies to mitigate healthcare personnel staffing shortages, see Contingency and crisis management. For healthcare professionals advising people in non-healthcare settings about isolation for laboratory-confirmed COVID-19, see Ending Isolation and Precautions for People with COVID-19.

Summary of Recent Changes

Updates as of September 23, 2022

- Updated to note that vaccination status is no longer used to inform source control, screening testing, or post-exposure recommendations
- Updated circumstances when use of source control is recommended
- Updated circumstances when universal use of personal protective equipment should be considered
- Updated recommendations for testing frequency to detect potential for variants with shorter incubation periods and to address the risk for false negative antigen tests in people without symptoms.
- Clarified that screening testing of asymptomatic healthcare personnel, including those in nursing homes, is at the discretion of the healthcare facility
- Updated to note that, in general, asymptomatic patients no longer require empiric use of Transmission-Based Precautions following close contact with someone with SARS-CoV-2 infection.
- Archived the Interim Infection Prevention and Control Recommendations to Prevent SARS-CoV-2 Spread in Nursing Homes and special considerations for nursing homes not otherwise covered in Sections 1 and 2 were added to Section 3: Setting-specific considerations
  - Updated screening testing recommendations for nursing home admissions
- Clarified the types of long-term care settings for whom the healthcare infection prevention and control recommendations apply

Key Points

- This guidance applies to all U.S. settings where healthcare is delivered, including nursing homes and home health.

Attach. 1

Introduction

This interim guidance has been updated based on currently available information about COVID-19 and the current situation in the United States. Updates were made to reflect the high levels of vaccine-and infection-induced immunity and the availability of effective treatments and prevention tools. This guidance provides a framework for facilities to implement select infection prevention and control practices (e.g., universal source control) based on their individual circumstances (e.g., levels of community transmission).

This guidance is applicable to all U.S. settings where healthcare is delivered (including nursing homes and home health). **This guidance is not intended for non-healthcare settings (e.g., restaurants) and not for persons outside of healthcare settings.** CDC's main landing page for COVID-19 content will help readers navigate to information regarding modes of transmission, clinical management, laboratory settings, COVID-19 vaccines and CDC guidance on other COVID-19-related topics.

Employers should be aware that other local, territorial, tribal, state, and federal requirements may apply, including those promulgated by the Occupational Safety and Health Administration (OSHA).

Defining Community Transmission of SARS-CoV-2

Select IPC measures (e.g., use of source control, screening testing of nursing home admissions) are influenced by levels of SARS-CoV-2 transmission in the community. Community Transmission is the metric currently recommended to guide select practices in healthcare settings to allow for earlier intervention, before there is strain on the healthcare system and to better protect the individuals seeking care in these settings. The Community Transmission metric is different from the COVID-19 Community Level metric used for non-healthcare settings. Community Transmission refers to measures of the presence and spread of SARS-CoV-2. COVID-19 Community Levels place an emphasis on measures of the impact of COVID-19 in terms of hospitalizations and healthcare system strain, while accounting for transmission in the community.

1. Recommended routine infection prevention and control (IPC) practices during the COVID-19 pandemic

Encourage everyone to remain up to date with all recommended COVID-19 vaccine doses.

- HCP, patients, and visitors should be offered resources and counseled about the importance of receiving the COVID-19 vaccine.

Establish a Process to Identify and Manage Individuals with Suspected or Confirmed SARS-CoV-2 Infection

- Ensure everyone is aware of recommended IPC practices in the facility.
  - Post visual alerts (e.g., signs, posters) at the entrance and in strategic places (e.g., waiting areas, elevators, cafeterias) These alerts should include instructions about current IPC recommendations (e.g., when to use source control and perform hand hygiene). Dating these alerts can let help ensure people know that they reflect current recommendations.
- Establish a process to make everyone entering the facility aware of recommended actions to prevent transmission to others if they have any of the following three criteria:
  - 1) a positive viral test for SARS-CoV-2
  - 2) symptoms of COVID-19, or
  - 3) close contact with someone with SARS-CoV-2 infection (for patients and visitors) or a higher-risk exposure (for healthcare personnel (HCP)).
    - For example:
      - Instruct HCP to report any of the 3 above criteria to occupational health or another point of contact designated by the facility so these HCP can be properly managed.
        - The definition of higher-risk exposure and recommendations for evaluation and work restriction of these HCP are in the Interim Guidance for Managing Healthcare Personnel with SARS-CoV-2 Infection or Exposure to SARS-CoV-2.

- Provide guidance (e.g., posted signs at entrances, instructions when scheduling appointments) about recommended actions for patients and visitors who have any of the above three criteria.
  - Patients should be managed as described in Section 2.
  - Visitors with confirmed SARS-CoV-2 infection or compatible symptoms should defer non-urgent in-person visitation until they have met the healthcare criteria to end isolation (see Section 2); this time period is longer than what is recommended in the community. For visitors who have had close contact with someone with SARS-CoV-2 infection or were in another situation that put them at higher risk for transmission, it is safest to defer non-urgent in-person visitation until 10 days after their close contact if they meet any of the criteria described in Section 2 (e.g., cannot wear source control).
    - Additional information about visitation from the Centers for Medicare & Medicaid Services (CMS) is available at Policy & Memos to States and Regions | CMS .

Implement Source Control Measures

Source control refers to use of respirators or well-fitting facemasks or cloth masks to cover a person's mouth and nose to prevent spread of respiratory secretions when they are breathing, talking, sneezing, or coughing. Further information about types of masks and respirators, including those that meet standards and the degree of protection offered to the wearer, is available at: Masks and Respirators (cdc.gov). People, particularly those at high risk for severe illness, should wear the most protective form of source control they can that fits well and that they will wear consistently.

Healthcare facilities may choose to offer well-fitting facemasks as a source control option for visitors but should allow the use of a mask or respirator with higher-level protection that is not visibly soiled by people who chose that option based on their individual preference. Additional information is available in the FAQ: What should visitors use for source control (masks or respirators) when visiting healthcare facilities?

Source control options for HCP include:

- A NIOSH-approved particulate respirator with N95 filters or higher;
- A respirator approved under standards used in other countries that are similar to NIOSH-approved N95 filtering facepiece respirators (Note: These should not be used instead of a NIOSH-approved respirator when respiratory protection is indicated);
- A barrier face covering that meets ASTM F3502-21 requirements including Workplace Performance and Workplace Performance Plus masks; OR
- A well-fitting facemask.

When used solely for source control, any of the options listed above could be used for an entire shift unless they become soiled, damaged, or hard to breathe through. If they are used during the care of patient for which a NIOSH-approved respirator or facemask is indicated for personal protective equipment (PPE) (e.g., NIOSH-approved particulate respirators with N95 filters or higher during the care of a patient with SARS-CoV-2 infection, facemask during a surgical procedure or during care of a patient on Droplet Precautions), they should be removed and discarded after the patient care encounter and a new one should be donned. Additional information is available in the FAQ: Can employees choose to wear respirators when not required by their employer?

When SARS-CoV-2 Community Transmission levels are high, source control is recommended for everyone in a healthcare setting when they are in areas of the healthcare facility where they could encounter patients.

- HCP could choose not to wear source control when they are in well-defined areas that are restricted from patient access (e.g., staff meeting rooms) if they do not otherwise meet the criteria described below and Community Levels are not also high. When Community Levels are high, source control is recommended for everyone.

When SARS-CoV-2 Community Transmission levels are **not** high, healthcare facilities could choose not to require universal source control. However, even if source control is not universally required, it remains recommended for individuals in healthcare settings who:

- Have suspected or confirmed SARS-CoV-2 infection or other respiratory infection (e.g., those with runny nose, cough, sneeze); or
- Had close contact (patients and visitors) or a higher-risk exposure (HCP) with someone with SARS-CoV-2 infection, for 10 days after their exposure; or
- Reside or work on a unit or area of the facility experiencing a SARS-CoV-2 outbreak; universal use of source control could be discontinued as a mitigation measure once no new cases have been identified for 14 days; or
- Have otherwise had source control recommended by public health authorities

Individuals might also choose to continue using source control based on personal preference, informed by their perceived level of risk for infection based on their recent activities (e.g., attending crowded indoor gatherings with poor ventilation) and their potential for developing severe disease. For example, if an individual or someone in their household is at increased risk for severe disease, they should consider wearing masks or respirators that provide more protection because of better filtration and fit to reduce exposure and infection risk, even if source control is not otherwise required by the facility. HCP and healthcare facilities might also consider using or recommending source control when caring for patients who are moderately to severely immunocompromised.

Implement Universal Use of Personal Protective Equipment for HCP

If SARS-CoV-2 infection is not suspected in a patient presenting for care (based on symptom and exposure history), HCP should follow Standard Precautions (and Transmission-Based Precautions if required based on the suspected diagnosis).

As community transmission levels increase, the potential for encountering asymptomatic or pre-symptomatic patients with SARS-CoV-2 infection also likely increases. In these circumstances, healthcare facilities should consider implementing broader use of respirators and eye protection by HCP during patient care encounters. For example, facilities located in counties where Community Transmission is high should also consider having HCP use PPE as described below:

- NIOSH-approved particulate respirators with N95 filters or higher used for:
  - All aerosol-generating procedures (refer to Which procedures are considered aerosol generating procedures in healthcare settings?).
  - All surgical procedures that might pose higher risk for transmission if the patient has SARS-CoV-2 infection (e.g., that generate potentially infectious aerosols or involving anatomic regions where viral loads might be higher, such as the nose and throat, oropharynx, respiratory tract).
  - NIOSH-approved particulate respirators with N95 filters or higher can also be used by HCP working in other situations where additional risk factors for transmission are present, such as the patient is unable to use source control and the area is poorly ventilated. They may also be considered if healthcare-associated SARS-CoV-2 transmission is identified and universal respirator use by HCP working in affected areas is not already in place.
  - To simplify implementation, facilities in counties with high transmission may consider implementing universal use of NIOSH-approved particulate respirators with N95 filters or higher for HCP during all patient care encounters or in specific units or areas of the facility at higher risk for SARS-CoV-2 transmission.
- Eye protection (i.e., goggles or a face shield that covers the front and sides of the face) worn during all patient care encounters.

Optimize the Use of Engineering Controls and Indoor Air Quality

- Optimize the use of engineering controls to reduce or eliminate exposures by shielding HCP and other patients from infected individuals (e.g., physical barriers at reception / triage locations and dedicated pathways to guide symptomatic patients through waiting rooms and triage areas).
- Take measures to limit crowding in communal spaces, such as scheduling appointments to limit the number of patients in waiting rooms or treatment areas.
- Explore options, in consultation with facility engineers, to improve ventilation delivery and indoor air quality in patient rooms and all shared spaces.
  - Guidance on ensuring that ventilation systems are operating properly, and other options for improving indoor air quality, are available in the following resources:
    - Guidelines for Environmental Infection Control in Health-Care Facilities

- American Society of Heating, Refrigerating and Air-Conditioning Engineers (ASHRAE) resources for healthcare facilities, which also provides COVID-19 technical resources for healthcare facilities
- Ventilation in Buildings, which includes options for non-clinical spaces in healthcare facilities

Perform SARS-CoV-2 Viral Testing

- Anyone with even mild symptoms of COVID-19, **regardless of vaccination status**, should receive a viral test for SARS-CoV-2 as soon as possible.
- Asymptomatic patients with close contact with someone with SARS-CoV-2 infection should have a series of three viral tests for SARS-CoV-2 infection. Testing is recommended immediately (but not earlier than 24 hours after the exposure) and, if negative, again 48 hours after the first negative test and, if negative, again 48 hours after the second negative test. This will typically be at day 1 (where day of exposure is day 0), day 3, and day 5.
  - Due to challenges in interpreting the result, testing is generally not recommended for asymptomatic people who have recovered from SARS-CoV-2 infection in the prior 30 days. Testing should be considered for those who have recovered in the prior 31-90 days; however, an antigen test instead of a nucleic acid amplification test (NAAT) is recommended. This is because some people may remain NAAT positive but not be infectious during this period.
  - Guidance for work restrictions, including recommended testing for HCP with higher-risk exposures, are in the Interim Guidance for Managing Healthcare Personnel with SARS-CoV-2 Infection or Exposure to SARS-CoV-2.
  - Guidance for use of empiric Transmission-Based Precautions for patients with close contact with someone with SARS-CoV-2 infection are described in Section 2.
- Testing considerations for healthcare facilities with an outbreak of SARS-CoV-2 are described below.
- The yield of screening testing for identifying asymptomatic infection is likely lower when performed on those in counties with lower levels of SARS-CoV-2 community transmission. However, these results might continue to be useful in some situations (e.g., when performing higher-risk procedures or for HCP caring for patients who are moderately to severely immunocompromised) to inform the type of infection control precautions used (e.g., room assignment/cohorting, or PPE used) and prevent unprotected exposures. If implementing a screening testing program, testing decisions should not be based on the vaccination status of the individual being screened. To provide the greatest assurance that someone does not have SARS-CoV-2 infection, if using an antigen test instead of a NAAT, facilities should use 3 tests, spaced 48 hours apart, in line with FDA recommendations.
  - In general, performance of pre-procedure or pre-admission testing is at the discretion of the facility. However, for residents admitted to nursing homes, admission testing is recommended as described in Section 3.
  - Performance of expanded screening testing of asymptomatic HCP without known exposures is at the discretion of the facility.

Create a Process to Respond to SARS-CoV-2 Exposures Among HCP and Others

Healthcare facilities should have a plan for how SARS-CoV-2 exposures in a healthcare facility will be investigated and managed and how contact tracing will be performed.

If healthcare-associated transmission is suspected or identified, facilities might consider expanded testing of HCP and patients as determined by the distribution and number of cases throughout the facility and ability to identify close contacts. For example, in an outpatient dialysis facility with an open treatment area, testing should ideally include all patients and HCP. Depending on testing resources available or the likelihood of healthcare-associated transmission, facilities may elect to initially expand testing only to HCP and patients on the affected units or departments, or a particular treatment schedule or shift, as opposed to the entire facility. If an expanded testing approach is taken and testing identifies additional infections, testing should be expanded more broadly. If possible, testing should be repeated every 3-7 days until no new cases are identified for at least 14 days.

Guidance for outbreak response in nursing homes is described in setting-specific considerations below.

Healthcare facilities responding to SARS-CoV-2 transmission within the facility should always notify and follow the recommendations of public health authorities.

2. Recommended infection prevention and control (IPC)

practices when caring for a patient with suspected or confirmed SARS-CoV-2 infection

The IPC recommendations described below (e.g., patient placement, recommended PPE) also apply to patients with symptoms of COVID-19 (even before results of diagnostic testing) and asymptomatic patients who have met the criteria for empiric Transmission-Based Precautions based on close contact with someone with SARS-CoV-2 infection. However, these patients should NOT be cohorted with patients with confirmed SARS-CoV-2 infection unless they are confirmed to have SARS-CoV-2 infection through testing.

Duration of Empiric Transmission-Based Precautions for Symptomatic Patients being Evaluated for SARS-CoV-2 infection

The decision to discontinue empiric Transmission-Based Precautions by excluding the diagnosis of current SARS-CoV-2 infection for a patient with symptoms of COVID-19 can be made based upon having negative results from at least one viral test.

- If using NAAT (molecular), a single negative test is sufficient in most circumstances. If a higher level of clinical suspicion for SARS-CoV-2 infection exists, consider maintaining Transmission-Based Precautions and confirming with a second negative NAAT.
- If using an antigen test, a negative result should be confirmed by either a negative NAAT (molecular) or second negative antigen test taken 48 hours after the first negative test.

If a patient suspected of having SARS-CoV-2 infection is never tested, the decision to discontinue Transmission-Based Precautions can be made based on time from symptom onset as described in the Isolation section below. Ultimately, clinical judgement and suspicion of SARS-CoV-2 infection determine whether to continue or discontinue empiric Transmission-Based Precautions.

Duration of Empiric Transmission-Based Precautions for Asymptomatic Patients following Close Contact with Someone with SARS-CoV-2 Infection

In general, asymptomatic patients do not require empiric use of Transmission-Based Precautions while being evaluated for SARS-CoV-2 following close contact with someone with SARS-CoV-2 infection. These patients should still wear source control and those who have not recovered from SARS-CoV-2 infection in the prior 30 days should be tested as described in the testing section.

Examples of when empiric Transmission-Based Precautions following close contact may be considered include:

- Patient is unable to be tested or wear source control as recommended for the 10 days following their exposure
- Patient is moderately to severely immunocompromised
- Patient is residing on a unit with others who are moderately to severely immunocompromised
- Patient is residing on a unit experiencing ongoing SARS-CoV-2 transmission that is not controlled with initial interventions

Patients placed in empiric Transmission-Based Precautions based on close contact with someone with SARS-CoV-2 infection should be maintained in Transmission-Based Precautions for the following time periods.

- Patients can be removed from Transmission-Based Precautions after day 7 following the exposure (count the day of exposure as day 0) if they do not develop symptoms and all viral testing as described for asymptomatic individuals following close contact is negative.
- If viral testing is not performed, patients can be removed from Transmission-Based Precautions after day 10 following the exposure (count the day of exposure as day 0) if they do not develop symptoms.

Patient Placement

- Place a patient with suspected or confirmed SARS-CoV-2 infection in a single-person room. The door should be kept closed (if safe to do so). Ideally, the patient should have a dedicated bathroom.

- If cohorting, only patients with the same respiratory pathogen should be housed in the same room. MDRO colonization status and/or presence of other communicable disease should also be taken into consideration during the cohorting process.

- Facilities could consider designating entire units within the facility, with dedicated HCP, to care for patients with SARS-CoV-2 infection when the number of patients with SARS-CoV-2 infection is high. Dedicated means that HCP are assigned to care only for these patients during their shifts. Dedicated units and/or HCP might not be feasible due to staffing crises or a small number of patients with SARS-CoV-2 infection.
- Limit transport and movement of the patient outside of the room to medically essential purposes.
- Communicate information about patients with suspected or confirmed SARS-CoV-2 infection to appropriate personnel before transferring them to other departments in the facility (e.g., radiology) and to other healthcare facilities.

Personal Protective Equipment

- HCP who enter the room of a patient with suspected or confirmed SARS-CoV-2 infection should adhere to Standard Precautions and use a NIOSH-approved particulate respirator with N95 filters or higher , gown, gloves, and eye protection (i.e., goggles or a face shield that covers the front and sides of the face).
- Respirators should be used in the context of a comprehensive respiratory protection program, which includes medical evaluations, fit testing and training in accordance with the Occupational Safety and Health Administration's (OSHA) Respiratory Protection standard (29 CFR 1910.134)

- Additional information about using PPE is available in Protecting Healthcare Personnel | HAI | CDC

Aerosol-Generating Procedures (AGPs)

- Procedures that could generate infectious aerosols should be performed cautiously and avoided if appropriate alternatives exist.
- AGPs should take place in an airborne infection isolation room (AIIR), if possible.
- The number of HCP present during the procedure should be limited to only those essential for patient care and procedure support. Visitors should not be present for the procedure.

Visitation

- For the safety of the visitor, in general, patients should be encouraged to limit in-person visitation while they are infectious. However, facilities should adhere to local, territorial, tribal, state, and federal regulations related to visitation. Additional information about visitation from the Centers for Medicare & Medicaid Services (CMS) is available at Policy & Memos to States and Regions | CMS .
  - Counsel patients and their visitor(s) about the risks of an in-person visit.
  - Encourage use of alternative mechanisms for patient and visitor interactions such as video-call applications on cell phones or tablets, when appropriate.
- Facilities should provide instruction, before visitors enter the patient's room, on hand hygiene, limiting surfaces touched, and use of PPE according to current facility policy.
- Visitors should be instructed to only visit the patient room. They should minimize their time spent in other locations in the facility.

Duration of Transmission-Based Precautions for Patients with SARS-CoV-2 Infection

The following are criteria to determine when Transmission-Based Precautions could be discontinued for patients with SARS-CoV-2 infection and are influenced by severity of symptoms and presence of immunocompromising conditions. Patients should self-monitor and seek re-evaluation if symptoms recur or worsen. If symptoms recur (e.g., rebound), these patients should be placed back into isolation until they again meet the healthcare criteria below to discontinue Transmission-Based Precautions for SARS-CoV-2 infection unless an alternative diagnosis is identified.

In general, patients who are hospitalized for SARS-CoV-2 infection should be maintained in Transmission-Based Precautions for the time period described for patients with severe to critical illness.

In general, patients should continue to wear source control until symptoms resolve or, for those who never developed symptoms, until they meet the criteria to end isolation below. Then they should revert to usual facility source control policies for patients.

Patients with mild to moderate illness who are *not* moderately to severely immunocompromised:

- At least 10 days have passed *since symptoms first appeared* **and**
- At least 24 hours have passed *since last fever* without the use of fever-reducing medications **and**
- Symptoms (e.g., cough, shortness of breath) have improved

Patients who were asymptomatic throughout their infection and are *not* moderately to severely immunocompromised:

- At least 10 days have passed since the date of their first positive viral test.

Patients with severe to critical illness and who are *not* moderately to severely immunocompromised:

- At least 10 days and up to 20 days have passed *since symptoms first appeared* **and**
- At least 24 hours have passed *since last fever* without the use of fever-reducing medications **and**
- Symptoms (e.g., cough, shortness of breath) have improved
- The test-based strategy as described for moderately to severely immunocompromised patients below can be used to inform the duration of isolation.

The exact criteria that determine which patients will shed replication-competent virus for longer periods are not known. Disease severity factors and the presence of immunocompromising conditions should be considered when determining the appropriate duration for specific patients. For a summary of the literature, refer to Ending Isolation and Precautions for People with COVID-19: Interim Guidance (cdc.gov)

Patients who are moderately to severely immunocompromised may produce replication-competent virus beyond 20 days after symptom onset or, for those who were asymptomatic throughout their infection, the date of their first positive viral test.

- Use of a test-based strategy and (if available) consultation with an infectious disease specialist is recommended to determine when Transmission-Based Precautions could be discontinued for these patients.

The criteria for the test-based strategy are:

Patients who are symptomatic:

- Resolution of fever without the use of fever-reducing medications **and**
- Symptoms (e.g., cough, shortness of breath) have improved, **and**
- Results are negative from at least two consecutive respiratory specimens collected 48 hours apart (total of two negative specimens) tested using an antigen test or NAAT

Patients who are not symptomatic:

- Results are negative from at least two consecutive respiratory specimens collected 48 hours apart (total of two negative specimens) tested using an antigen test or NAAT

Environmental Infection Control

- Dedicated medical equipment should be used when caring for a patient with suspected or confirmed SARS-CoV-2 infection.
  - All non-dedicated, non-disposable medical equipment used for that patient should be cleaned and disinfected according to manufacturer's instructions and facility policies before use on another patient.
- Routine cleaning and disinfection procedures (e.g., 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) are appropriate for SARS-CoV-2 in healthcare settings, including those patient-care areas in which AGPs are performed.
    - Refer to List N on the EPA website for EPA-registered disinfectants that kill SARS-CoV-2; the disinfectant selected should also be appropriate for other pathogens of concern at the facility (e.g., a *difficile* sporicidal agent is recommended to disinfect the rooms of patients with *C. difficile* infection).
- Management of laundry, food service utensils, and medical waste should be performed in accordance with routine procedures.
- Once the patient has been discharged or transferred, HCP, including environmental services personnel, should refrain from entering the vacated room without all recommended PPE until sufficient time has elapsed for enough air changes to remove potentially infectious particles [more information (to include important footnotes on its application) on clearance rates under differing ventilation conditions is available]. After this time has elapsed, the room should undergo appropriate cleaning and surface disinfection before it is returned to routine use.

3. Setting-specific considerations

In addition to the recommendations described in the guidance above, here are additional considerations for the settings listed below.

Dialysis Facilities

Considerations for Patient Placement

- Patients on dialysis with suspected or confirmed SARS-CoV-2 infection or who have reported close contact should be dialyzed in a separate room with the door closed.
    - Hepatitis B isolation rooms can be used if: 1) the patient is hepatitis B surface antigen-positive or 2) the facility has no patients on the census with hepatitis B infection who would require treatment in the isolation room.
- If a separate room is not available, patients with confirmed SARS-CoV-2 infection should be cohorted to a specific well-ventilated unit or shift (e.g., consider the last shift of the day). Only patients with confirmed SARS-CoV-2 infection should be cohorted together:
    - In the context of an outbreak or an increase in the number of confirmed SARS-CoV-2 infections at the facility, if a separate shift or unit is not initially available, efforts should be made to create specific shifts or units for patients with confirmed SARS-CoV-2 infection to separate them from patients without SARS-CoV-2 infection.

Additional Guidance for Use of Isolation Gowns

- When caring for patients with suspected or confirmed SARS-CoV-2 infection, gowns should be worn over or instead of the cover gown (e.g., laboratory coat, gown, or apron with incorporate sleeves) that is normally worn by hemodialysis personnel.

Cleaning and Disinfecting Dialysis Stations

- Current procedures for routine cleaning and disinfection of dialysis stations are appropriate for patients with SARS-CoV-2 infection.
- Internal disinfection of dialysis machines is not required immediately after use unless otherwise indicated (e.g., post-blood leak). It should be done according to the dialysis machine manufacturer's instructions (e.g., at the end of the day).

Emergency Medical Services

Considerations for vehicle configuration when transporting a patient with suspected or confirmed SARS-CoV-2 infection

- Isolate the ambulance driver from the patient compartment and keep pass-through doors and windows tightly shut.
- When possible, use vehicles that have isolated driver and patient compartments that can provide separate ventilation to each area.
    - Before entering the isolated driver's compartment, the driver (if they were involved in direct patient care) should

remove and dispose of PPE and perform hand hygiene to avoid soiling the compartment.
  - Close the door/window between these compartments before bringing the patient on board.
  - During transport, vehicle ventilation in both compartments should be on non-recirculated mode to maximize air changes that reduce potentially infectious particles in the vehicle.
  - If the vehicle has a rear exhaust fan, use it to draw air away from the cab, toward the patient-care area, and out the back end of the vehicle.
  - Some vehicles are equipped with a supplemental recirculating ventilation unit that passes air through high-efficiency particulate air (HEPA) filters before returning it to the vehicle. Such a unit can be used to increase the number of air changes per hour (ACH) Health Hazard Evaluation Report 95-0031-2601 pdf .
  - After patient unloading, allowing a few minutes with ambulance module doors open will rapidly dilute airborne viral particles.
- If a vehicle without an isolated driver compartment must be used, open the outside air vents in the driver area and turn on the rear exhaust ventilation fans to the highest setting to create a pressure gradient toward the patient area.
  - Before entering the driver's compartment, the driver (if they were involved in direct patient care) should remove their gown, gloves and eye protection and perform hand hygiene to avoid soiling the compartment. They should continue to wear their NIOSH-approved particulate respirator with N95 filters or higher.

Additional considerations when performing AGPs on patients with suspected or confirms SARS-CoV-2 infection:

- If possible, consult with medical control before performing AGPs for specific guidance.
- Bag valve masks (BVMs) and other ventilatory equipment should be equipped with HEPA filtration to filter expired air.
- EMS systems should consult their ventilator equipment manufacturer to confirm appropriate filtration capability and the effect of filtration on positive-pressure ventilation.
- If possible, the rear doors of the stationary transport vehicle should be opened and the HVAC system should be activated during AGPs. This should be done away from pedestrian traffic.
- If possible, discontinue AGPs prior to entering the destination facility or communicate with receiving personnel that AGPs are being implemented.

Dental Facilities

- Dental healthcare personnel (DHCP) should regularly consult their state dental boards and state or local health departments for current information and recommendations and requirements specific to their jurisdictions, which might change based on SARS-CoV-2 transmission levels in the county where their healthcare facility is located.
- Patients with suspected or confirmed SARS-CoV-2 infection should postpone all non-urgent dental treatment until they meet criteria to discontinue Transmission-Based Precautions. Because dental patients cannot wear a mask, in general, those who have had close contact with someone with SARS-CoV-2 infection should also postpone all non-urgent dental treatment until they meet the healthcare criteria to end quarantine.
  - Dental care for these patients should only be provided if medically necessary. Follow all recommendations for care and placement for patients with suspected or confirmed SARS-CoV-2 infection. Extra attention may be required to ensure HVAC ventilation to the dental treatment area does not reduce or deactivate during occupancy based on temperature demands.
  - If a patient has a fever strongly associated with a dental diagnosis (e.g., pulpal and periapical dental pain and intraoral swelling are present) but no other symptoms consistent with COVID-19 are present, dental care can be provided following the practices recommended for routine health care during the pandemic.
- When performing aerosol-generating procedures on patients who are not suspected or confirmed to have SARS-CoV-2 infection, ensure that DHCP correctly wear the recommended PPE (including consideration of a NIOSH-approved particulate respirator with N95 filters or higher in counties with high levels of transmission) and use mitigation methods such as four-handed dentistry, high evacuation suction, and dental dams to minimize droplet spatter and aerosols.
  - Commonly used dental equipment known to create aerosols and airborne contamination include ultrasonic scaler, high-speed dental handpiece, air/water syringe, air polishing, and air abrasion.
- Dental treatment should be provided in individual patient rooms whenever possible with the HVAC in constant ventilation mode.
- For dental facilities with open floor plans, strategies to prevent the spread of pathogens include:
  - At least 6 feet of space between patient chairs.

- Adjunct use of portable HEPA air filtration systems to enhance air cleaning
- Physical barriers between patient chairs. Easy-to-clean floor-to-ceiling barriers will enhance effectiveness of portable HEPA air filtration systems (check to make sure that extending barriers to the ceiling will not interfere with fire sprinkler systems).
- Operatories oriented parallel to the direction of airflow when possible.
- Where feasible, consider patient orientation carefully, placing the patient's head near the return air vents, away from pedestrian corridors, and toward the rear wall when using vestibule-type office layouts.
- Ensure to account for the time required to clean and disinfect operatories between patients when calculating your daily patient volume.

Nursing Homes

- Assign one or more individuals with training in IPC to provide on-site management of the IPC program
  - This should be a full-time role for at least one person in facilities that have more than 100 residents or that provide on-site ventilator or hemodialysis services. Smaller facilities should consider staffing the IPC program based on the resident population and facility service needs identified in the IPC risk assessment.
- Stay connected with the healthcare-associated infection program in your state health department, as well as your local health department, and their notification requirements. Report SARS-CoV-2 infection data to National Healthcare Safety Network (NHSN) Long-term Care Facility (LTCF) COVID-19 Module. See Centers for Medicare & Medicaid Services (CMS) COVID-19 reporting requirements .
- Managing admissions and residents who leave the facility:
  - In general, admissions in counties where Community Transmission levels are high should be tested upon admission; admission testing at lower levels of Community Transmission is at the discretion of the facility.
    - Testing is recommended at admission and, if negative, again 48 hours after the first negative test and, if negative, again 48 hours after the second negative test.

    They should also be advised to wear source control for the 10 days following their admission. Residents who leave the facility for 24 hours or longer should generally be managed as an admission.

- Empiric use of Transmission-Based Precautions is generally not necessary for admissions or for residents who leave the facility for less than 24 hours (e.g., for medical appointments, community outings) and do not meet criteria described in section 2.
- Placement of residents with suspected or confirmed SARS-CoV-2 infection
  - Ideally, residents should be placed in a single-person room as described in Section 2.
  - If limited single rooms are available, or if numerous residents are simultaneously identified to have known SARS-CoV-2 exposures or symptoms concerning for COVID-19, residents should remain in their current location.
- Responding to a newly identified SARS-CoV-2-infected HCP or resident
  - When performing an outbreak response to a known case, facilities should always defer to the recommendations of the jurisdiction's public health authority.
  - A single new case of SARS-CoV-2 infection in any HCP or resident should be evaluated to determine if others in the facility could have been exposed.
  - The approach to an outbreak investigation could involve either contact tracing or a broad-based approach; however, a broad-based (e.g., unit, floor, or other specific area(s) of the facility) approach is preferred if all potential contacts cannot be identified or managed with contact tracing or if contact tracing fails to halt transmission.
  - Perform testing for all residents and HCP identified as close contacts or on the affected unit(s) if using a broad-based approach, regardless of vaccination status.
    - Testing is recommended immediately (but not earlier than 24 hours after the exposure) and, if negative, again 48 hours after the first negative test and, if negative, again 48 hours after the second negative test. This will typically be at day 1 (where day of exposure is day 0), day 3, and day 5.
    - Due to challenges in interpreting the result, testing is generally not recommended for asymptomatic people who have recovered from SARS-CoV-2 infection in the prior 30 days. Testing should be considered for those who have recovered in the prior 31-90 days; however, an antigen test instead of a nucleic acid amplification test (NAAT) is recommended. This is because some people may remain NAAT positive but not be infectious during this period.

- Empiric use of Transmission-Based Precautions for residents and work restriction for HCP are not generally necessary unless residents meet the criteria described in Section 2 or HCP meet criteria in the Interim Guidance for Managing Healthcare Personnel with SARS-CoV-2 Infection or Exposure to SARS-CoV-2, respectively. However, source control should be worn by all individuals being tested.
    - In the event of ongoing transmission within a facility that is not controlled with initial interventions, strong consideration should be given to use of Empiric use of Transmission-Based Precautions for residents and work restriction of HCP with higher-risk exposures. In addition, there might be other circumstances for which the jurisdiction's public authority recommends these and additional precautions.
    - If no additional cases are identified during contact tracing or the broad-based testing, no further testing is indicated. Empiric use of Transmission-Based Precautions for residents and work restriction for HCP who met criteria can be discontinued as described in Section 2 and the Interim Guidance for Managing Healthcare Personnel with SARS-CoV-2 Infection or Exposure to SARS-CoV-2, respectively.
    - If additional cases are identified, strong consideration should be given to shifting to the broad-based approach if not already being performed and implementing quarantine for residents in affected areas of the facility. As part of the broad-based approach, testing should continue on affected unit(s) or facility-wide every 3-7 days until there are no new cases for 14 days.
        - If antigen testing is used, more frequent testing (every 3 days), should be considered.
- **Indoor visitation during an outbreak response:**
    - Facilities should follow guidance from CMS about visitation.
    - Visitors should be counseled about their potential to be exposed to SARS-CoV-2 in the facility.
    - If indoor visitation is occurring in areas of the facility experiencing transmission, it should ideally occur in the resident's room. The resident and their visitors should wear well-fitting source control (if tolerated) and physically distance (if possible) during the visit.

Assisted Living, Group Homes and Other Residential Care Settings (excluding nursing homes)

In general, long-term care settings (excluding nursing homes) whose staff provide non-skilled personal care* similar to that provided by family members in the home (e.g., many assisted livings, group homes), should follow community prevention strategies based on COVID-19 Community Levels, similar to independent living, retirement communities or other non-healthcare congregate settings. Residents should also be counseled about strategies to protect themselves and others, including recommendations for source control if they are immunocompromised or at high risk for severe disease. CDC has information and resources for older adults and for people with disabilities.

Visiting or shared healthcare personnel who enter the setting to provide healthcare to one or more residents (e.g., physical therapy, wound care, intravenous injections, or catheter care provided by home health agency nurses) should follow the healthcare IPC recommendations in this guidance. In addition, if staff in a residential care setting are providing in-person services for a resident with SARS-CoV-2 infection, they should be familiar with recommended IPC practices to protect themselves and others from potential exposures including the hand hygiene, personal protective equipment and cleaning and disinfection practices outlined in this guidance.

*Non-skilled personal care consists of any non-medical care that can reasonably and safely be provided by non-licensed caregivers, such as help with daily activities like bathing and dressing; it may also include the kind of health-related care that most people do themselves, like taking oral medications. In some cases where care is received at home or a residential setting, care can also include help with household duties such as cooking and laundry.

Definitions:

Healthcare Personnel (HCP): HCP refers to all paid and unpaid persons serving in healthcare settings who have the potential for direct or indirect exposure to patients or infectious materials, including body substances (e.g., blood, tissue, and specific body fluids); contaminated medical supplies, devices, and equipment; contaminated environmental surfaces; or contaminated air. HCP include, but are not limited to, emergency medical service personnel, nurses, nursing assistants, home healthcare personnel, physicians, technicians, therapists, phlebotomists, pharmacists, dental healthcare personnel, students and trainees, contractual staff not employed by the healthcare facility, and persons not directly involved in patient care, but

who could be exposed to infectious agents that can be transmitted in the healthcare setting (e.g., clerical, dietary, environmental services, laundry, security, engineering and facilities management, administrative, billing, and volunteer personnel).

Healthcare settings refers to places where healthcare is delivered and includes, but is not limited to, acute care facilities, long-term acute-care facilities, nursing homes, home healthcare, vehicles where healthcare is delivered (e.g., mobile clinics), and outpatient facilities, such as dialysis centers, physician offices, dental offices, and others.

Source control: Use of respirators, well-fitting facemasks, or well-fitting cloth masks to cover a person's mouth and nose to prevent spread of respiratory secretions when they are breathing, talking, sneezing, or coughing. Source control devices should not be placed on children under age 2, anyone who cannot wear one safely, such as someone who has a disability or an underlying medical condition that precludes wearing one safely, or anyone who is unconscious, incapacitated, or otherwise unable to remove their source control device without assistance. Face shields alone are not recommended for source control. At a minimum, source control devices should be changed if they become visibly soiled, damaged, or hard to breathe through. Further information about source control options is available at: Masks and Respirators (cdc.gov)

Cloth mask: Textile (cloth) covers that are intended primarily for source control in the community. **They are not personal protective equipment (PPE) appropriate for use by healthcare personnel.** Guidance on design, use, and maintenance of cloth masks is available.

Facemask: OSHA defines facemasks as "a surgical, medical procedure, dental, or isolation mask that is FDA-cleared, authorized by an FDA EUA, or offered or distributed as described in an FDA enforcement policy. Facemasks may also be referred to as 'medical procedure masks'." Facemasks should be used according to product labeling and local, state, and federal requirements. FDA-cleared surgical masks are designed to protect against splashes and sprays and are prioritized for use when such exposures are anticipated, including surgical procedures. Other facemasks, such as some procedure masks, which are typically used for isolation purposes, may not provide protection against splashes and sprays.

Respirator: A respirator is a personal protective device that is worn on the face, covers at least the nose and mouth, and is used to reduce the wearer's risk of inhaling hazardous airborne particles (including dust particles and infectious agents), gases, or vapors. Respirators are certified by CDC/NIOSH, including those intended for use in healthcare.

Airborne Infection Isolation Rooms (AIIRs):

- AIIRs are single-patient rooms at negative pressure relative to the surrounding areas, and with a minimum of 12 ACH (6 ACH are allowed for AIIRs last renovated or constructed prior to 1997).
- Air from these rooms should be exhausted directly to the outside or be filtered through a HEPA filter directly before recirculation.
- Room doors should be kept closed except when entering or leaving the room, and entry and exit should be minimized.
- Facilities should monitor and document the proper negative-pressure function of these rooms.

Immunocompromised: For the purposes of this guidance, moderate to severely immunocompromising conditions include, but might not be limited to, those defined in the Interim Clinical Considerations for Use of COVID-19 Vaccines

- Other factors, such as end-stage renal disease, may pose a lower degree of immunocompromise. However, people in this category should still consider continuing to use of source control while in a healthcare facility.
- Ultimately, the degree of immunocompromise for the patient is determined by the treating provider, and preventive actions are tailored to each individual and situation.

Close contact: Being within 6 feet for a cumulative total of 15 minutes or more over a 24-hour period with someone with SARS-CoV-2 infection.

SARS-CoV-2 Illness Severity Criteria (adapted from the NIH COVID-19 Treatment Guidelines)

The studies used to inform this guidance did not clearly define "severe" or "critical" illness. This guidance has taken a conservative approach to define these categories. Although not developed to inform decisions about duration of Transmission-Based Precautions, the definitions in the National Institutes of Health (NIH) COVID-19 Treatment Guideline s are one option for defining severity of illness categories. The highest level of illness severity experienced by the patient at

any point in their clinical course should be used when determining the duration of Transmission-Based Precautions. Clinical judgement regarding the contribution of SARS-CoV-2 to clinical severity might also be necessary when applying these criteria to inform infection control decisions.

Mild Illness: Individuals who have any of the various signs and symptoms of COVID-19 (e.g., fever, cough, sore throat, malaise, headache, muscle pain) without shortness of breath, dyspnea, or abnormal chest imaging.

Moderate Illness: Individuals who have evidence of lower respiratory disease by clinical assessment or imaging, and a saturation of oxygen (SpO2) ≥94% on room air at sea level.

Severe Illness: Individuals who have respiratory frequency >30 breaths per minute, SpO2 <94% on room air at sea level (or, for patients with chronic hypoxemia, a decrease from baseline of >3%), ratio of arterial partial pressure of oxygen to fraction of inspired oxygen (PaO2/FiO2) <300 mmHg, or lung infiltrates >50%.

Critical Illness: Individuals who have respiratory failure, septic shock, and/or multiple organ dysfunction.

In pediatric patients, radiographic abnormalities are common and, for the most part, should not be used as the sole criteria to define COVID-19 illness category. Normal values for respiratory rate also vary with age in children, thus hypoxia should be the primary criterion to define severe illness, especially in younger children.

More Information

Interim Clinical Considerations for Use of COVID-19 Vaccines

Management of Patients with Confirmed 2019-nCoV

Interim Guidance for Managing Healthcare Personnel with SARS-CoV-2 Infection or Exposure to SARS-CoV-2

Strategies to Mitigate Healthcare Personnel Staffing Shortages

Clinical Questions about COVID-19: Questions and Answers

Management of Patients with Confirmed 2019-nCoV

Previous Updates

Updates as of February 2, 2022

Due to concerns about increased transmissibility of the SARS-CoV-2 Omicron variant, this guidance is being updated to enhance protection for healthcare personnel, patients, and visitors and to address concerns about potential impacts on the healthcare system given a surge in SARS-CoV-2 infections. These updates will be refined as additional information becomes available to inform recommended actions.

- Empiric use of Transmission-Based Precautions (quarantine) is recommended for patients who have had close contact with someone with SARS-CoV-2 infection if they are not up to date with all recommended COVID-19 vaccine doses.
  - In general, quarantine is not needed for asymptomatic patients who are up to date with all recommended COVID-19 vaccine doses or who have recovered from SARS-CoV-2 infection in the prior 90 days; potential exceptions are described in the guidance. However, some of these patients should still be tested as described in the testing section of the guidance.
- A test-based strategy and (if available) consultation with infectious disease experts is now recommended for determining the duration of Transmission-Based Precautions for patients with SARS-CoV-2 infection who are moderately to severely immunocompromised.

- Included additional examples when universal respirator use could be considered
- Additional updates that will have implications for healthcare facilities were made in the following guidance documents:
  - Interim Guidance for Managing Healthcare Personnel with SARS-CoV-2 Infection or Exposure to SARS-CoV-2
  - Strategies to Mitigate Healthcare Personnel Staffing Shortages
  - Interim Infection Prevention and Control Recommendations to Prevent SARS-CoV-2 Spread in Nursing Homes

Updates as of September 10, 2021

- Updated source control recommendations to address limited situations for healthcare facilities in counties with low to moderate community transmission where select fully vaccinated individuals could choose not to wear source control. However, in general, the safest practice is for everyone in a healthcare setting to wear source control.
- Updated quarantine recommendations for fully vaccinated patients who have had close contact with someone with SARS-CoV-2 infection to more closely align with recommendations for the community.
- Clarified the recommended intervals for testing asymptomatic HCP with a higher-risk exposure and patients with close contact with someone with SARS-CoV-2 infection.
- Added content from previously posted CDC guidance addressing:
  - Recommendations for fully vaccinated HCP, patients, and visitors
  - SARS-CoV-2 testing
  - Duration of Transmission-Based Precautions for patients with SARS-CoV-2 infection
  - Specialized healthcare settings (e.g., dental, dialysis, EMS)

As of February 10, 2021

- Updated the Implement Universal Use of Personal Protective Equipment section to expand options for source control and patient care activities in areas of moderate to substantial transmission and describe strategies for improving fit of facemasks. Definitions of source control are included at the end of this document.
- Included a reference to Optimizing Personal Protective Equipment (PPE) Supplies that include a hierarchy of strategies to implement when PPE are in short supply or unavailable.

As of December 14, 2020

- Added links to Frequently Asked Questions addressing Environmental Cleaning and Disinfection and assessing risks to patients and others exposed to healthcare personnel who worked while infected with SARS-CoV-2
- Described recommended IPC practices when caring for patients who have met **criteria for a 14-day quarantine based on prolonged close contact with someone with SARS-CoV-2 infection.**
- **Added reminders that:**
  - Double gloving is not recommended when providing care to patients with suspected or confirmed SARS-CoV-2 infection
  - In general, HCP caring for patients with suspected or confirmed SARS-CoV-2 infection should not wear more than one isolation gown at a time.

As of November 4, 2020

- Provided different options for screening individuals (healthcare personnel, patients, visitors) prior to their entry into a healthcare facility
- Provided information on factors that could impact thermometer readings
- Provided resources for evaluating and managing ventilation systems in healthcare facilities
- Added link to Frequently Asked Questions about use of Personal Protective Equipment

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop C2-21-16
Baltimore, Maryland 21244-1850

CENTERS FOR MEDICARE & MEDICAID SERVICES

Center for Clinical Standards and Quality/Survey & Certification Group

Ref: QSO-20-38-NH

DATE: **August 26, 2020** ***REVISED 09/23/2022***

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: **Interim Final Rule (IFC), CMS-3401-IFC, Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency related to Long-Term Care (LTC) Facility Testing Requirements**

Memorandum Summary

- CMS is committed to taking critical steps to ensure America's healthcare facilities continue to respond effectively to the Coronavirus Disease 2019 (COVID-19) Public Health Emergency (PHE).
- On August 25, 2020, CMS published an interim final rule with comment period (IFC). This rule establishes **Long-Term Care (LTC) Facility Testing Requirements for Staff and Residents.** Specifically, facilities are required to test residents and staff, including individuals providing services under arrangement and volunteers, for COVID-19 based on parameters set forth by the HHS Secretary. This memorandum provides guidance for facilities to meet the new requirements.
- *Routine testing of asymptomatic staff is no longer recommended but may be performed at the discretion of the facility.*
- *Updated recommendations for testing individuals who have recovered from COVID-19.*

On August 25, 2020, CMS published an interim final rule with comment period (IFC), CMS-3401-IFC, entitled "Medicare and Medicaid Programs, Clinical Laboratory Improvement Amendments of 1988 (CLIA), and Patient Protection and Affordable Care Act; Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency". CMS's recommendation below to test with authorized nucleic acid or antigen detection assays is an important addition to other infection prevention and control (IPC) recommendations aimed at preventing COVID-19 from entering nursing homes, detecting cases quickly, and stopping transmission. Swift identification of confirmed COVID-19 cases allows the facility to take immediate action to remove exposure risks to nursing home residents and staff. CMS has added 42 CFR § 483.80(h) which requires that the facility test all residents and staff for COVID-19. Guidance related to the requirements is located below. Noncompliance related to this new requirement will be cited at new tag F886.

Attach. 2

§ 483.80 Infection control

* * * * *

§ 483.80(h) *COVID-19 Testing*. The LTC facility must test residents and facility staff, including individuals providing services under arrangement and volunteers, for COVID-19. At a minimum, for all residents and facility staff, including individuals providing services under arrangement and volunteers, the LTC facility must:

(1) Conduct testing based on parameters set forth by the Secretary, including but not limited to:

(i) Testing frequency;

(ii) The identification of any individual specified in this paragraph diagnosed with COVID-19 in the facility;

(iii) The identification of any individual specified in this paragraph with symptoms consistent with COVID-19 or with known or suspected exposure to COVID-19;

(iv) The criteria for conducting testing of asymptomatic individuals specified in this paragraph, such as the positivity rate of COVID-19 in a county;

(v) The response time for test results; and

(vi) Other factors specified by the Secretary that help identify and prevent the transmission of COVID-19.

(2) Conduct testing in a manner that is consistent with current standards of practice for conducting COVID-19 tests;

(3) For each instance of testing:

(i) Document that testing was completed and the results of each staff test; and

(ii) Document in the resident records that testing was offered, completed (as appropriate to the resident's testing status), and the results of each test.

(4) Upon the identification of an individual specified in this paragraph with symptoms consistent with COVID-19, or who tests positive for COVID-19, take actions to prevent the transmission of COVID-19.

(5) Have procedures for addressing residents and staff, including individuals providing services under arrangement and volunteers, who refuse testing or are unable to be tested.

(6) When necessary, such as in emergencies due to testing supply shortages, contact state and local health departments to assist in testing efforts, such as obtaining testing supplies or processing test results.

F886

DEFINITIONS

"Close contact " refers to someone who has been within 6 feet of a COVID-19 positive person for a cumulative total of 15 minutes or more over a 24-hour period.

"Higher-risk exposure" refers to exposure of an individual's eyes, nose, or mouth to material potentially containing SARS-CoV-2, particularly if present in the room for an aerosol-generating

procedure. This can occur when staff do not wear adequate personal protective equipment during care or interaction with an individual. For more information, see CDC's "Interim Guidance for Managing Healthcare Personnel with SARS-CoV-2 Infection or Exposure to SARS-CoV-2."

GUIDANCE

Testing of Nursing Home Staff and Residents

To enhance efforts to keep COVID-19 from entering and spreading through nursing homes, facilities are required to test residents and staff based on parameters and a frequency set forth by the HHS Secretary.

Facilities can meet the testing requirements through the use of rapid point-of-care (POC) diagnostic testing devices or through an arrangement with an offsite laboratory. POC testing is diagnostic testing that is performed at or near the site of resident care. For a facility to conduct these tests with their own staff and equipment (including POC devices provided by the Department of Health and Human Services), the facility must have, at a minimum, a CLIA Certificate of Waiver. Information on obtaining a CLIA Certificate of Waiver can be found here.

Facilities without the ability to conduct COVID-19 POC testing should have arrangements with a laboratory to conduct tests to meet these requirements. Laboratories that can quickly process large numbers of tests with rapid reporting of results (e.g., within 48 hours) should be selected to rapidly inform infection prevention initiatives to prevent and limit transmission.

"Facility staff" includes employees, consultants, contractors, volunteers, and caregivers who provide care and services to residents on behalf of the facility, and students in the facility's nurse aide training programs or from affiliated academic institutions. For the purpose of testing "individuals providing services under arrangement and volunteers," facilities should prioritize those individuals who are regularly in the facility (e.g., weekly) and have contact with residents or staff. We note that the facility may have a provision under its arrangement with a vendor or volunteer that requires them to be tested from another source (e.g., their employer or on their own). However, the facility is still required to obtain documentation that the required testing was completed during the timeframe that corresponds to the facility's testing frequency, as described in Table 2 below.

When prioritizing individuals to be tested, facilities should prioritize individuals with signs and symptoms of COVID-19 first, then perform testing triggered by an outbreak investigation (as specified below).

Instruct facility staff, regardless of their vaccination status, to report any of the following criteria to occupational health or another point of contact designated by the facility so they can be properly managed:

- *a positive viral test for SARS-CoV-2,*
- *symptoms of COVID-19, or*
- *a higher-risk exposure to someone with SARS-CoV-2 infection*

Table 1: Testing Summary

Testing Trigger	Staff	Residents
Symptomatic individual identified	Staff, regardless of vaccination status, with signs or symptoms must be tested.	Residents, regardless of vaccination status, with signs or symptoms must be tested.
Newly identified COVID-19 positive staff or resident in a facility that can identify close contacts	Test all staff, regardless of vaccination status, that had a higher-risk exposure with a COVID-19 positive individual.	Test all residents, regardless of vaccination status, that had close contact with a COVID-19 positive individual.
Newly identified COVID-19 positive staff or resident in a facility that is unable to identify close contacts	Test all staff, regardless of vaccination status, facility-wide or at a group level if staff are assigned to a specific location where the new case occurred (e.g., unit, floor, or other specific area(s) of the facility).	Test all residents, regardless of vaccination status, facility-wide or at a group level (e.g., unit, floor, or other specific area(s) of the facility).
Routine testing	*Not generally recommended*	Not generally recommended

Testing of Staff and Residents with COVID-19 Symptoms or Signs

Staff with symptoms or signs of COVID-19, regardless of vaccination status, must be tested *as soon as possible* and are expected to be restricted from the facility pending the results of COVID-19 testing. If COVID-19 is confirmed, staff should follow Centers for Disease Control and Prevention (CDC) guidance "Interim Guidance for Managing Healthcare Personnel with SARS-CoV-2 Infection or Exposure to SARS-CoV-2." Staff who do not test positive for COVID-19 but have symptoms should follow facility policies to determine when they can return to work.

Residents who have signs or symptoms of COVID-19, regardless of vaccination status, must be tested *as soon as possible*. While test results are pending, residents with signs or symptoms should be placed on transmission-based precautions (TBP) in accordance with CDC guidance. Once test results are obtained, the facility must take the appropriate actions based on the results.

NOTE: Concerns related to initiating and/or maintaining TBP should be investigated under F880, Infection Control.

Testing of Staff with a Higher-Risk Exposure and Residents who had a Close Contact

For information on testing staff with a higher-risk exposure to COVID-19 and residents who had close contact with a COVID-19 positive individual, when the facility is not in an outbreak status, see the CDC's "Interim Infection Prevention and Control Recommendations for Healthcare Personnel During the Coronavirus Disease 2019 (COVID-19) Pandemic" and "Interim Guidance for Managing Healthcare Personnel with SARS-CoV-2 Infection or Exposure to SARS-CoV-2." Examples may include exposures from a visitor, while on a leave of absence, or during care of a resident on the COVID-19 unit.

Testing of Staff and Residents During an Outbreak Investigation

An outbreak investigation is initiated when a single new case of COVID-19 occurs among residents or staff to determine if others have been exposed. An outbreak investigation would not be triggered when a resident with known COVID-19 is admitted directly into TBP, or when a resident known to have close contact with someone with COVID-19 is admitted directly into TBP and develops COVID-19 before TBP are discontinued. In an outbreak investigation, rapid identification and isolation of new cases is critical in stopping further viral transmission.

Upon identification of a single new case of COVID-19 infection in any staff or residents, testing should begin immediately *(but not earlier than 24 hours after the exposure, if known)*. Facilities have the option to perform outbreak testing through two approaches, contact tracing or broad-based (e.g. facility-wide) testing.

If the facility has the ability to identify close contacts of the individual with COVID-19, they could choose to conduct focused testing based on known close contacts. If a facility does not have the expertise, resources, or ability to identify all close contacts, they should instead investigate the outbreak at a facility-wide or group-level (e.g., unit, floor, or other specific area(s) of the facility). Broader approaches might also be required if the facility is directed to do so by the jurisdiction's public health authority, or in situations where all potential contacts are unable to be identified, are too numerous to manage, or when contact tracing fails to halt transmission.

For further information on contact tracing and broad-based testing, including frequency of repeat testing, see CDC guidance "Interim Infection Prevention and Control Recommendations for Healthcare Personnel During the Coronavirus Disease 2019 (COVID-19) Pandemic"

For individuals who test positive for COVID-19, facilities should follow the CDC "Interim Infection Prevention and Control Recommendations for Healthcare Personnel During the Coronavirus Disease 2019 (COVID-19) Pandemic" guidance for *discontinuing TBP for* residents and the "Interim Guidance for Managing Healthcare Personnel with SARS-CoV-2 Infection or Exposure to SARS-CoV-2." for staff.

Routine Testing of Staff

Routine screening testing of asymptomatic staff is no longer recommended but may be performed at the discretion of the facility. See the CDC's Interim Infection Prevention and Control Recommendations for Healthcare Personnel During the Coronavirus Disease 2019 (COVID-19) Pandemic guidance for additional information.

State and local officials may also direct facilities to monitor other factors that increase the risk for COVID-19 transmission, such as rates of Emergency Department visits of individuals with COVID-19-like symptoms. Facilities should consult with state and local officials on these factors, and the actions that should be taken to reduce the spread of the virus.

Facilities should inform resident transportation services (such as non-emergency medical transportation) and receiving healthcare providers (such as hospitals) regarding a resident's COVID-19 status to ensure appropriate infection control precautions are followed. Routine communication between the nursing home and other entities about the resident's status should ideally occur prior to the resident leaving the nursing home for treatment. Coordination between the nursing home and the other healthcare entity is vital to ensure healthcare staff are informed of the most up to date information relating to the resident's health status, including COVID-19 status, and to allow for proper planning of care and operations. Additionally, facilities should maintain communications with the local ambulance and other contracted providers that transport residents between facilities, to ensure appropriate infection control precautions are followed as described by the CDC.

Resident Testing – New Admissions

For testing information of residents who are newly admitted or readmitted to the facility and those who leave the facility for 24 hours or longer, see the Managing admissions and residents who leave the facility section of the CDC's Interim Infection Prevention and Control Recommendations for Healthcare Personnel During the Coronavirus Disease 2019 (COVID-19) Pandemic webpage.

Refusal of Testing

Facilities must have procedures in place to address staff who refuse testing. Procedures should ensure that staff who have signs or symptoms of COVID-19 and refuse testing are prohibited from entering the building until the return to work criteria are met. If outbreak testing has been triggered and a staff member refuses testing, the staff member should be restricted from the building until the procedures for outbreak testing have been completed. The facility should follow its occupational health and local jurisdiction policies with respect to any asymptomatic staff who refuses routine testing.

Residents (or resident representatives) may exercise their right to decline COVID-19 testing in accordance with the requirements under 42 CFR § 483.10(c)(6). In discussing testing with residents, staff should use person-centered approaches when explaining the importance of testing for COVID-19. Facilities must have procedures in place to address residents who refuse testing. Procedures should ensure that residents who refuse testing *managed in accordance with the CDC guidance for use of TBP.*

Clinical discussions about testing may include alternative specimen collection sources that may be more acceptable to residents than nasopharyngeal swabs (e.g., anterior nares). Providing information about the method of testing and reason for pursuing testing may facilitate discussions with residents or resident representatives.

Other Testing Considerations

In general, testing is not necessary for asymptomatic people who have recovered from SARS-CoV-2 infection in the prior *30* days; *testing should be considered for those who have recovered in the prior 31-90 days* however, if testing is performed on these people, an antigen test instead of a nucleic acid amplification test (NAAT) is recommended. This is because some people may remain NAAT positive but not be infectious during this period. Facilities should continue to monitor *CMS and CDC guidance* and FAQs for the latest information. For residents or staff who test positive, facilities should *follow the guidance in the Testing Staff and Residents During an Outbreak section above and* contact the appropriate state or local entity for contact tracing.

Conducting Testing

In accordance with 42 CFR § 483.50(a)(2)(i), the facility must obtain an order from a physician, physician assistant, nurse practitioner, or clinical nurse specialist in accordance with state law, including scope of practice laws to provide or obtain laboratory services for a resident, which includes COVID-19 testing (see F773). This may be accomplished through the use of physician approved policies (e.g., standing orders), or other means as specified by scope of practice laws and facility policy.

NOTE: Concerns related to orders for laboratory and/or POC testing should be investigated under F773.

Rapid POC testing devices are prescription use tests under the Emergency Use Authorization and must be ordered by a healthcare professional licensed under the applicable state law or a pharmacist under HHS guidance. Accordingly, the facility must have an order from a healthcare professional or pharmacist, as previously described, to perform a rapid POC COVID-19 test on an individual.

A diagnostic test shows if a patient has an active coronavirus infection. As of the date of this guidance, there are two types of diagnostic tests which detect the active virus – molecular tests, such as RT-PCR tests, that detect the virus's genetic material, and antigen tests that detect specific proteins on the surface of the virus. An antibody test looks for antibodies that are made by the immune system in response to a threat, such as a specific virus. An antibody test does not identify an active coronavirus infection; therefore, conducting an antibody test on a staff or resident would not meet the requirements under this regulation.

Frequently asked questions related to the use of these testing devices in high-risk congregate settings such as nursing homes can be found *on the CMS Current Emergencies webpage, in the For Labs section*. In addition, when testing residents, a facility's selection of a test should be person-centered.

Collecting and handling specimens correctly and safely is imperative to ensure the accuracy of test results and prevent any unnecessary exposures. The specimen should be collected and, if necessary, stored in accordance with the manufacturer's instructions for use for the test and CDC guidelines.

During specimen collection, facilities must maintain proper infection control and use recommended personal protective equipment (PPE), which includes a NIOSH-approved N95 or equivalent or higher-level respirator (or facemask if a respirator is not available), eye protection, gloves, and a gown, when collecting specimens.

The CDC has provided guidance on proper specimen collection:

- Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens from Persons for Coronavirus Disease 2019 (COVID-19): https://www.cdc.gov/coronavirus/2019-ncov/lab/guidelines-clinical-specimens.html.
- CDC's Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with Coronavirus Disease 2019 (COVID-19): https://www.cdc.gov/coronavirus/2019-ncov/lab/lab-biosafety-guidelines.html.

For additional considerations for antigen testing, see CDC's Perform SARS-CoV-2 Viral Testing

As a reminder, per 42 CFR § 483.50(a), the facility must provide or obtain laboratory services to meet the needs of its residents. If a facility provides its own laboratory services or performs any laboratory tests directly (e.g., SARS-CoV-2 point-of-care test) the provisions of 42 CFR Part 493 apply and the facility must have a current CLIA certificate appropriate for the level of testing performed within the facility. Surveyors should only verify that the facility has a current CLIA certificate and not attempt to determine compliance with the requirements in 42 CFR Part 493.

Reporting Test Results

Facilities conducting tests are required to have a CLIA certificate and are subject to regulations that require laboratories to report results for all testing completed, for each individual tested, to state or local health departments. For additional information on reporting requirements see:

- Frequently Asked Questions: COVID-19 Testing at Skilled Nursing Facilities/Nursing Homes
- CMS memorandum: Interim Final Rule (IFC). CMS-3401-IFC, Updating Requirements for Reporting of SARS-CoV-2 Test Results by Clinical Laboratory Improvement Amendments of 1988 (CLIA) Laboratories, and Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency

Surveyors should report concerns related to CLIA certificates or laboratory reporting requirements to their CLIA State Agency contact. When reporting concerns include the CLIA number; name and address of laboratory (facility); number of days that results were not reported, if known; and number of results not reported, if known.

In addition to reporting in accordance with CLIA requirements, facilities must continue to report COVID-19 information to the CDC's National Healthcare Safety Network (NHSN), in accordance with 42 CFR § 483.80(g)(1)–(2). See "Interim Final Rule Updating Requirements for Notification of Confirmed and Suspected COVID-19 Cases Among Residents and Staff in Nursing Homes," CMS Memorandum QSO-20-29-NH (May 6, 2020).

NOTE: Concerns related to informing residents, their representatives and families of new or suspected cases of COVID-19 should be investigated under F885.

NOTE: Concerns related to the reporting to state and local public health authority of communicable diseases and outbreaks, including for purposes such as contact tracing, should be investigated under F880.

Documentation of Testing

Facilities must demonstrate compliance with the testing requirements. To do so, facilities should do the following:

- For symptomatic residents and staff, document the date(s) and time(s) of the identification of signs or symptoms, when testing was conducted, when results were obtained, and the actions the facility took based on the results.
- Upon identification of a new COVID-19 case in the facility, document the date the case was identified, the date that other residents and staff are tested, the dates that staff and residents who tested negative are retested, and the results of all tests (see section "Testing of Staff and Residents During an Outbreak Investigation" above).
- Document the facility's procedures for addressing residents and staff that refuse testing or are unable to be tested, and document any staff or residents who refused or were unable to be tested and how the facility addressed those cases.
- When necessary, such as in emergencies due to testing supply shortages, document that the facility contacted state and local health departments to assist in testing efforts, such as obtaining testing supplies or processing test results.

Facilities may document the conducting of tests in a variety of ways, such as a log of community transmission levels, schedules of completed testing, and/or staff and resident records. However, the results of tests must be done in accordance with standards for protected health information. For residents, the facility must document testing results in the medical record. For staff, including individuals providing services under arrangement and volunteers, the facility must document testing results in a secure manner consistent with requirements specified in 483.80(h)(3).

Surveying for Compliance

Compliance will be assessed through the following process using the COVID-19 Focused Survey and during the Standard Survey for Nursing Homes:

1. Surveyors will ask for the facility's documentation noted in the "Documentation of Testing" section above, and review the documentation for compliance.
2. Surveyors will also review records of those residents and staff selected as a sample as part of the survey process.
3. If possible, surveyors should observe how the facility conducts testing in real-time. In this process, surveyors will assess if the facility is conducting testing and specimen collection in a manner that is consistent with current standards of practice for conducting COVID-19 tests, such as ensuring PPE is used correctly to prevent the transmission of the virus. If observation is not possible, surveyors should interview an individual responsible for testing and inquire on how testing is conducted (e.g., "what are the steps taken to conduct each test?").

4. If the facility has a shortage of testing supplies, or cannot obtain test results within 48 hours, the surveyor should ask for documentation that the facility contacted state and local health departments to assist with these issues.

Facilities that do not comply with the testing requirements in § 483.80(h) will be cited for noncompliance at F886. Additionally, enforcement remedies (such as civil money penalties) will be imposed based on the resident outcome (i.e., the scope and severity of the noncompliance), in accordance with Chapter 7 of the State Operations Manual.

If the facility has documentation that demonstrates their attempts to perform and/or obtain testing in accordance with these guidelines (e.g., timely contacting state officials, multiple attempts to identify a laboratory that can provide testing results within 48 hours), surveyors should not cite the facility for noncompliance. Surveyors should also inform the state or local health authority of the facility's lack of resources.

The current Survey/Infection Prevention, Control & Immunization Pathway (CMS-20054) can be found in the LTC Survey Pathways zipfile located at https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/GuidanceforLawsAndRegulations/Nursing-Homes

Contact: Questions related to the nursing home testing requirement may be submitted to: DNH_TriageTeam@cms.hhs.gov.

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

/s/
David R. Wright

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/Survey & Certification Group

Ref: QSO-20-39-NH

DATE: **September 17, 2020** ***REVISED 09/23/2022***

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Nursing Home Visitation - COVID-19 *(REVISED)*

Memorandum Summary

- CMS is committed to continuing to take critical steps to ensure America's healthcare facilities are prepared to respond to the Coronavirus Disease 2019 (COVID-19) Public Health Emergency (PHE).
- **Visitation Guidance:** CMS is issuing new guidance for visitation in nursing homes during the COVID-19 PHE.
- **Visitation is allowed for all residents at all times.**
- ***Updated guidance for face coverings and masks during visits.***
- ***Removed vaccination status from the guidance.***

Background

Nursing homes have been severely impacted by COVID-19, with outbreaks causing high rates of infection, morbidity, and mortality. The vulnerable nature of the nursing home population combined with the inherent risks of congregate living in a healthcare setting have required aggressive efforts tolimit COVID-19 exposure and to prevent the spread of COVID-19 within nursing homes.

In March 2020, CMS issued memorandum QSO 20-14-NH providing guidance to facilities on restricting visitation of all visitors and non-essential healthcare personnel, except for certain compassionate care situations, such as an end-of-life situation.

While CMS guidance has focused on protecting nursing home residents from COVID-19, we recognize that physical separation from family and other loved ones has taken a physical and emotional toll on residents and their loved ones. Residents may feel socially isolated, leading to increased risk for depression, anxiety, and expressions of distress. Residents living with cognitive impairment or other disabilities may find visitor restrictions and other ongoing changes related to COVID-19 confusing or upsetting. CMS understands that nursing home residents derive value from the physical, emotional, and spiritual support they receive through visitation from family and friends. In light of this, CMS is

Attach. 3

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revising the guidance regarding visitation in nursing homes during the COVID-19 PHE. The information contained in this memorandum supersedes and replaces previously issued guidance and recommendations regarding visitation.

Since the release of QSO memorandum 20-39-NH on September 17, 2020, COVID-19 vaccines have received full approval and Emergency Use Authorization from the Food and Drug Administration. Millions of Vaccinations have since been administered to nursing home residents and staff, and these vaccines have been shown to help prevent symptomatic SARS-CoV-2 infection (i.e., COVID-19). In addition, CMS requires nursing homes to educate residents and staff on the risks and benefits of the vaccines, offer to administer the vaccine, and report residentand staff vaccination data to CDC's National Healthcare Safety Network. CMS now posts this information on the CMS COVID-19 Nursing Home Data website along with other COVID-19 data, such as the weekly number of COVID-19 cases and deaths. **Therefore, CMS, in conjunction with the Centers for Disease Control and Prevention (CDC), is updating its visitation guidance accordingly, but emphasizing the importance of maintaining infection prevention practices.**

We note that the reason for visitation restrictions during the COVID-19 PHE were to mitigate the opportunity for visitors to introduce COVID-19 into the nursing home. Per 42 CFR § 483.10(f)(4), aresident has the right to receive visitors of his or her choosing at the time of his or her choosing, andin a manner that does not impose on the rights of another resident, such as a clinical or safety restriction (see 42 CFR § 483.10(f)(4)(v)). In other words, while all residents have a right to visitation, fully open and unrestricted visitation posed a clinical health and safety risk to other residents during this PHE, and therefore, it was reasonable to place limits on visitation. However, current nursing home COVID-19 data shows approximately 87% of residents and *83%* of staff are fully vaccinated as of February 2022.

On November 4, 2021, CMS issued a regulation requiring that all nursing home staff be vaccinated against COVID-19 as a requirement for participating in the Medicare and Medicaid programs. This requirement also applies to nearly all Medicare and Medicaid-certified providers and suppliers. CMS will continue to monitor vaccination and infection rates, including the effects of COVID-19 variants on nursing home residents, which have recently caused the number of cases to slightly increase. However, at this time, continued restrictions on this vital resident's right are no longer necessary.

We acknowledge that there *may* still *be* concerns associated with visitation, however, adherence to the core principles of COVID-19 infection prevention mitigates these concerns. Furthermore, we remind stakeholders that, per 42 CFR § 483.10(f)(2), theresident has the right to make choices about aspects of his or her life in the facility that are significant to the resident. We further note that residents may deny or withdraw consent for a visit at any time, per 42 CFR § 483.10(f)(4)(ii) and (iii). Therefore, if a visitor, resident, or their representative is aware of the risks associated with visitation, and the visit occurs in a manner that does not place other residents at risk (e.g., in the resident's room), the resident must be allowed to receive visitors as he/she chooses.

Guidance

Visitation can be conducted through different means based on a facility's structure and residents' needs, such as in resident rooms, dedicated visitation spaces, *and* outdoors. Regardless of how visitsare conducted, certain core principles and best practices reduce the risk of COVID-19 transmission:

Core Principles of COVID-19 Infection Prevention

- *Facilities should provide guidance (e.g., posted signs at entrances) about recommended actions for visitors who have a positive viral test for COVID-19, symptoms of COVID-19, or have had close contact with someone with COVID-19. Visitors with confirmed COVID-19 infection or compatible symptoms should defer non-urgent in-person visitation until they meet CDC criteria for healthcare settings to end isolation. For visitors who have had close contact with someone with COVID-19 infection, it is safest to defer non-urgent in-person visitation until 10 days after their close contact if they meet criteria described in CDC healthcare guidance (e.g., cannot wear source control).*
- Hand hygiene (use of alcohol-based hand rub is preferred)
- Face covering or mask (covering mouth and nose) in accordance with CDC guidance
- Instructional signage throughout the facility and proper visitor education on COVID-19 signs and symptoms, infection control precautions, other applicable facility practices (e.g., use of face covering or mask, specified entries, exits and routes to designated areas, hand hygiene)
- Cleaning and disinfecting high-frequency touched surfaces in the facility often, and designated visitation areas after each visit
- Appropriate staff use of Personal Protective Equipment (PPE)
- Effective cohorting of residents (e.g., separate areas dedicated to COVID-19 care)
- Resident and staff testing conducted as required at 42 CFR § 483.80(h) (see QSO-20-38-NH)

These core principles are consistent with the Centers for Disease Control and Prevention (CDC) guidance for nursing homes, and should be **adhered to at all times**. Additionally, visitation should be person-centered, consider the residents' physical, mental, and psychosocial well-being, and support their quality of life. The risk of transmission can be further reduced through the use of physical barriers (e.g., clear Plexiglass dividers, curtains). Also, nursing homes should enable visits to be conducted with an adequate degree of privacy. Visitors who are unable to adhere to the core principles of infection prevention should not be permitted to visit or should be asked to leave. By following a person-centered approach and adhering to these core principles, visitation can occur safely based on the below guidance.

Outdoor Visitation

Outdoor visits generally pose a lower risk of transmission due to increased space and airflow. For outdoor visits, facilities should create accessible and safe outdoorspaces for visitation, such as in courtyards, patios, or parking lots, including the use of tents, if available. However, weather considerations (e.g., inclement weather, excessively hot or cold temperatures, poor air quality) or an individual resident's health status (e.g., medical condition(s), COVID-19 status, quarantine status) may hinder outdoor visits. When conducting outdoor visitation, all appropriate infection control and prevention practices should be followed.

Indoor Visitation

Facilities must allow indoor visitation at all times and for all residents as permitted under the regulations. While previously acceptable during the PHE, facilities can no longer limit the frequency and length of visits for residents, the number of visitors, or require advance scheduling of visits.

Although there is no limit on the number of visitors that a resident can have at one time, visits should be conducted in a manner that adheres to the core principles of COVID-19 infection prevention and does not increase risk to other residents. *During peak times of visitation and large gatherings (e.g., parties, events) facilities should encourage physical distancing.* Facilities may contact their local health authorities for guidance or direction on how to structure their visitation to reduce the risk of COVID-19 transmission.

Face Coverings and *masks* during visits

If the nursing home's county COVID-19 community transmission is **high**, *everyone in a healthcare setting* should wear face coverings or masks.

If the nursing home's county COVID-19 community transmission is ***not high***, the safest practice is for residents and visitors to wear face coverings or masks, *however, the facility could choose not to require visitors wear face coverings or masks while in the facility, except during an outbreak. The facility's policies regarding face coverings and masks should be based on recommendations from the CDC, state and local health departments, and individual facility circumstances.*

Regardless of the community transmission level, residents and their visitors when alone in the resident's room or in a designated visitation area, may choose not to wear face coverings or masks and may choose to have close contact (including touch). Residents (or their representative) and their visitors should be advised of the risks of physical contact prior to the visit. *If a roommate is present during the visit, it is safest for the visitor to wear a face covering or mask.*

Additional information on levels of community transmission is available on the CDC's COVID-19 Integrated County View webpage.

NOTE: CDC states that Community ***Transmission*** *is the metric currently recommended to guide select practices in healthcare settings to allow for earlier intervention, before there is strain on the healthcare system, including its workforce, and better protect the vulnerable individuals seeking care in these settings. The* ***Community Transmission*** *metric is different than the COVID-19* ***Community Level*** *metric used for non-healthcare settings.*

Nursing homes should use the Community Transmission Level metric not the Community Level metric.

While not recommended, residents who are on transmission-based precautions (TBP) or quarantine can still receive visitors. In these cases, visits should occur in the resident's room and the resident should wear a well-fitting facemask (if tolerated). Before visiting residents, who are on TBP or quarantine, visitors should be made aware of the potential risk of visiting and precautions necessary in order to visit the resident. Visitors should adhere to the core principles of infection prevention. Facilities may offer well-fitting facemasks or other appropriate PPE, if available; however,

facilitiesare not required to provide PPE for visitors.

Indoor Visitation during an Outbreak Investigation

An outbreak investigation is initiated when a *single* new *case* of COVID-19 occurs among residents or staff *to determine if others have been exposed.* To swiftly detect cases, we remind facilities to adhere to CMS regulations and guidance for COVID-19 testing, including routine staff testing, testing of individuals with symptoms, and outbreak testing.

When a new case of COVID-19 among residents or staff is identified, a facility should immediately *(but not earlier than 24 hours after the exposure, if known)* begin outbreak testing in accordance with CMS QSO 20-38-NH REVISED and CDC guidelines.

While it is safer for visitors not to enter the facility during an outbreak investigation, visitors must still be allowed in the facility. Visitors should be made aware of the potential risk of visiting during an outbreak investigation and adhere to the core principles of infection prevention. If residents or their representative would like to have a visit during an outbreak investigation, they should wear face coverings or masks during visits and visits should ideally occur in the resident's room. *While an outbreak investigation is occurring,* facilities should limit visitor movement in the facility. For example, visitors should not walk around different halls of the facility. Rather, they should go directly to the resident's room or designated visitation area. *Also, visitors should physically distance themselves from other residents and staff, when possible.* Facilities may contact their local health authorities for guidance or direction on how to structure their visitation to reduce the risk of COVID-19 transmission during an outbreak investigation.

Visitor Testing and Vaccination

While not required, we encourage facilities in counties with high levels of community transmission to offer testing to visitors, if feasible. If facilities do not offer testing, they should encourage visitors to be tested on their own before coming to the facility (e.g., within2–3 days).

CMS strongly encourages all visitors to become vaccinated and facilities should educate and also encourage visitors to become vaccinated. Visitor testing and vaccination can help prevent the spread of COVID-19 and facilities may ask about a visitors' vaccination status, however, **visitors are not required to be tested or vaccinated** (or show proof of such) as a condition of visitation.If the visitor declines to disclose their vaccination status, the visitor should wear a face coveringor mask at all times. This also applies to representatives of the Office of the State Long-Term Care Ombudsman and protection and advocacy systems, as described below.

Compassionate Care Visits

Compassionate care visits are allowed at all times. Previously during the PHE, there were some scenarios where residents should only have compassionate care visits. However, visitation is now allowed at all times for all residents, in accordance with CMS regulations. Therefore, we believe there are few scenarios when visitation should be limited only to compassionate care visits. In the event a scenario arises that would limit visitation for a resident (e.g., a resident is severely immunocompromised and the number of visitors the resident is exposed to needs to be kept to a minimum), compassionate care visits would still be allowed at all times. CMS expects these scenarios to be rare events.

Required Visitation

Facilities shall not restrict visitation without a reasonable clinical or safety cause, consistent with 42 CFR § 483.10(f)(4)(v). In previous nursing home visitation guidance during the PHE, CMS outlined some scenarios related to COVID-19 that would constitute a clinical or safety reason for limited visitation. However, there are no longer scenarios related to COVID-19 where visitation should be limited, except for certain situations when the visit is limited to being conducted in the resident's room or the rare event that visitation is limited to compassionate care. Therefore, a nursing home **must** facilitate in-person visitation consistent with the applicable CMS regulations, which can be done by applying the guidance stated above. Failure to facilitate visitation, per 42 CFR § 483.10(f)(4), which states "The resident hasa right to receive visitors of his or her choosing at the time of his or her choosing, subject to the resident's right to deny visitation when applicable, and in a manner that does not impose onthe rights of another resident," would constitute a potential violation and the facility would be subject to citation and enforcement actions.

As stated above, we acknowledge that there are still risks associated with visitation and COVID-19. However, the risks are reduced by adhering to the core principles of COVID-19 infection prevention. Furthermore, we remind facilities and all stakeholders that, per 42 CFR § 483.10(f)(2), residents have the right to make choices about aspects of his or her life in the facility that are significant to the resident. Visitors, residents, or their representative should be made aware of the potential risk of visiting and necessary precautions related to COVID-19 in order to visit the resident. However, if a visitor, resident, or their representative is aware of the risks associated with visitation, and the visit occurs in a manner that does not place other residents at risk (e.g., in the resident's room), the resident must be allowed to receive visitors as he/she chooses.

Access to the Long-Term Care Ombudsman

As stated in previous CMS guidance QSO-20-28-NH (revised), regulations at 42 CFR § 483.10(f)(4)(i)(C) require that a Medicare and Medicaid-certified nursing home provide representatives of the Office of the State Long-Term Care Ombudsman with immediate access to any resident. If an ombudsman is planning to visit a resident who is in TBP or quarantine in a nursing home in a county where the level of community transmission is high in the past 7 days, the resident and ombudsman should be made aware of the potential risk of visiting, and the visit should take place in the resident's room. We note that representatives of the Office of the Ombudsman should adhere to the core principles of COVID- 19 infection prevention as described above. If the resident or the Ombudsman program requests alternative communication in lieu of an in-person visit, facilities must, at a minimum, facilitate alternative resident communication with the Ombudsman program, such as by phone or through the use of other technology. Nursing homes are also required under 42 CFR § 483.10(h)(3)(ii) to allow the Ombudsman to examine the resident's medical, social, and administrative records as otherwiseauthorized by State law.

Federal Disability Rights Laws and Protection & Advocacy (P&A) Programs

42 CFR § 483.10(f)(4)(i)(E) and (F) requires the facility to allow immediate access to a resident by any representative of the protection and advocacy systems, as designated by the state, and as established under the Developmental Disabilities Assistance and Bill of Rights Act of 2000 (DD Act), and of the agency responsible for the protection and advocacy system for individuals with a mental disorder (established under the Protection and Advocacy for Mentally Ill Individuals Act of 2000). P&A programs authorized under the DD Act protect the rights of individuals with

developmental and other disabilities and are authorized to "investigate incidents of abuse and neglect of individuals with developmental disabilities if the incidents are reported to the system orif there is probable cause to believe the incidents occurred." 42 U.S.C. § 15043(a)(2)(B). Under its federal authorities, representatives of P&A programs are permitted access to all facility residents, which includes "the opportunity to meet and communicate privately with such individuals regularly, both formally and informally, by telephone, mail and in person." 42 CFR § 51.42(c); 45 CFR § 1326.27.

If the P&A is planning to visit a resident who is in TBP or quarantine in a county where the level of community transmission is high in the past 7days, the resident and P&A representative should be made aware of the potential risk of visiting and the visit should take place in the resident's room.

Additionally, each facility must comply with federal disability rights laws such as Section 504 of the Rehabilitation Act of 1973, 29 U.S.C. § 794 (Section 504) and the Americans with Disabilities Act of 1990, 42 U.S.C. §§ 12101 et seq. (ADA).

For example, if communicating with individuals who are deaf or hard of hearing, it is recommended to use a clear mask or mask with a clear panel. Face coverings should not be placed on anyone who has trouble breathing or is unable to wear a mask due to a disability, or anyone who is unconscious, incapacitated, or otherwise unable to remove the mask without assistance.

In addition, if a resident requires assistance to ensure effective communication (e.g., a qualified interpreter or someone to facilitate communication) and the assistance is not available by onsite staff or effective communication cannot be provided without such entry (e.g., video remote interpreting), the facility must allow the individual entry into the nursing home to interpret or facilitate, with some exceptions. This would not preclude nursing homes from imposing legitimate safety measures that are necessary for safe operations, such as requiring such individuals to adhere to the core principles of COVID-19 infection prevention. Any questions about or issues related to enforcement or oversight of the non-CMS requirements and citations referenced above under this section subject heading should be referred to the HHS Office for Civil Rights (Toll-free: 800-368-1019) (TDD toll-free: 800-537-7697), the Administration for Community Living (202-401-4634),or other appropriate oversight agency.

Entry of Healthcare Workers and Other Providers of Services

All healthcare workers must be permitted to come into the facility as long as they are not subject to a *work exclusion* or showing signs or symptoms of COVID-19. In addition to health care workers, personnel educating and assisting in resident transitions to the community should be permitted entry consistent with this guidance. We note that EMS personnel do not need to be screened, so they can attend to an emergency without delay. We remind facilities that all staff, including individuals providing services under arrangement as well as volunteers, should adhere to the core principles of COVID-19 infection prevention and must comply with COVID-19 testing requirements.

Communal Activities, Dining and Resident Outings

While adhering to the core principles of COVID-19 infection prevention, communal activities and dining may occur. Book clubs, crafts, movies, exercise, and bingo are all activities that can be facilitated with alterations to adhere to the guidelines for preventing transmission. The safest approach is for everyone, *particularly those at high risk for severe illness*, to wear a face covering

or mask while in communal areas of the facility. For more information, see the Implement Source Control section of the CDC guidance "Interim Infection Prevention and Control Recommendations for Healthcare Personnel During the Coronavirus Disease 2019 (COVID-19) Pandemic."

Facilities must permit residents to leave the facility as they choose. Should a resident choose to leave, the facility should remind the resident and any individual accompanying the resident to follow all recommended infection prevention practices *such as* wearing a face covering or mask, *especially for those at high risk for severe illness and when community transmission is high, performing* hand hygiene and encouraging those around them to do the same.

Upon the resident's return, nursing homes should screen residents upon return for signs or symptoms of COVID-19:

- If the resident or family member reports possible close contact to an individual with COVID-19 while outside of the nursing home, *see the CDC's guidance for residents who have had close contact for next steps regarding testing and quarantine.*
- If the resident develops signs or symptoms of COVID-19 after the outing, *see the CDC's guidance for residents with symptoms of COVID-19.*

In most circumstances, quarantine is not recommended for residents who leave the facility for less than 24 hours (e.g., for medical appointments, community outings with family or friends) except in certain situations, described in the CDC's empiric transmission-based precautions guidance.

Residents who leave the facility for 24 hours or longer should generally be managed as a new admission, as recommended by the *CDC in the Managing admissions and residents who leave the facility section.*

Survey Considerations

State survey agencies and CMS are ultimately responsible for ensuring surveyors are compliant withthe applicable expectations. Therefore, LTC facilities are not permitted to restrict access to surveyors based on vaccination status, nor ask a surveyor for proof of his or her vaccination status as a condition of entry. If facilities have questions about the process a state is using to ensure surveyors can enter a facility safely, those questions should be addressed to the State Survey Agency. Surveyors should not enter a facility if they have a positive viral test for COVID-19, signs or symptoms of COVID-19, or currently meet the criteria for quarantine. Surveyors should also adhereto the core principles of COVID-19 infection prevention and adhere to any COVID-19 infection prevention requirements set by federal and state agencies (including Executive Orders).

- For concerns related to resident communication with and access to persons and services inside and outside the facility, surveyors should investigate for non-compliance at 42 CFR § 483.10(b), F550.
- For concerns related to a facility limiting visitors, surveyors should investigate for non-compliance at 42 CFR § 483.10(f)(4), F563.
- For concerns related to ombudsman access to the resident and the resident's medical record, surveyors should investigate for non-compliance at 42 CFR §§ 483.10(f)(4)(i)(C), F562 and 483.10(h)(3)(ii), F583.
- For concerns related to lack of adherence to infection control practices, surveyors should investigate for non-compliance at 42 CFR § 483.80(a), F880.

Contact: Questions related to this memorandum may be submitted to:
DNH_TriageTeam@cms.hhs.gov.

Effective Date: Immediately. This policy should be communicated with all survey andcertification staff, their managers, and the State/CMS Locations within 30 days of this memorandum.

/s/
David R. Wright

cc: Survey Operations Group

September 23, 2022

Nursing Home Visitation - Frequently Asked Questions (FAQs)

CMS is providing clarification to recent guidance for visitation (see CMS memorandum QSO-20-39-NH REVISED). While CMS cannot address every aspect of visitation that may occur, we provide additional details about certain scenarios below. However, the bottom line is visitation must be permitted at all times with very limited and rare exceptions, in accordance with residents' rights. In short, nursing homes should enable visitation following these three key points:

- Adhere to the core principles of infection prevention, especially wearing a mask and performing hand hygiene;
- *Encourage physical distancing* during large gatherings; and
- Work with your state or local health department when an outbreak occurs.

States may instruct nursing homes to take additional measures to make visitation safer, while ensuring visitation can still occur. This includes *recommending* that, during visits, residents and visitors wear masks *in accordance with CDC recommendations. Masks should be* well-fitting, and preferably those with better protection, such as surgical masks or KN95. States should work with CMS on specific actions related to additional measures they are considering.

1. **What is the best way for residents, visitors, and staff to protect themselves from the Omicron variant?**

   A: The most effective tool to protect anyone from the COVID-19 Omicron variant (or any version of COVID-19) is to be up-to-date with all recommended COVID-19 vaccine doses. Also, we urge all residents, staff, and visitors to follow the guidelines for preventing COVID-19 from spreading, including wearing a well-fitting mask (preferably those with better protection, such as surgical masks or KN95) while in a nursing home, practicing physical distancing *in large gatherings*, and performing hand hygiene by using an alcohol-based hand rub or soap and water.

2. **How should nursing homes address visitation when they expect a high volume of visitors, such as over the holidays?**

   A: In general, visitation should be allowed for all residents at all times. However, as stated in CMS memorandum QSO-20-39-NH REVISED, "*During peak times of visitation and large gatherings (e.g., parties, events) facilities should encourage physical distancing.*" The facility may restructure the visitation policy, such as asking visitors to schedule their visit at staggered time-slots throughout the day, and/or limiting the number of visitors in the facility or a resident's room at any time, *to reduce the risk of COVID-19 transmission*. Note: While these may be strategies used during the holidays or when a high volume of visitors is expected (especially in light of the uncertain impact of the Omicron variant in facilities), we expect these strategies to only be used *to enable* physical distancing. Also, there is no limit on length of visits, in general, as long as the visit poses no risk to or infringes upon other residents' rights.

3. **Can visits occur in a resident's room if they have a roommate?**

   A: Yes. Ideally an in-room visit would be conducted when the roommate is not present, however if that is not an option, the visit *could* occur in a different area of the facility, occur at a time when the roommate is not in the room, or the visitors should be asked to limit the number of visitors that are in the room at one time. If a visit does occur in the resident's room and the roommate is present, it is safest for the visitors to wear a face covering or mask. Also, visitors and residents should adhere to the principles of infection control, including wearing a mask and performing frequent hand hygiene.

4. **Can a visitor share a meal with or feed the resident they are visiting?**

   A: Visitors may eat with a resident if the resident (or representative) and the visitor are aware of the risks and adhere to the core principles of infection prevention. Eating in a separate area is preferred, however if that is not possible, then the meal could occur in a common area as long as the visitor wears a mask *(in accordance with CDC recommendations),* except while eating or drinking.

5. **How should nursing homes work with their state or local health department when there is an COVID-19 outbreak?**

   A: Prior to the COVID-19 Public Health Emergency (PHE), there were occasions when a local or state health department advised a nursing home to pause visitation and new admissions due to a large outbreak of an infectious disease. Consultation with state health departments on how to address outbreaks should still occur. In fact, we remind nursing homes that they are still expected to contact their health department when *responding to COVID-19 transmission within the facility.*

   While residents have the right to receive visitors at all times and make choices about aspects of their life in the facility that are significant to them, there may be times when the scope and severity of an outbreak warrants the health department to intervene with the facility's operations. We expect these situations to be extremely rare and only occur after the facility has been working with the health department to manage and prevent escalation of the outbreak. Wealso expect that if the outbreak is severe enough to warrant pausing visitation, it would also warrant a pause on accepting new admissions (as long as there is adequate alternative access to care for hospital discharges). For example, in a nursing homes where, despite collaborating with the health department over several days, there continues to be uncontrolled transmission impacting a large number of residents (e.g., more than 30% of residents became infected*), and the health department advised the facility to pause visitation and new admissions temporarily. In this situation, the nursing home would not be out of compliance with CMS' requirements.

   *CMS does not define a specific threshold for what constitutes a large outbreak and this could vary based on facility size or structure. However, we emphasize that any visitation limits should be rare and applied when there are many cases in multiple areas of the facility.

Nursing facilities should continue to consult with state and local health departments when outbreaks occur to determine when modifications to visitation policy would be appropriate. Facilities should document their discussions with the health department, and the actions they took to attempt to control the transmission of COVID-19.

6. **Should the facility pause communal activities and dining during an outbreak investigation?**

   A: *No. Communal activities and dining do not have to be paused during an outbreak, unless directed by the state or local health department. Residents who are on TBP (i.e. isolation or quarantine) should not participate in communal activities and dining until the criteria to discontinue TBP has been met.*

7. **Is a resident (not on transmission-based precautions or quarantine) who is unable or unwilling to wear a mask, *when expected based on CDC recommendations,* allowed to attend communal dining and activities?**

   A: A resident who is unable to wear a mask due to a disability or medical condition may attend communal activities, however they should physically distance from others *during large gatherings*. If possible, facilities should educate the resident on the core principles of infection prevention, such as hand hygiene, physical distancing, cough etiquette, etc. and staff should provide frequent reminders to adhere to infection prevention principles.

   A resident who is unable to wear a mask and whom staff cannot prevent having close contact with others should not attend *large gatherings*. To help residents prevent having close contact, such as in the case of a memory care unit, the staff should limit the size of group activities. They should also encourage frequent hand hygiene, assist with maintaining physical distancing as much as possible, and frequently cleaning high-touch surfaces.

   If a resident refuses to wear a mask and physically distance from others *during large gatherings*, the facility should educate the resident on the importance of masking and physical distancing, document the education in the resident's medical record, and the resident should not participate in *large gatherings*.

8. **How can a long-term care provider coordinate an onsite clinic to provide COVID-19 vaccine and boosters for staff and residents?**

   A: Many LTC providers have already identified strategies and partnerships to obtain and administer COVID-19 vaccines for residents and staff, including: working with established LTC partners and retail pharmacy partners or coordinating with state and local health departments. You may request vaccination support from a pharmacy partner enrolled in the Federal Retail Pharmacy Program. If you are having difficulties arranging COVID-19 vaccination for your residents and staff, contact your state or local health department's immunization program for assistance. If the state or jurisdictional immunization program is unable to connect your LTC setting with a vaccine provider, CDC is available as a safety net support (Contact CDC INFO at 800-232-4636 for additional support).

9. **With COVID-19 cases spiking due to the Omicron variant, should facilities continue to permit**

visitation?

A: Yes. While CMS is concerned about COVID-19 cases due to the Omicron variant, we're also concerned about the effects of isolation and separation of residents from their loved ones. Earlier in the pandemic we issued guidance for certain limits to visitation, but we've learned a few key things since then. Isolation and limited visitation can be traumatic for residents, resulting in physical and psychosocial decline. So, we know it can lead to worse outcomes for people in nursing homes. Furthermore, we know visitation can occur in a manner that doesn't place other residents at increased risk for COVID-19 by adhering to the practices for infection prevention, such as physical distancing *when in large gatherings*, masking, and frequent hand hygiene. There are also a variety of ways that visitation can be structured to reduce the risk of COVID-19 spreading. So, CMS believes it is critical for residents to receive visits from their friends, family, and loved ones in a manner that does not impose on the rights of another resident. Lastly, as indicated above, facilities should consult with their state or local public health officials, and questions about visitation should be addressed on a case by case basis.

10. Why can a resident choose to have a visit even when COVID-19 cases are increasing?

A: It is important to note that federal regulations explicitly state that residents have the right to make choices about significant aspects of their life in the facility and the right to receive visitors, as long as it doesn't infringe on the rights of other residents (42 CFR 483.10(f)(2) and (4), respectively). In this case, as long as a visit doesn't increase the risk of COVID-19 for other residents (i.e., by using the guidance for conducting safe visits), the resident still has the right to choose to have a visitor. Therefore, if the resident is aware of the risks of the visit, and the visit is conducted in a manner that doesn't increase the risk of COVID-19 transmission for other residents,the visit must still be permitted in accordance with the requirements.

11. Are there any suggestions for how to conduct visits that reduce the risk of COVID-19 transmission?

A: There are ways facilities can and should take extra precautions, such as hosting the visit outdoors, if possible; creating dedicated visitation space indoors; permitting in-room visits when the resident's roommate is not present; and the resident and visitor should wear a well-fitting mask (preferably those with better protection, such as surgical masks or KN95), *in accordance with CDC recommendations,* perform frequent hand-hygiene, and practice physical distancing *when in large gatherings*. Some other recommendations include:

- Offering visitors surgical masks or KN95 masks.
- *Limiting* the visitor's movement in the facility*, during an outbreak,* to only the location of the visit.
- Increasing air-flow and improving ventilation and air quality.
- Cleaning and sanitizing the visitation area after each visit.
- Providing reminders in common areas (e.g., signage) to maintain physical distancing *in large gatherings*, perform hand-hygiene, and wear well-fitting masks.

12. Are there best practices for improving air quality to reduce risks during visitation?

A: Yes, a facility may consider a number of options related to air quality such as:

- Adding ultraviolet germicidal irradiation (UVGI) to the heating ventilation and air conditioning system (HVAC),
- Adding portable room air cleaners with high-efficiency particulate air (HEPA, H-13 or -14) filters to communal areas.
- Ensure proper maintenance of HVAC system to ensure maximum outdoor air intake.

For additional information on air cleaning and disinfecting, see CDC's Ventilation FAQs or the American Society of Heating, Refrigerating and Air-Conditioning Engineers site on Filtration and Disinfection.

13. What are ways a facility can improve and or manage air flow during visitation?

A: A facility may consider implementing the following:

- The use of a portable fan placed close to an open window could enable ventilation. A portable fan facing towards the window (i.e. facing outside) serves to pull the room and exhaust air to the outside; a fan facing towards the interior of the room (i.e. facing inside) serves to pull in the outdoor air and push it inside the room. Direct the fan discharge towards an unoccupied corner and wall spaces or up above the occupied zone.
- The use of ceiling fans at low velocity and potentially in the reverse-flow direction (so that air is pulled up toward the ceiling), especially when windows are closed.
- Avoid the use of the high-speed settings for any fan.
- Keeping doors to resident rooms or visitation areas closed during visits to control air flow and reducing spread of infection.

For additional information on improving air quality, optimizing air flow and use of barriers, see the Centers for Disease Control and Prevention (CDC) site on Ventilation in Buildings.

14. Is there funding available for environmental changes which reduce transmission of COVID-19?

A: Yes, a facility may request the use of Civil Money Penalty (CMP) Reinvestment funds to purchase portable fans and portable room air cleaners with high-efficiency particulate air (HEPA, H-13 or -14) to increase or improve air quality. A maximum use of $3,000 per facility including shipping costs may be requested.

15. Can a state require facilities to test visitors as a condition of entering the facility?

A: States can require visitors to be tested prior to entry if the facility is able to provide a rapid antigen test (i.e., the visitor is not responsible for obtaining a test). If the facility cannot provide the rapid antigen test, then the visit must occur without a test being performed if the visitor(s) has not had a positive viral test, does not report COVID-19 symptoms or meet the criteria for quarantine.

Health

COVID-19 FACILITY REQUIRMENTS
Temporary Structures

3/17/2020

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 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	Ft² 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]

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 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	Ft² per person
Inpatient treatment departments	240
Sleeping Departments	120

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

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

Ref: QSO-22-15-NH & NLTC & LSC

DATE: **April 7, 2022**

TO: State Survey Agency Directors

FROM: Director
Quality, Safety & Oversight Group

SUBJECT: Update to COVID-19 Emergency Declaration Blanket Waivers for Specific Providers

Memorandum Summary

- CMS continues to review the need for existing emergency blanket waivers issued in response to the Coronavirus Disease 2019 (COVID-19) Public Health Emergency (PHE).
- Over the course of the COVID-19 PHE, skilled nursing facilities/nursing facilities (SNFs/NFs), inpatient hospices, intermediate care facilities for individuals with intellectual disabilities (ICF/IIDs), and end-stage renal disease (ESRD) facilities have developed policies or other practices that we believe mitigates the need for certain waivers.
- Applicable waivers will remain in effect for hospitals and critical access hospitals (CAH).
- CMS will end the specified waivers in two groups:
  - 60 days from issuance of this memorandum
  - 30 days from issuance of this memorandum

Background

In response to the COVID-19 PHE and under the Secretary's authority set out at section 1135 of the Social Security Act, CMS enacted several temporary emergency declaration blanket waivers which were intended to provide health care providers with extra flexibilities required to respond to the COVID-19 pandemic.[1] CMS continues to evaluate the impact of these waivers on patient care and providers along with corresponding data.

While the waivers of regulatory requirements have provided flexibility in how nursing homes may operate, they have also removed the minimum standards for quality that help ensure residents' health and safety are protected. Findings from onsite surveys have revealed significant concerns with resident care that are unrelated to infection control (e.g., abuse, weight-loss, depression, pressure ulcers, etc.). We are concerned that the waiver of certain regulatory requirements has contributed to these outcomes and raises the risk of other issues. For example, by waiving requirements for training, nurse aides and paid feeding assistants may not have received the necessary training to help identify and prevent weight-loss. Similarly, CMS waived requirements for physicians and practitioners to perform in-person assessments, which may have

[1] COVID-19-emergency-declaration-waivers.pdf

prevented these individuals from performing an accurate assessment of the resident's clinical needs, contributing to depression or pressure ulcers. Lastly, due to the waiver of certain life-safety code requirements, facilities may not have had their fire prevention systems inspected to ensure they operate effectively to detect or prevent fire. As a result, CMS is very concerned about how residents' health and safety has been impacted by the regulations that have been waived, and the length of time for which they have been waived.

We note that CMS is still concerned about the risk COVID-19 poses to nursing home residents. We expect providers to continue to implement actions to reduce the likelihood of COVID-19 transmission and follow all existing requirements. For example, COVID-19 vaccines are the strongest tool we have to protect the health and safety of residents and staff, and facilities should use all available resources to support their residents and staff in getting vaccinated, and in doing so, adhere to the requirements for educating residents and staff regarding the benefits and potential side effects associated with the COVID-19 vaccine, and offering the vaccine (per Interim Final Rule CMS-3414-IFC).

However, in addition to taking actions to reduce the likelihood of the transmission of COVID-19, the minimum regulatory requirements need to be restored to protect residents' health and safety. This is particularly true in light of the increased protection against serious illness and death from COVID-19 afforded by the high and growing vaccination rates among nursing home residents and staff (see generally https://www.cdc.gov/nhsn/covid19/ltc-vaccination-dashboard.html), including as a result of the implementation and enforcement of Medicare and Medicaid Programs; Omnibus COVID-19 Health Care Staff Vaccination, 86 Fed. Reg. 61,555, 61,556 (Nov. 5, 2021). Therefore, we believe it is imperative that requirements to protect residents' health and safety be restored as soon as possible. The waivers listed below have been identified as those requirements that should be restored to address the risks to resident health and safety that are not related to infection control. Furthermore, we believe that at this time, nursing homes should be able to adjust their operations to meet these regulatory requirements, while also addressing any issues related to COVID-19. We note that states and individual facilities are still able to request regulatory waivers for issues unique to their facility or location (similar to actions taken in response to natural disasters) to provide flexibility.

Waiver Terminations:

CMS is ending the specific emergency declaration blanket waivers for SNFs/NFs, inpatient hospices, ICF/IIDs and ESRD facilities listed below. The termination of these blanket waivers will have no effect on other blanket waivers that remain in place such as those for hospitals and CAHs. Those blanket waivers remain in effect to assist hospitals and CAHs, among others, in dealing with their response to the surges of COVID-19 cases in the community. Providers are expected to take immediate steps so that they may return to compliance with the reinstated requirements according to the timeframes listed below. We also recommend that providers continue to follow CDC guidance for preventing the spread of COVID-19 especially during activities that may increase patient or resident contact. For additional information on individual waivers or flexibilities providers can apply for, please visit the Coronavirus waivers & flexibilities webpage.

Emergency Declaration Blanket Waivers Ending for SNF/NFs 30 Days from Publication of this Memorandum:

- Resident Groups - 42 CFR §483.10(f)(5)

- CMS waived the requirements which ensure residents can participate in-person in resident groups. This waiver permitted the facility to restrict in-person meetings during the COVID-19 PHE.

- Physician Delegation of Tasks in SNFs - 42 CFR §483.30(e)(4)
  - CMS waived the requirement that prevents a physician from delegating a task when the regulations specify that the physician must perform it personally. This waiver gave physicians the ability to delegate any tasks to a physician assistant, nurse practitioner, or clinical nurse specialist, but specified that any task delegated under this waiver must continue to be under the supervision of the physician.
- Physician Visits - 42 CFR §483.30(c)(3)
  - CMS waived the requirement that all required physician visits (not already exempted in §483.30(c)(4) and (f)) must be made by the physician personally. The waiver modified this provision to permit physicians to delegate any required physician visit to a nurse practitioner, physician assistant, or clinical nurse specialist who is not an employee of the facility, who is working in collaboration with a physician, and who is licensed by the State and performing within the state's scope-of-practice laws.
- Physician Visits in Skilled Nursing Facilities/Nursing Facilities - 42 CFR §483.30
  - CMS waived the requirement for physicians and non-physician practitioners to perform in-person visits for nursing home residents and allow visits to be conducted, as appropriate, via telehealth options.
- Quality Assurance and Performance Improvement (QAPI) – 42 CFR §483.75(b)–(d) and (e)(3)
  - CMS modified certain requirements which require long-term care facilities to develop, implement, evaluate, and maintain an effective, comprehensive, data-driven QAPI program. This waiver gave providers the ability to focus on adverse events and infection control, and those aspects of care delivery most closely associated with COVID-19 during the PHE.
- Detailed Information Sharing for Discharge Planning for Long-Term Care (LTC) Facilities - 42 CFR §483.21(c)(1)(viii)
  - CMS waived the discharge planning requirement which requires LTC facilities to assist residents and their representatives in selecting a post-acute care provider using data, such as standardized patient assessment data, quality measures and resource use. CMS maintained all other discharge planning requirements.
- Clinical Records - 42 CFR §483.10(g)(2)(ii)
  - CMS modified the requirement which requires long-term care (LTC) facilities to provide a resident a copy of their records within two working days (when requested by the resident).

Emergency Declaration Blanket Waivers For Various Provider-Types Ending <u>60 Days</u> from Publication of this Memorandum:

- Physical Environment for SNF/NFs - 42 CFR §483.90
  - CMS waived requirements to allow for a non-SNF building to be temporarily certified and available for use by a SNF in the event there were needs for isolation processes for COVID-19 positive residents, which may not be feasible in the existing SNF structure to ensure care and services during treatment for COVID-19, provided that the state has approved the location as one that sufficiently addresses safety and comfort for patients and staff.

- Certain conditions of participation and certification requirements for opening a NF if the state determines there is a need to quickly stand up a temporary COVID-19 isolation and treatment location.
- Requirements to temporarily allow for rooms in a long-term care facility not normally used as a resident's room, to be used to accommodate beds and residents for resident care in emergencies and situations needed to help with surge capacity.

- Equipment Maintenance & Fire Safety Inspections for ESRD facilities - 42 CFR §494.60(b) and(d)
  - CMS waived the requirement for on-time preventive maintenance of dialysis machines and ancillary dialysis equipment. Additionally, CMS waived the requirements for ESRD facilities to conduct on-time fire inspections.
- Facility and Medical Equipment Inspection, Testing & Maintenance (ITM) for Inpatient Hospice, ICF/IIDs and SNFs/NFs – 42 CFR §§418.110(c)(2)(iv), 483.470(j), and 483.90
  - CMS waived ITM requirements for facility and medical equipment to reduce disruption of patient care and potential exposure/transmission of COVID-19.
- Life Safety Code (LSC) and Health Care Facilities Code (HCFC) ITM for Inpatient Hospice, ICF/IIDs and SNFs/NFs - 42 CFR §§ 418.110(d)(1)(i) and (e), 483.470(j)(1)(i) and (5)(v), and 483.90(a)(1)(i) and (b)
  - CMS waived ITM required by the LSC and HCFC, with specified exceptions, which permitted facilities to adjust scheduled ITM frequencies and activities to the extent necessary.
- Outside Windows and Doors for Inpatient Hospice, ICF/IIDs and SFNs/NFs – 42 CFR §§418.110(d)(6), 483.470(e)(1)(i), and 483.90(a)(7)
  - CMS waived the requirement to have an outside window or outside door in every sleeping room. This permitted spaces not normally used for patient care to be utilized for patient care and quarantine.
- Life Safety Code for Inpatient Hospice, ICF/IIDs, and SNFs/NFs - 42 CFR §§418.110(d), 483.470(j), and 483.90(a)
  - CMS waived these specific LSC provisions:
    - Fire Drills: Due to the inadvisability of quarterly fire drills that move and mass staff together, CMS permitted a documented orientation training program related to the current fire plan, which considered current facility conditions.
    - Temporary Construction: CMS waived requirements that would otherwise not permit temporary walls and barriers between patients.
- Paid Feeding Assistants for LTC facilities: 42 CFR §§483.60(h)(1)(i) and 483.160(a)
  - CMS modified the requirements regarding required training of paid feeding assistants to allow that training can be a minimum of one hour in length. CMS did not waive other requirements related to paid feeding assistants or required training content.
- In-Service Training for LTC facilities – 42 CFR §483.95(g)(1)
  - CMS modified the nurse aide training requirements for SNFs and NFs, which required the nursing assistant to receive at least 12 hours of in-service training annually.
- Training and Certification of Nurse Aides for SNF/NFs - 42 CFR §483.35(d) (Modification and Conditional Termination)
  - CMS waived the requirements which require that a SNF and NF may not employ anyone for longer than four months unless they met the training and certification requirements under §483.35(d). CMS previously provided information related to

nurse aides working under this blanket waiver in CMS memorandum QSO-21-17-NH. This memo provides additional information as well on the modification of this waiver below.

We remind states that all nurse aides, including those hired under the above blanket waiver at 42 CFR §483.35(d), must complete a state approved Nurse Aide Competency Evaluation Program (NATCEP) to become a certified nurse aide. State approved NATCEPs must have a curriculum that includes training in the areas defined at 42 CFR §483.152(b), such as respecting residents' rights, basic nursing skills, personal care skills, and caring of cognitively impaired residents. Additionally, the requirements at 42 CFR §483.154(b)(i) and (ii) requires these nurse aides pass a written or oral exam, and demonstrate skills learned. Lastly, we note that CMS did not waive the requirement that the individual employed as a nurse aide be competent to provide nursing and nursing related services at 42 CFR §483.35(d)(1)(i), and that requirement must continue to be met.

We are aware that there may be instances where the volume of aides that must complete a state approved NATCEP exceed the available capacity for enrollees in a training program or taking the exam. This may cause delays in in nurse aides becoming certified. If a facility or nurse aide has documentation that demonstrates their attempts to complete their training and testing (e.g., timely contacts to state officials, multiple attempts to enroll in a program or test), a waiver of these requirements (42 CFR §483.35(d)) is still available and the aide may continue to work in the facility while continuing to attempt to become certified as soon as possible. However, **for all other situations, this waiver is terminated**. When capacity issues exist, facilities should inform their state officials of the issue. State agencies should also verify the capacity issues that are reported. Lastly, state agencies should provide their CMS Location with information about the status of their NATCEPs.

Poor quality of care, such as improper transfers, turning and positioning, poor incontinent/skin care, or weight loss related to poor assistive dining techniques could be related to inadequate training, as these skills are required components of NATCEP programs. We acknowledge that federal requirements allow states to use a variety of means to administer the curriculum (e.g., online, classroom, or onsite training). However, all programs must adequately provide the required training. For example, if a state has approved a NATCEP that allows for the time worked onsite by a nurse aide over the COVID-19 PHE to qualify for the 75 hours training in the required areas, yet, observes trends in poor quality of care among certified nurse aides that were hired under the nurse aide training waiver, this could indicate that the NATCEP does not adequately address the components of the required curriculum specified at 42 CFR §483.152(b). In these cases, the state should re-evaluate the approved NATCEP to see if the components of the program need to be adjusted to ensure the regulatory requirements are met and avoid poor quality of care. As stated in CMS memorandum QSO-21-17-NH, "states must ensure that all of the required areas of training per 42 CFR §483.152(b) are addressed, and any gaps in onsite training that are identified are fulfilled through supplemental training."

Contact:
DNH_TriageTeam@cms.hhs.gov for questions related to nursing homes;
QSOG_LifeSafetyCode@cms.hhs.gov for questions related to physical environment and life safety code.

Effective Date: The emergency declaration blanket waivers identified above will end according to the timeframes described in this memorandum.

/s/
David R. Wright

cc: Survey and Operations Group Management

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Logan Grant
Executive Director

Caroline Tippens
Director, Licensure and Regulation

Board for Licensing Health Care Facilities PM 86

Policy Memorandum

SUBJECT: **ACLF ADMINISTRATOR SERVING MULTIPLE LOCATIONS**

DATE: **NOVEMBER 22, 2022**

POLICY: **86**

EFFECTIVE: **NOVEMBER 22, 2022**

APPROVED: **NOVEMBER 22, 2022**

The Board issues this policy to facilitate qualified individuals to serves as Assisted Care Living Facility (ACLF) Administrators. The Board interprets its rules related to ACLF Administrators, as follows:

An individual shall serve as the administrator of only one licensed ACLF, unless the Board approves that individual to be the administrator of multiple facilities. The Board may approve an administrator to serve multiple facilities:

1) that are operated on a single campus, or
2) upon determining that such an arrangement shall not compromise the safety of and/or care provided to residents if the facilities are not on a campus.
3) no single individual shall be the administrator of more than two (2) separately licensed facilities not on a single campus.

ANY ACLF ADMINISTRATOR CURRENTLY SERVING MORE THAN ONE FACILITY MUST APPLY TO THE BOARD BEFORE THE BOARD MEETING ON APRIL 5, 2023.

This policy shall remain in effect until the Board's rule change is effective or at an earlier date as determined by the Board.

Chair, Board for Licensing Health Care Facilities

Caroline Tippens, Esq., CHC
Director, Licensure and Regulation
Health Facilities Commission

HFC

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PM 87

Board for Licensing Health Care Facilities

Policy Memorandum

SUBJECT: **INACTIVE LICENSE EXTENSION BY ADMINISTRATION**

DATE: **NOVEMBER 22, 2022**

POLICY: **87**

EFFECTIVE: **NOVEMBER 22, 2022**

APPROVED: **NOVEMBER 22, 2022**

The Board issues this policy to facilitate inactive license status requests pending a meeting of the Board.

The Board vests the Executive Director and Director of Licensure and Regulation with the authority to grant an extension of an inactive license status previously granted by the Board until the next publicly noticed Board meeting.

This policy shall remain in effect until it is revoked by the Board.

Chair, Board for Licensing Health Care Facilities

Caroline Tippens, Esq., CHC
Director, Licensure and Regulation
Health Facilities Commission

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PM 88

Board for Licensing Health Care Facilities

Policy Memorandum

SUBJECT: Sharing of Rooms or Suites in ACLF and Tenn. Comp. R. & Regs. 0720-26-.09(18)(B) [Building Standards]

DATE: June 6, 2023

POLICY: A facility may accommodate a written request from two competent, consenting adults to occupy a room and/or suite by requesting a waiver of Tenn. Comp. R. & Regs. 0720-26-.09(18)(B) which requires 80 square feet of bedroom space for each resident, if the room and/or suite is capable of meeting the requirements of the ACLF Rules & Regulations and current adopted codes. When a facility wishes to apply for this waiver, they shall notify licensure and plans review for approval. Staff are hereby given the authority to review the request from the facility and provide a recommendation to the Board. Approvals will be subject to Board ratification.

The request by a facility for waiver under this policy must be made in good faith and not used to increase the facility's bed count. Any waiver shall be specific to the two residents requesting the waiver from the facility.

EFFECTIVE: June 6, 2023

APPROVED:

Christopher D. Wilson, M.D., Chairman
Board for Licensing Health Care Facilities

Caroline Tippens, Esq. CHC
Director, Licensure and Regulation
Board for Licensing Health Care Facilities

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PM 89

Health Facilities Commission

Policy Memorandum

SUBJECT: **Acute Hospital Care at Home Initiative and Tenn. Comp. R. & Regs. 0720-14-.06(3)(m)&(n) [Housekeeping]; 0720-14-.06(4)(a) [Nursing Services]; and 0720-14-.06(9) [Food and Dietetic Services].**

DATE: **February 1, 2023**
REVISED: March 26, 2025

POLICY: **The above rules are waived by the Commission for licensed hospitals which participate and provide services in the hospital at home program, pursuant to the Acute Hospital Care at Home Initiative. Further, the Commission does not consider a patient's bed at home a licensed hospital bed, allowing hospitals to provide care at home in the patient's bed. The Commission will no longer need to approve waiver requests, provided that the Secretary of Health and Human Services has granted a waiver to individual hospitals that are approved to participate in the Acute Hospital Care at Home Initiative. This policy is a result of the federal extension of the Acute Hospital Care at Home Initiative through September 30, 2025.**

EFFECTIVE: March 26, 2025

APPROVED:

Logan Grant/JC

Logan Grant
Executive Director
Health Facilities Commission

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PM 90

Board for Licensing Health Care Facilities

Policy Memorandum

SUBJECT: Board Waivers and Interpretative Guidelines – End of Public Health Emergency (PHE)

DATE: April 5, 2023

POLICY: All Board waivers and interpretative guidelines granted as a result of the PHE will expire May 11, 2023 with the exception of Interpretative Guideline for ACLF Tenn. Comp. R. & Regs. 0720-26-.08(1)(c) regarding admission or retention of resident with COVID -19 which will extend until February 2024.

EFFECTIVE: April 5, 2023

APPROVED:

Christopher Wilson, M.D., Chairman
Board for Licensing Health Care Facilities

Caroline Tippens, Esq., C.H.C.
Director, Licensure and Regulation
Board for Licensing Health Care Facilities

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PM 91

Board for Licensing Health Care Facilities

Policy Memorandum

SUBJECT: Rural Emergency Hospital Designation

DATE: June 6, 2023

POLICY: As a result of the expiration of the Emergency Rules concerning the recognition of Rural Emergency Hospital designation on June 25, 2023, the Board formally adopts attachment 1, in its entirety, until this policy is rescinded by the Board or until adoption of permanent rules, whichever occurs first.

EFFECTIVE: June 26, 2023

APPROVED:

Christopher Wilson, M.D., Chairman
Board for Licensing Health Care Facilities

Caroline Tippens, Esq, CHC
Director, Licensure and Regulation
Board for Licensing Health Care Facilities

Attach. 1

Place substance of rules and other info here. Please be sure to include a detailed explanation of the changes being made to the listed rule(s). Statutory authority must be given for each rule change. For information on formatting rules go to https://sos.tn.gov/products/division-publications/rulemaking-guidelines.

Chapter Number 0720-14
Standards for Hospitals

Rule 0720-14-.01 Definitions is amended by deleting paragraph (23) in its entirety and substituting instead the following language, and is further amended by adding new paragraphs (82) and (83), and renumbering the remaining paragraphs accordingly, so that as amended, the new paragraphs shall read:

(23) Designation. An official finding and recognition by the Commission that an acute care hospital meets Tennessee State Rural Health Care Plan requirements to be a Critical Access Hospital or Rural Emergency Hospital.

(82) Rural Emergency Hospital. A Rural Emergency Hospital ("REH") is a facility that:

(a) meets the eligibility requirements for a licensed hospital in Tennessee pursuant to Tenn. Comp. R. & Regs. 0720-14-.01(37), and the following additional requirements:

1. is enrolled for reimbursement as a rural emergency hospital by the federal Centers for Medicare and Medicaid Services pursuant to 42 U.S.C. §§1395x(kkk) et. seq. and 42 U.S.C. §1395cc(j), or any successor statute;

2. provides rural emergency hospital services;

3. provides an emergency department which maintains:

(i) availability twenty-four (24) hours a day seven (7) days per week.

(ii) a physician, physician assistant, or nurse practitioner, who performs such services as such individual is legally authorized to perform in accordance with state law and who meets training, education, and experience requirements required by state law.

(iii) such clinician must be on call at all times and available on-site within thirty (30) minutes to sixty (60) minutes depending on the facility's location.

(iv) staffed twenty-four (24) hours per day and (7) seven days per week by individuals competent in the skills needed to address emergency medical care and must be able to receive patients and activate appropriate medical resources to meet the care needed by patients.

4. has a transfer agreement in effect with a level I or level II trauma center; and

5. meets such other licensure, staff training and education requirements as the Health Facilities Commission finds necessary in the interest of the health and safety of individuals who are provided rural emergency hospital services.

6. A Rural Emergency Hospital does not have inpatient beds or provide any acute inpatient services, other than those which are rendered by a licensed skilled nursing facility to furnish post-hospital extended care services, which is a distinct part unit of the Rural Emergency Hospital.

7. Nothing in this definition expands on the scope of a licensed healthcare professional's ability to practice under their respective regulated profession.

(83) Rural Emergency Hospital Services. The term "rural emergency hospital services" means the following services, provided by a Rural Emergency Hospital, that do not exceed an annual per-patient average of twenty-four (24) hours in such Rural Emergency Hospital:

(a) Emergency department services, and observation care; and

(b) At the election of the Rural Emergency Hospital, for services provided on an outpatient basis, other medical and health services as specified in regulations adopted by the United States Secretary of Health and Human Services and authorized by the applicable rules or statutes of the Health Facilities Commission.

Authority: 42 U.S.C. 1395x(kkk); 42 U.S.C. §1395cc(j); T.C.A. §§ 39-11-106, 68-11-202, 68-11-204, 68-11-207, 68-11-209, 68-11-210, 68-11-211, 68-11-213, 68-11-224, 68-11-255, 68-11-1802, 68-57-101, 68-57-102, and 68-57-105.

Rule 0720-14-.06 is amended by adding new paragraph (11), so that as amended, the new paragraph shall read:

(11) Rural Emergency Hospital.

(a) A hospital shall be eligible to apply for a Rural Emergency Health ("REH") designation as such and conversion to a Rural Emergency Hospital, if the facility, as of December 27th, 2020, was a:

1. Critical Access Hospital as defined under Tenn. Comp. R. & Regs. 0720-14-.01(19); or

2. General hospital with no more than 50 licensed beds located in an area designated by State or federal law as a rural area; or

3. General hospital with no more than 50 licensed beds located in an area designated as rural under 42 U.S.C. §1395ww(d)(8)(E), or any successor statute.

(b) A facility applying for designation as a Rural Emergency Hospital shall include in its licensure application:

1. a detailed transition plan that lists the services that the facility will retain, modify, add, and discontinue.

2. a description of services that the facility intends to furnish on an outpatient basis pursuant to Tenn. Comp. R. & Regs. 0720-14-.01(83)(b).

3. a description of any additional services the hospital would be supporting, such as furnishing telehealth services and ambulance services, including operating the facility and maintaining the emergency department to provide such services covered by these rules.

4. any such other information as the rules and regulations of the Health Facilities Commission may require.

(c) A Rural Emergency Hospital may be allowed to own and operate an entity that provides ambulance services.

(d) A licensed general hospital or critical access hospital that applies for and receives licensure as a Rural Emergency Hospital and elects to operate as a Rural Emergency Hospital shall retain its original license as a general hospital or critical access hospital. Such original license shall remain inactive while the Rural Emergency Hospital license is in effect.

(e) A licensed Rural Emergency Hospital may enter into any contracts required to be eligible for federal reimbursement as a Rural Emergency Hospital.

Authority: 42 U.S.C. 1395x(kkk); 42 U.S.C. §1395cc(j); T.C.A. §§ 39-11-106, 68-11-202, 68-11-204, 68-11-207, 68-11-209, 68-11-210, 68-11-211, 68-11-213, 68-11-224, 68-11-255, 68-11-1802, 68-57-101, 68-57-102, and 68-57-105.

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PM 92

Board for Licensing Health Care Facilities

Policy Memorandum

SUBJECT: Activity Director Program Requirements

DATE: June 6, 2023

POLICY: The Board adopts the following requirements for any educational program seeking approval from the state to satisfy 42 C.F.R. 483.24(c)(2).

In order for the Board to approve an activity director education program, the following requirements must be met.

1. The prospective program must submit the Curriculum Vitae of each instructor showing:
    a. High School diploma or General Education Diploma;
    b. A minimum of two (2) years of experience in a social or recreational role within the last five (5) years, one of which was full-time in a therapeutic activities program; or
    c. Certified as an Activity Director; or
    d. Qualified therapist or occupational therapy assistant.
    e. If an instructor changes, a Notice of Change of Instructor must be submitted in writing for approval within ten (10) days.

2. The Course Content Requirements are:
    a. Minimum of forty-five (45) hours;
    b. Course must be In-person; or Interactive/synchronous.
        i. This interactive/synchronous requirement would not be met by email interaction with the instructor after the conclusion of a presentation, or reacting to slides at the conclusion of the presentation.

3. The following materials must be submitted to the Board for review.
    a. A course outline;
    b. All content material to be used during the course;
    c. A list of key objectives to be achieved by the course;

d. Proof that the following topics are included in the course content:
    i. Dementia and cognition;
    ii. Documentation;
    iii. Special population to include, but not limited to:
        1. Age specific training;
        2. Younger populations;
        3. Non-English speakers;
        4. Differently-abled Residents
    iv. Management:
        1. Small group facilitation;
        2. Large group facilitation;
    v. Ethics;
    vi. Communication Skills;
    vii. Resident Safety;
    viii. Resident Counsel and family/friend engagement;
    ix. Rules and Regulations;
    x. Mental Health wellbeing;
    xi. Leadership;
    xii. Crisis or Emergency Management to include:
        1. Resident-to-Resident Conflict Resolution;
    xiii. Travel and Transportation for outings.

4. Competency must be evaluated at the end of the course, by one of the following:
    a. An exam with a passing rate of 75 percent rate; or
    b. Competency evaluation; or
    c. Capstone project.

5. Certificate of Completion
    a. Verify Identity of, and indicate on, a certificate of completion the identity of the person completing the course.

6. Review of course material must be approved in writing:
    a. Every five (5) years by the Board or Administrative staff.
    b. Any course previously approved by the Board must be reviewed by December 2026.

The Board formally adopts this policy until it is rescinded by the Board or until adoption of permanent rules, whichever occurs first.

EFFECTIVE: June 6, 2023

APPROVED:

Christopher Wilson, M.D., Chairman
Board for Licensing Health Care Facilities

Caroline Tippens, Esq, CHC
Director, Licensure and Regulation
Board for Licensing Health Care Facilities

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PM 93

Board for Licensing Health Care Facilities

Policy Memorandum

SUBJECT: CHOW Requirement for Limited Liability Company (LLC)

DATE: June 6, 2023

POLICY: For all facility types, a membership interest in a Limited Liability Company shall be treated the same as an ownership interest in a Corporation.

EFFECTIVE: June 6, 2023

APPROVED:

Christopher Wilson, M.D., Chairman
Board for Licensing Health Care Facilities

Caroline Tippens, Esq, CHC
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PM 94

Board for Licensing Health Care Facilities

Policy Memorandum

SUBJECT: Home Medical Equipment (Quinnlee's Law)

DATE: AUGUST 29, 2023

POLICY: As a result of the expiration of the Emergency Rules concerning the recognition of changes to the Home Medical Equipment rules on December 23, 2023, the Board formally adopts attachment 1, in its entirety, until this policy is rescinded by the Board or until the permanent rules become effective, whichever occurs first.

EFFECTIVE: August 30, 2023

APPROVED:

Christopher Wilson, M.D., Chairman
Board for Licensing Health Care Facilities

Caroline Tippens, Esq, CHC
Director, Licensure and Regulation
Board for Licensing Health Care Facilities

Place substance of rules and other info here. Please be sure to include a detailed explanation of the changes being made to the listed rule(s). Statutory authority must be given for each rule change. For information on formatting rules go to https://sos.tn.gov/products/division-publications/rulemaking-guidelines.

Chapter Number 0720-30
Standards for Home Care Organizations
Providing Home Medical Equipment

Rule 0720-30-.01 Definitions is amended by deleting paragraph (21) and adding new paragraphs (12), (22) and (45), and renumbering the remaining paragraphs accordingly, so that as amended, the new paragraphs shall read:

(12) Contact Person. The individual selected by the agency who will serve as the point-of-contact to communicate with the Health Facilities Commission. The agency must provide a name, title, telephone number, and electronic mail address of the contact person on the appropriate form.

(22) Home medical equipment provider. Any agency which provides home medical equipment services.

(a) Providers may fall into the following categories:

1. In-state providers who have a physical location;

2. In-state providers who have no physical location;

3. Out-of-state providers who do not have a physical location; or

4. Mail order companies.

(b) Providers who do not have a physical location must comply with survey requirements and provide access and documentation to surveyors necessary to conduct a survey.

(c) Designation on whether or not an agency has a physical location shall be located on the agency's wall certificate.

(45) Survey material. Survey material is any material stored in electronic or physical format that may be necessary to conduct a survey. The survey material includes, but is not limited to, personnel files, patient medical records, policies and procedures, data, background checks, abuse registry checks, facility reported incidents, litigation and bankruptcy history, current licensure status, copies of investigations, discipline records in any other state in which the provider is licensed, and video records or files, if available.

Authority: T.C.A. §§ 68-11-201, 68-11-202, 68-11-204, 68-11-207, 68-11-209, 68-11- 210, 68-11-211, 68-11-213, 68-11-224, 68-11-226, 68-11-268, and 68-11-303.

Rule 0720-30-.02 Licensing Procedures is amended by deleting paragraph (1) and subparagraph (2)(f) and adding new paragraph (1), subparagraphs (2)(f) and (2)(g), and paragraph (5), so that as amended, the new paragraphs and subparagraphs shall read:

(1) No person, partnership, association, corporation, or state, county or local government unit, or any division, department, board or agency thereof, shall establish, conduct, operate, or maintain in the State of Tennessee any home care organization providing home medical equipment without having a license.

(a) A license shall be issued to the person or persons named and for the premises listed in the application for licensure, if a physical location in Tennessee is listed.

(b) The name of the home care organization providing home medical equipment shall not be changed without first notifying the Commission in writing.

(c) Licenses are not transferable or assignable and shall expire and become invalid annually on the anniversary date of their original issuance.

(d) The license shall be conspicuously posted in the home care organization providing home medical equipment, if a physical location in Tennessee is listed.

(e) If a provider does not desire an in-state location, this information is required to be provided at the time of application.

(2) In order to make application for a license:

(f) The applicant, through the designated contact person, shall allow the home care organization providing home medical equipment to be inspected by a Commission surveyor and provide access to survey material. In the event that deficiencies are noted, the applicant shall submit a plan of corrective action to the Board that must be accepted by the Board. Once the deficiencies have been corrected, then the Board shall consider the application for licensure.

(g) If a physical location in Tennessee is not desired, the provider shall designate the type of category desired upon initial application.

(5) Conversion of Designated License Category. If a licensee wishes to convert to a different designated license category under paragraph (22) of Rule 0720-30-.01, a Notice of Intent to Convert must be received by the Commission.

Authority: T.C.A. §§ 68-11-201, 68-11-202, 68-11-204, 68-11-206, 68-11-209, 68-11-210, 68-11-216, 68-11-226, and Chapter 846 of the Public Acts of 2008, § 1.

Rule 0720-30-.03 Disciplinary Procedures is amended by deleting subparagraphs (1)(d) and (1)(e) and adding new subparagraphs (1)(d), (1)(e) and (1)(f), and paragraph (5), so that the new paragraph and subparagraphs shall read:

(1) The Board may suspend or revoke a license for:

(d) Conduct or practices found by the Board to be detrimental to the health, safety, or welfare of the patients of the agency;

(e) Failure to renew the license; and

(f) Failure to comply with survey document requests after three (3) written requests to the contact person are made by a surveyor.

(5) When an agency contact person fails to respond to the third written request for documentation from a surveyor, the agency shall be subject to a civil monetary penalty ranging from five hundred dollars ($500.00) to five thousand dollars ($5,000.00), and disciplinary action up to revocation of the license. If the same violation has occurred within the last twelve (12) months, the civil monetary penalty may be doubled.

Authority: T.C.A. §§ 4-5-219, 4-5-312, 4-5-316, 4-5-317, 68-11-202, 68-11-204, 68-11-206 through 68-11-209, and 68-11-226.

Rule 0720-30-.04 Administration is amended by adding new paragraph (10), so that the new paragraph shall read:

(10) An agency without a physical location in Tennessee shall not be subject to the requirements of 0720-30-.04(7)-(9).

Authority: T.C.A. §§ 39-17-1803, 39-17-1805, 68-11-201, 68-11-202, 68-11-204, 68-11-206, 68-11-209, 68-11-226, 68-11-268, and 71-6-121.

Rule 0720-30-.06 Basic Agency Functions is amended by deleting paragraph (5) and substituting the following new language, so that as amended, the new paragraph shall read:

(5) Location.

(a) If a provider chooses to have a physical location in Tennessee, each parent and/or branch shall:

1. Be located in Tennessee;

2. Be staffed during normal business hours and have a working telephone;

3. Be used for the dispensing, servicing, and storage of home medical equipment or be used to provide home medical equipment services;

4. Meet all local zoning requirements; and

5. Have all required current licenses and/or permits conspicuously posted in the agency.

(b) If an agency chooses not to have a physical location in Tennessee, each parent and/or branch shall:

1. Be licensed in Tennessee;

2. Be staffed during normal business hours and have a working telephone and electronic mail address;

3. Be used for the dispensing, servicing, and storage of home medical equipment or be used to provide home medical equipment services;

4. Have all required current licenses with appropriate designation and/or permits available for inspection; and

5. Upon initial licensure, provide to the Commission the means and method of entry to a virtual portal for surveyors to access survey material.

Authority: T.C.A. §§ 68-11-202, 68-11-206, 68-11-209, 68-11-226, and 68-11-304.

Rule 0720-30-.11 Records and Reports is amended by adding new paragraph (5), so that as amended, the new paragraph shall read:

(5) Survey Material. The agency shall have written policies dealing with survey material. Survey material shall be immediately available upon request of a Commission surveyor to the electronic mail address on record with the Commission. Survey material is any material stored in electronic or physical format that may be necessary to conduct a survey. Survey material shall include, but is not limited to the following:

(a) Personnel files;

(b) Patient medical records;

(c) Policies and procedures;

(d) Data;

(e) Background checks;

(f) Abuse registry checks;

(g) Facility reported incidents;

(h) Litigation and bankruptcy history;

(i) Current licensure status;

(j) Copies of investigations;

(k) Discipline records in any other state in which the provider is licensed;

(l) Video records or files, if available.

Authority: T.C.A. §§ 68-11-202, 68-11-209, 68-11-211, 68-11-226, and 68-11-260.

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PM 95

Board for Licensing Health Care Facilities

Policy Memorandum

SUBJECT: Assisted Care Living Facility Regulatory Standards under 0720-26-.05

DATE: February 7, 2024

POLICY: For purposes of Rule 0720-26-.05 *et seq.*, concerning the civil penalties to include the maximum amount of penalties allowed by statute, the Board formally adopts attachment 1, in its entirety, until this policy is rescinded by the Board or until the permanent rules become effective, whichever occurs first.

EFFECTIVE: February 7, 2024

APPROVED:

Christopher Wilson, M.D., Chairman
Board for Licensing Health Care Facilities

Caroline Tippens, Esq, CHC
Director, Licensure and Regulation
Board for Licensing Health Care Facilities

(Rule 0720-26-.05, continued)

(b) The date upon which each deficiency will be corrected;

(c) What measures or systemic changes will be put in place to ensure that the deficient practice does not recur; and

(d) How the corrective action will be monitored to ensure that the deficient practice does not recur.

(3) Either failure to submit a plan of correction in a timely manner or a finding by the Department of Health that the plan of correction is unacceptable may subject the ACLF's license to disciplinary action.

(4) Upon a finding by the Board that an ACLF has violated any provision of the Health Facilities and Resources Act, Part 2—Regulation of Health and Related Facilities (T.C.A. §§ 68-11-201, et seq.) or the rules promulgated pursuant thereto, action may be taken, upon proper notice to the licensee, to impose a civil penalty, deny, suspend, or revoke its license.

(5) Civil Penalties. The Board may, in a lawful proceeding respecting licensing (as defined in the Uniform Administrative Procedures Act), in addition to or in lieu of other lawful disciplinary action, assess civil penalties for violations of statutes, rules or orders enforceable by the Board in accordance with the following schedule:

(a) Violation	Penalty per Violation:
1. T.C.A. § 68-11-201(4)(B) (Provision of Room and Board and Non-Medical Living Assistance Services)	$0-$1000
2. T.C.A. § 68-11-201(4)(C) (Provision of Medical and other Professional Services; Medicare Services; Oversight of Medical Services; Plan of Care & Assessment; Personal and Medical Records; and, Fire Safety)	$0-$31000
3. T.C.A. § 68-11-213(i)(2) (Admission or Retention of inappropriately Placed Resident. Each resident shall constitute a separate violation.)	$0-$3000
4. T.C.A. § 68-11-213(i)(1) (Operating ACLF without Required License. Each day of operation shall constitute a separate violation.)	$0-$5000

(b) In determining the amount of any civil penalty to be assessed pursuant to this rule the Board may consider such factors as the following:

~~(a)~~ 1. Willfulness of the violation;

~~(b)~~ 2. Repetitiveness of the violation;

~~(c)~~ 3. Magnitude of the risk of harm caused by the violation.

Attach. 1

(Rule 0720-26-.05, continued)

(6) Each violation of any statute, rule or order enforceable by the Board shall constitute a separate and distinct offense and may render the ACLF committing the offense subject to a separate penalty for each violation.

(7) A licensee may appeal any disciplinary action taken against it in accordance with the Uniform Administrative Procedures Act, Tennessee Code Annotated § 4-5-101, et seq.

(8) Reconsideration and Stays. The Board authorizes the member who chaired the Board for a contested case to be the agency member to make the decisions authorized pursuant to rule 1360-04-01-.18 regarding petitions for reconsiderations and stays in that case.

Authority: *T.C.A. §§ 4-5-202, 4-5-204, 68-11-202, 68-11-204, 68-11-206, 68-11-209, 68-11-213 (i), and 68-11-257.* ***Administrative History:*** *Original rule filed February 9, 1998; effective April 25, 1998. Amendment filed November 25, 1998; effective February 8, 1999. Amendment filed February 15, 2000; effective April 30, 2000. Amendment filed September 13, 2002; effective November 27, 2002. Amendment filed May 24, 2004; effective August 7, 2004. Amendment filed April 20, 2006; effective July 4, 2006. Amendment filed February 23, 2007; effective May 9, 2007. Public necessity rule filed May 13, 2009; effective through October 25, 2009. Emergency rule filed October 22, 2009; effective through April 20, 2010. Amendment filed September 24, 2009; effective December 23, 2009. Transferred from chapter 1200-08-25 pursuant to Public Chapter 1119 of 2022 effective July 1, 2022.*

0720-26-.06 ADMINISTRATION.

(1) Each ACLF shall meet the following staffing and procedural standards:

(a) Staffing Requirements:

1. The licensee must designate in writing a capable and responsible person to act on administrative matters and to exercise all the powers and responsibilities of the licensee as set forth in this chapter in the absence of the licensee.

2. If the licensee is a natural person, the licensee shall be at least eighteen (18) years of age, of reputable and responsible character, able to comply with these rules, and must maintain financial resources and income sufficient to provide for the needs of the residents, including their room, board, and personal services.

3. An ACLF shall have an identified responsible attendant who is alert and awake at all times and a sufficient number of employees to meet the residents' needs, including medical services as prescribed. The responsible attendant and direct care staff must be at least eighteen (18) years of age and capable of complying with statutes and rules governing ACLFs.

4. An ACLF shall have a licensed nurse available as needed.

5. An ACLF shall employ a qualified dietitian, full time, part-time, or on a consultant basis.

6. An ACLF may not employ an individual listed on the Abuse Registry maintained by the Department of Health.

(b) Policies and Procedures:

1. An ACLF shall have a written statement of policies and procedures outlining the facility's responsibilities to its residents, any obligation residents have to the facility, and methods by which residents may file grievances and complaints.

HFC

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PM 96

Board for Licensing Health Care Facilities

Policy Memorandum

SUBJECT: Charge Nurse definition under ESRD Rule 0720-33-.01, *et seq.*

DATE: February 7, 2024

POLICY: For purposes of Rule 0720-33-.01, *et seq.*, the federal requirements concerning "Charge Nurse" have changed. The state requirements must not conflict with federal requirements found under 42 CFR 494.140. Therefore, the Board formally adopts the following definition until this policy is rescinded by the Board/Commission or until the permanent rules updating the definition section become effective, whichever occurs first.

Charge Nurse. The charge nurse responsible for each shift must:

(a) Be a registered nurse, a licensed practical nurse, or vocational nurse who meets the practice requirements in Tennessee under T.C.A. § 63-7-101, et seq.;

(b) Have at least 12 months experience in providing nursing care, including 3 months of experience in providing nursing care to patients on maintenance dialysis; and

(c) If such nurse is a licensed practical nurse or licensed vocational nurse, work under the supervision of a registered nurse in accordance with Tennessee nursing practice act provisions under T.C.A. § 63-7-101, et seq., and Tenn. Comp. R. & Regs 1000-01, et seq. and 1000-02, et seq, or successor sections.

EFFECTIVE: February 7, 2024

APPROVED:

Christopher Wilson, M.D., Chairman
Board for Licensing Health Care Facilities

Caroline Tippens, Esq. CHC
Director, Licensure and Regulation
Board for Licensing Health Care Facilities

HFC

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PM 97

Health Facilities Commission

Policy Memorandum

SUBJECT: Surgical Technologist Requirements under the following rules:
Standards for Hospitals under 0720-14-.07; and
Standards for Ambulatory Surgical Treatment Centers under 0720-20-.06.

DATE: June 5, 2024
Amended: December 11, 2024

POLICY: Pursuant to 2024 Public Chapter 0932, the rule sections cited above shall be amended as follows, until this policy is rescinded by the Commission or until the permanent rules become effective, whichever occurs first.

Chapter Number 0720-14
Standards for Hospitals

Rule 0720-14-.07 Optional Hospital Services is amended by deleting sub-paragraph (1)(h) and adding new sub-paragraph (1)(h), so that as amended, the new paragraph shall read:

(h) The health facilities commission shall publish an approved list of accredited surgical technology programs.

1. Surgical technologists must meet one (1) or more of the following:

(i) Successfully completed a nationally accredited surgical technology program, and holds and maintains certification as a surgical technologist from a national certifying body that certifies surgical technologists and is recognized by the health facilities commission;

(ii) Successfully completed an accredited surgical technologist program;

(I) Has not, as of the date of hire, obtained certification as a surgical technologist from a national certifying body that certifies surgical technologists and is recognized by the health facilities commission; and

(II) Obtains such certification no later than eighteen (18) months after completion of the program.

(iii) Successfully completed a training program for surgical technology in the armed forces of the United States, the national guard, or the United States public health service; or

(iv) Performed surgical technology services as a surgical technologist in a healthcare facility on or before May 21, 2007, and has been designated by the healthcare facility as being competent to perform surgical technology services based on prior experience or specialized training validated by competency in current practice. The healthcare facility employing or retaining such person as a surgical technologist under this subsection (a) obtains proof of such person's prior experience, specialized training, and current continuing competency as a surgical technologist and makes the proof available to the health facilities commission upon request of the commission.

2. This section does not prohibit a person from performing surgical technology services if the person is acting within the scope of the person's license, certification, registration, permit, or designation, or is a student or intern under the direct supervision of a healthcare provider.

Authority: T.C.A. §§ 4-5-202, 4-5-204, 68-3-511, 68-11-202, 68-11-204, 68-11-209, 68-57-101, 68-57-102, 68-57-104, and 68-57-105.

Chapter Number 0720-20
Standards for Ambulatory Surgical Treatment Centers

Rule 0720-20-.06 Basic Services is amended by deleting sub-paragraph (1)(j) and adding new sub-paragraph (1)(j), so that as amended, the new paragraph shall read:

(j) The health facilities commission shall publish an approved list of accredited surgical technology programs.

1. Surgical technologists must meet one (1) or more of the following:

(i) Successfully completed a nationally accredited surgical technology program, and holds and maintains certification as a surgical technologist from a national certifying body that certifies surgical technologists and is recognized by the health facilities commission;

(ii) Successfully completed an accredited surgical technologist program;

(I) Has not, as of the date of hire, obtained certification as a surgical technologist from a national certifying body that certifies surgical technologists and is recognized by the health facilities commission; and

(II) Obtains such certification no later than eighteen (18) months after completion of the program.

(iii) Successfully completed a training program for surgical technology in the armed forces of the United States, the national guard, or the United States

public health service; or

(iv) Performed surgical technology services as a surgical technologist in a healthcare facility on or before May 21, 2007, and has been designated by the healthcare facility as being competent to perform surgical technology services based on prior experience or specialized training validated by competency in current practice. The healthcare facility employing or retaining such person as a surgical technologist under this subsection (a) obtains proof of such person's prior experience, specialized training, and current continuing competency as a surgical technologist and makes the proof available to the health facilities commission upon request of the commission.

2. This section does not prohibit a person from performing surgical technology services if the person is acting within the scope of the person's license, certification, registration, permit, or designation, or is a student or intern under the direct supervision of a healthcare provider.

Authority: T.C.A. §§ 4-5-202, 4-5-204, 68-11-201, 68-11-202, 68-11-204, 68-11-206, 68, 68-11-209, 68-11-216, 68-57-101, 68-57-102, 68-57-104, and 68-57-105.

As proposed, the meaning of "Nationally accredited surgical technology program" will be interpreted as follows:

Any program offered by an institution that is accredited at the institutional or programmatic level by an accreditor recognized by the national organization Council for Higher Education Accreditation (CHEA) and/or the United States Department of Education (USDE).

(Context Note: This would include programs offered within accredited institutions since all programs offered by an accredited institution would be covered under those accreditation standards. All institutional and programmatic accreditations can be considered 'national' in scope (since those accreditors formerly known as 'regional' are now regarded nationally))

EFFECTIVE: June 5, 2024
Amended: December 11, 2024

APPROVED:

Rick Chinn, Chairman
Health Facilities Commission

Caroline Tippens, Esq. CHC
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Certified Surgical Technologists

Section 17 of Public Chapter 932 amends current statute on the requirements of surgical technologists employed by healthcare facilities. This section of the law went into effect on May 6, 2024. The statute expands the approved accrediting entities that certify surgical technologist programs. The Health Facilities Commission may promulgate rules to effectuate this section.

Including Tennessee, thirteen states have laws related to the education and certification of certified surgical techs. Only five states require surgical techs to register with the state. In all other states, the employing facilities set credentialing requirements and oversight regarding who can provide surgical technologists services.

In Tennessee, the current law now states that an individual employed as a surgical technologist must meet one or more of the following requirements:

(l) Successfully completed a nationally accredited surgical technology program, and holds and maintains certification as a surgical technologist from a national certifying body that certifies surgical technologists and is recognized by the health facilities commission;

(2)

(A) Successfully completed an accredited surgical technologist program;
(B) Has not, as of the date of hire, obtained certification as a surgical technologist from a national certifying body that certifies surgical technologists and is recognized by the health facilities commission; and
(C) Obtains such certification no later than eighteen **(18)** months after completion of the program;

(3) Performed surgical technology services as a surgical technologist in a healthcare facility on or before May 21, 2007, and has been designated by the healthcare facility as being competent to perform surgical technology services based on prior experience or specialized training validated by competency in current practice. The healthcare facility employing or retaining such person as a surgical technologist under this subsection (a) obtains proof of such person's prior experience, specialized training, and current continuing competency as a surgical technologist and makes the proof available to the health facilities commission upon request of the commission; or

(4) Successfully completed a training program for surgical technology in the armed forces of the United States, the national guard, or the United States public health service.

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Prior to Public Chapter 932, the Commission on Accreditation of Allied Health Education Programs (CAAHEP) was the only available accrediting body accepted in Tennessee. The "CST" by the National Board of Surgical Technology and Surgical Assisting (NBSTSA) was the only available certification accepted in Tennessee.

The following certifying and accrediting bodies have requested to be recognized:

Accrediting Organizations:

- Accrediting Bureau of Health Education Schools (ABHES)
- Commission on Accreditation of Allied Health Education Programs (CAAHEP)
- Southern Association of Colleges and Schools Commission on Colleges (SACSCOC)

Apprenticeship Programs:

- U.S. Department of Labor Apprenticeship Program for Surgical Technologists

Certifying Organizations:

- National Board of Surgical Technology and Surgical Assisting (NBSTSA)
- National Center for Competency Testing (NCCT)

The education accrediting organizations offer accreditation for education. The certification organizations issue the certification and credentials.

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PM 98

Board for Licensing Health Care Facilities

Policy Memorandum

SUBJECT: Standards for Temporary Healthcare Staffing Agencies

DATE: June 5, 2024

POLICY: For purposes of Rule 0720-46-.01, *et seq.*, the state must begin issuing registrations for Temporary Healthcare Staffing Agencies on July 1, 2024. The Emergency Rules expired May 5, 2024, and the permanent rules are not yet effective. Therefore, the Board formally adopts the following Attachment 1 (Chapter 0720-46) until this policy is rescinded by the Board/Commission or until the permanent rules become effective, whichever occurs first.

EFFECTIVE: June 5, 2024

APPROVED:

Christopher Wilson, M.D., Chairman
Board for Licensing Health Care Facilities

Caroline R. Tippens

Caroline Tippens, Esq, CHC
Director, Licensure and Regulation
Board for Licensing Health Care Facilities

Place substance of rules and other info here. Please be sure to include a detailed explanation of the changes being made to the listed rule(s). Statutory authority must be given for each rule change. For information on formatting rules go to https://sos.tn.gov/products/division-publications/rulemaking-guidelines.

Chapter 0720-46
Standards for Temporary Healthcare Staffing Agencies

New Rule Chapter

0720-46-.01 Definitions

(1) Addresses. For legal entities and individuals, the physical address from which the agency operates its Tennessee business and mailing address if different from the physical address.

(2) Agency. A temporary healthcare staffing agency.

(3) Certified nurse aide (C.N.A.). An individual who has successfully completed an approved nursing assistant training program and is registered with the Commission.

(4) Commission. The Tennessee Health Facilities Commission.

(5) Controlling Person. An individual, business entity, officer, program administrator, or director whose responsibilities include the direction of the management or policies of a temporary healthcare staffing agency. The term "controlling person" shall also mean an individual who, directly or indirectly, holds an ownership interest of five percent (5%) or more in a corporation, partnership, or other business association that is itself a controlling person.

(6) Digital website. An online webpage operated by an agency that maintains applications from direct care staff submitted to the agency online, for referral to a healthcare facility.

(7) Digital smart phone application. A computer program or software application operated by an agency that maintains applications from direct care staff submitted to the agency for referral to a health care facility that is designed to run on a mobile device such as a phone, tablet, or watch.

(8) Direct Care Staff.

(a) An individual who is a medication aide, medication technician, certified nurse aide, licensed practical nurse, or registered nurse and contracts with or is employed by a temporary healthcare staffing agency to provide direct care services to residents or patients in a healthcare facility.

(b) A certified nurse practitioner or an advanced practice registered nurse certified or registered under title 63, chapter 7 and engaged in the practice of nursing is not a direct care staff.

(9) Executive director. The executive director of the health facilities commission.

(10) Healthcare facility. A nursing home or an assisted-care living facility as those terms are defined by T.C.A. § 68-11-201;

(11) Immediately available. Immediately available means available to the Commission or its agent within one (1) business day following written requests made by means of email, fax, or in-person delivery, or within (1) hour of requests made during inspection visits.

(12) Medication Aide or medication technician. An individual who administers medications under the general supervision of a licensed registered or practical nurse pursuant to T.C.A. § 63-7-127.

(13) Owner. Any person with an ownership interest of five percent (5%) or more in the agency.

(14) Person. An individual, firm, corporation, partnership, or association.

(15) Temporary healthcare staffing agency.

Attach. 1

(a) A person, or other business entity that is:

1. Engaged in whole or in part in the business of providing or procuring temporary employment in healthcare facilities for direct care staff; or

2. That operates a digital website or digital smartphone application that facilitates the provision of the engagement of direct care staff and accepts requests from healthcare facilities for direct care staff through its digital website or digital smartphone application.

(b) The term shall not include an individual who engages, only on the individual's own behalf, to provide the individual's services on a temporary basis to a healthcare facility without the use or involvement of a temporary healthcare staffing agency; or a staffing agency operated by a hospital, assisted- care living facility, or nursing home as those terms are defined by T.C.A. § 68-11-201, or an affiliate of a hospital, assisted- care living facility, or nursing home, if the purpose of the agency is solely procuring, furnishing, or referring temporary or permanent direct care staff for employment at that healthcare provider, or any affiliates under common ownership.

Authority: T.C.A. § 68-11-2201.

0720-46-.02 Registration Fees and Procedures

(1) No person, partnership, association, corporation, or state, county or local government unit, or any division, department, board or agency thereof, shall establish, conduct, operate, maintain, or advertise in the State of Tennessee any temporary healthcare staffing agency, or provide or procure temporary employment in healthcare facilities for direct care staff without first registering with the Commission.

(2) An individual who engages, only on the individual's own behalf, to provide the individual's services on a temporary basis to a healthcare facility without the use or involvement of a temporary healthcare staffing agency is not required to register under these rules.

(3) An agency operated by a hospital, assisted- care living facility, or nursing home as those terms are defined by T.C.A. § 68-11-201, or an affiliate of a hospital, assisted- care living facility, or nursing home, if the purpose of the agency is solely procuring, furnishing, or referring temporary or permanent direct care staff for employment at that healthcare provider, or any affiliates under common ownership, is not required to register under these rules.

(4) In order to make application for a registration:

(a) The applicant shall submit an application on a form prepared by the Commission.

(b) Each healthcare staffing agency making application for registration under this chapter shall pay annually to the Registry administrative office, a fee based on the number of staff employed by the agency, as follows:

1.	Less than 25 staff	$1,040.00
2.	25 to 49 staff	$1,300.00
3.	50 to 74 staff	$1,560.00
4.	75 to 99 staff	$1,820.00
5.	100 to 124 staff	$2,080.00
6.	125 to 149 staff	$2,340.00
7.	150 to 174 staff	$2,600.00
8.	175 to 199 staff	$2,860.00
9.	200 staff or more	$3,060.00

(c) The fee shall be submitted with the application or renewal application and is not refundable.

(d) Each agency shall submit to the Registry's administrative office an application fee of one hundred eighty dollars ($180.00). The fee shall be submitted with the initial application or renewal application and is not refundable.

(5) An agency seeking registration shall provide the Commission with all information requested in the application form, and any other relevant information the Commission determines is necessary to properly evaluate an application for registration, which shall include, but not be limited to:

(a) The names and addresses of any controlling person;

(b) The names and addresses of any owner who does not meet the definition of a controlling person. If the owner is a corporation, then the application must include copies of the corporation's articles of incorporation and current bylaws, and the names and addresses of its officers and directors;

(c) The names and addresses of the person or persons under whose management or supervision the temporary healthcare staffing agency will be operated; and

(d) A policy and procedure that describes how the agency's records will be immediately available to the Commission upon request.

(6) In addition to the application form, each agency shall submit an affidavit, executed by a controlling person, attesting that the agency:

(a) Does not restrict the employment opportunities of its direct care staff in any way inconsistent with T.C.A. § 68-11-2203, or the rules promulgated by the Commission that apply to the agency;

(b) Ensures that each direct care staff contracted with or employed by the agency meets all licensing, certification, training, and continuing education standards for the position in which the direct care staff will be working, in compliance with any federal, state, or local requirements;

(c) Ensures that all direct care staff contracted with or employed by the agency comply with requirements related to background checks under federal and Tennessee law and regulations, or that are adopted by any healthcare facility with which the agency contracts;

(d) Maintains workers' compensation coverage as required by Tennessee law for all direct care staff; and

(e) Is familiar with the laws and regulations governing a temporary healthcare staffing agency and will maintain compliance with those requirements.

(7) If an agency fails to provide sufficient registration fee(s) or a completed registration application, the Commission shall reject the application and return the fee(s). An agency may then resubmit an application.

(8) A registration issued by the Commission to an agency is effective for a period of one (1) year from the date of its issuance unless the registration is revoked for noncompliance pursuant to these rules.

(9) An agency's registration is valid only for the entity and/or person identified on the registration issued at the address shown thereon and is not subject to sale, assignment, or other transfer.

(10) If a controlling person changes, the temporary healthcare staffing agency is sold, or management is transferred, then the registration of the agency is voided and the new controlling person, owner, or manager may apply for a new registration.

(11) An agency which is a partnership, limited partnership, limited liability company, or corporation that undergoes any of the following changes, or whose operation is assumed by a new corporation, partnership, limited partnership, limited liability company, or other entity, whether by one (1) or by more than one (1) action, shall apply for a new registration:

(a) With respect to a partnership, a change in the majority interest of general partners;

(b) With respect to a limited partnership, a change in the general partner or in the majority interest of limited partners;

(c) With respect to a limited liability company, a change in any manager or in the majority interest of members; or

(d) With respect to a corporation, a change in the persons who own, hold, or have the power to vote the majority of any class of securities issued by the corporation.

Authority: T.C.A. § 68-11-2204.

0720-46-.03 Annual Renewal of Registration

(1) An agency's registration is valid for one (1) year and shall expire on the annual anniversary of the date the registration was originally issued.

(2) An agency may renew its registration. An agency's renewal application must be received at least sixty (60) days prior to the expiration of the current registration.

(3) If an agency fails to renew its registration prior to the date of its expiration but submits the renewal form and fee within sixty (60) days thereafter, the agency may renew late by paying, in addition to the renewal fee, a late penalty of one hundred dollars ($100) per month for each month or fraction of a month that renewal is late; provided that the late penalty shall not exceed twice the renewal fee.

(4) An agency must send a copy of its current registration to any member of the general public upon request.

Authority: T.C.A. § 68-11-2204.

0720-46-.04 Minimum Requirements and Record Retention

(1) Corporate Documents. An agency shall retain current and legible copies and have immediately available during the agency's regular operating hours:

(a) The articles and bylaws for the registrant entity;

(b) Copies of records required by the United States Internal Revenue Services to be prepared by the agency for each direct care staff employee or independent contractor;

(c) Records documenting the work performed by each direct care staff including date of personnel referral by the agency and the dates and locations of each personnel placement. Copies of time records or invoices identifying the services provided are acceptable documentation for this requirement; and

(d) Evidence of current worker's compensation coverage as required by T.C.A § 50-6-406.

(2) Direct Care Staff Records. An agency shall have immediately available during the agency's regular operating hours an individual file for each direct care staff. Each individual file shall contain current copies of the following information:

(a) The person's name and address, Social Security number, and date of birth;

(b) A copy and verification of the current license or certification, when licensure or certification is applicable for a particular job;

(c) Documentation to verify each person's employment eligibility in compliance with the immigration laws of the United States;

(d) Documentation of each personnel's employment history;

(e) Health and medical records sufficient to document adequate medical screenings have been performed of each employee to exclude communicable diseases, and to ensure required immunizations have been received;

(f) Accurate information as to the education, training, experience and personnel background of the employee, including documentation that references were verified;

(g) Documentation that each direct care staff contracted with or employed by the agency meets all licensing, certification, training, and continuing education standards for the position in which the direct care staff will be working. Each direct care staff shall comply with any federal, state, or local requirements;

(h) Documentation the agency has, for any direct care staff assigned by the agency to provide services to a healthcare facility, determined that the individual is not currently nor has ever been included on the U.S. Department of Health and Human Services' Office of Inspector General's List of Excluded Individuals/Entities (located at https://www.oig.hhs.gov) or the System for Award Management's Exclusion List (located at https://www.sam.gov);

(i) Documentation the agency has conducted any name and/or registry checks required by federal or Tennessee law, including, but not limited to, the abuse and sex offender registry checks required by T.C.A.§ 68-11-271 and T.C.A.§ 68-11-1004; and verified that any individual assigned by the agency to provide services is not listed on any such registry; and

(j) The agency must send copies of direct care staff records required by this rule to any healthcare facility with which it contracts or refers direct care staff, upon the request of that healthcare facility.

(3) Healthcare Facility Specific Requirements. If the healthcare facility to which the direct care staff has been assigned by the agency requires additional requirements or screening of its facility employees, the agency must perform such screenings of the direct care staff before referral by the agency. The agency shall maintain evidence that it has completed any such screenings of its direct care staff referred to the applicable healthcare facility.

(4) Direct Care Staff Agreements. The agency must retain current and legible copies of any written employment contracts or other agreements entered into between the agency and each direct care staff. These copies must be immediately available during the agency's regular operating hours.

(a) Any such contract or agreement shall specifically and clearly advise if the direct care staff is an employee of the agency or is an independent contractor referred by the agency.

(b) If the direct care staff is retained as an independent contractor, the contract or agreement shall specifically state that the independent contractor is responsible for paying federal income taxes.

(c) Prior to placement in a health care facility, the agency shall provide a document to each direct care staff, for his or her signature, which states that the individual understands his or her relationship with the agency, either as an employee or independent contractor. The signed acknowledgement shall be filed in each direct care staff's file.

(5) Healthcare Facility Agreements. Current and legible copies of contracts, if any, between an agency and a health care facility setting forth terms and conditions under which the agency will provide specific health services staff to the facility must be retained by the agency and be immediately available during the agency's regular operating hours. Such contracts shall state whether the staff provided by the agency are referred as employees of the agency or as independent contractors.

(6) Record Retention and Availability. Each agency shall retain legible copies of the records and reports required by this rule for five (5) years. The agency shall make such records and reports immediately available to the Commission upon request.

(7) Response to Investigations. Each agency shall provide any records in its possession, unless otherwise privileged, that are pertinent to an investigation conducted by any of the following:

(a) A representative of adult protective services actively involved in the conduct of an investigation pursuant to title 71, chapter 6;

(b) The department of health or its representatives, designees, or employees under T.C.A. § 63-1-117, in the same manner that a healthcare provider must make records available;

(c) The Commission, if related to a violation of these rules or any law or regulation of the board for licensing healthcare facilities relating to a healthcare facility with which the agency contracts;

(d) Any law enforcement agency conducting a criminal investigation of the agency, staff, or contractors, including, but not limited to, the Medicaid Fraud Control Unit; and

(e) Such records must be provided within five (5) business days, unless required to be provided in a shorter period by court order, law, or regulation.

(8) No Retaliation for Complaints. No agency shall retaliate against or, in any manner, discriminate against any person because of a complaint made in good faith and without malice to the Commission, the Tennessee Department of Health (TDH), the Department of Human Services Adult Protective Services, the long-term care ombudsman, or any government agency. An agency shall neither retaliate, nor discriminate, because of information lawfully provided to these authorities, because of a person's cooperation with them, or because a person is subpoenaed to testify at a hearing involving one of these authorities.

Authority: T.C.A. §§ 68-11-2202 and 68-11-2205.

0720-46-.05 Prohibited Actions and Business Practices

A temporary healthcare staffing agency shall not:

(1) Restrict in any manner the employment opportunities of any direct care staff that is contracted with or employed by the agency, including, but not limited to, using contract buy-out provisions or contract non-compete clauses.

(2) Require the payment of liquidated damages, employment fees, or other compensation in any contract with direct care staff or a healthcare facility, if the direct care staff is hired as a permanent employee of the healthcare facility.

(3) Solicit or recruit the current staff of a healthcare facility, or require, as a condition of employment, assignment, or referral, that the agency direct care staff recruit new employees for the agency from among the current employees of the healthcare facility to which the agency direct care staff are employed, assigned, or referred.

(4) Any of the provisions of a contract between a temporary healthcare staffing agency and either direct care staff or a healthcare facility that violate T.C.A. § 68-11-2203 are void and unenforceable in a court of law.

(5) Any agency that repeatedly violates the provisions of this rule or that contracts repeatedly in violation of T.C.A. § 68-11-2203 may be subject to disciplinary action up to and including revocation of registration.

Authority: T.C.A. §§ 68-11-2203 and 2206.

0720-46-.06 Reporting

(1) A temporary healthcare staffing agency shall submit biannual reports to the Commission.

(2) Biannual reports required by this rule are considered proprietary information that is confidential and not subject to public inspection pursuant to title 10, chapter 7, part 5. However, the Commission shall annually prepare reports of aggregate data that does not identify any data specific to any temporary healthcare staffing agency.

(3) Biannual reports must include:

(a) The name, professional licensure or certification, and assigned healthcare facility for each direct care staff;

(b) The length of time the direct care staff has been assigned to each healthcare facility and the total hours worked;

(c) A detailed listing of the average amount charged during each reporting period to a healthcare facility for each category of direct care staff providing services to the healthcare facility. "Average amount charged" shall mean the average hourly rates or set pricing charged to a health care facility by an agency for each applicable individual direct care staff.

(d) A detailed listing of the average amount paid during each reporting period to direct care staff for their services for each category of direct care staff providing services to the healthcare facility. "Average amount paid" shall mean the average hourly rates or set pricing paid by the agency to each applicable individual health care personnel;

(e) The agency's certification that each direct care staff contracted to a healthcare facility during the reporting period had a current, unrestricted license or certification in good standing and met the training and continuing education standards for the position with the healthcare facility throughout the entirety of the reporting period; and

(f) The agency's certification that each direct care staff contracted to a healthcare facility had successfully completed all background and abuse registry checks required by federal and state law and rule relating to the position and healthcare facility in which the direct care staff was placed or assigned during the reporting period.

Authority: T.C.A. § 68-11-2205.

0720-46-.07 Disciplinary Procedures

(1) Upon a finding by the Commission that an agency has violated any provision of these rules, the Commission may impose any of the following actions separately or in any combination deemed appropriate to the offense:

(a) Probation - This is a formal disciplinary action which places an agency on close scrutiny for a fixed period of time determined by the Commission. This action may be combined with conditions which must be met before probation will be lifted and/or which restrict the agency's registration during the probationary period.

(b) Registration Suspension - this is a formal disciplinary action which suspends an agency's right to operate for a fixed period of time. It contemplates the reentry of the agency into operation under the registration previously issued. When the Commission suspends a registration, the agency may not operate during the period of suspension.

(c) Revocation for cause. This is the most severe form of disciplinary action which terminates a registration and removes a registration from the registry. The Commission may allow reinstatement of a revoked registration upon conditions and after a period of time it deems appropriate. No petition for reinstatement and no new application for registration from an agency whose registration was revoked shall be considered prior to the expiration of at least five (5) years unless otherwise stated in the Commission's revocation order.

(d) Conditions - These include any action deemed appropriate by the Commission to be required of an agency disciplined during any period of probation or suspension or as a prerequisite to the lifting of probation or suspension or the reinstatement of a revoked registration.

(e) Civil penalty – A monetary disciplinary action assessed by the Commission.

(2) Once ordered, probation, suspension, revocation, assessment of a civil penalty, or any other condition of any type of disciplinary action may not be lifted unless and until the agency petitions the Commission, after the period of initial probation, suspension, revocation, or other conditioning has run, and all

conditions placed on the probation, suspension, revocation, have been met, and after any civil penalties assessed have been paid.

(3) Order of Compliance - This procedure is a necessary adjunct to previously issued disciplinary orders and is available only when a petitioner has completely complied with the provisions of a previously issued disciplinary order, including an unregistered practice civil penalty order, and wishes or is required to obtain an order reflecting that compliance.

(a) The Commission will entertain petitions for an Order of Compliance as a supplement to a previously issued Order upon strict compliance with the procedures set forth in the following three (3) circumstances:

1. When the petitioner can prove compliance with all the terms of the previously issued order and is seeking to have an order issued reflecting that compliance;

2. When the petitioner can prove compliance with all the terms of the previously issued order and is seeking to have an order issued lifting a previously ordered suspension or probation; or

3. When the petitioner can prove compliance with all the terms of the previously issued order and is seeking to have an order issued reinstating a license previously revoked.

(b) Procedures

1. The petitioner shall submit a Petition for Order of Compliance to the Commission's staff that shall contain all of the following:

(i) A copy of the previously issued order; and

(ii) A statement of which provision of subparagraph (a) the petitioner is relying upon as a basis for the requested order; and

(iii) A copy of all documents that prove compliance with all the terms or conditions of the previously issued order. If proof of compliance requires testimony of an individual(s), including that of the petitioner, the petitioner must submit signed statements from every individual the petitioner intends to rely upon attesting, under oath, to the compliance. The Commission and its staff, in their discretion, may require such signed statements to be notarized. No documentation or testimony other than that submitted will be considered in making an initial determination on, or a final order in response to, the petition.

2. The Commission authorizes its staff to make an initial determination on the petition and take one of the following actions:

(i) Certify compliance and present the petition to the Commission as an uncontested matter; or

(ii) Deny the petition, after consultation with legal staff, if compliance with all of the provisions of the previous order is not proven and notify the petitioner of what provisions remain to be fulfilled and/or what proof of compliance was either not sufficient or not submitted.

3. The petitioner may not submit any additional documentation or testimony other than that contained in its petition as submitted to the Commission and its staff.

4. If the Commission finds that the petitioner has complied with all the terms of the previous order the Commission shall issue an Order of Compliance.

5. If the petition is denied either initially by the Commission's staff or after review by the Commission, and the petitioner believes compliance with the order has been sufficiently proven, the petitioner may, as authorized by law, file a request for a hearing with the

Commission's staff and a Notice of Hearing will be filed to be heard by an Administrative Law Judge sitting alone.

(c) Form Petition

Petition for Order of Compliance
Temporary Healthcare Staffing Registry

Petitioner's Name: _____
Petitioner's Mailing Address: _____

Petitioner's E-Mail Address: _____
Telephone Number: _____

Attorney for Petitioner: _____
Attorney's Mailing Address: _____
Attorney's E-Mail Address: _____
Attorney's Telephone Number: _____

The petitioner respectfully represents, as substantiated by the attached documentation, that all provisions of the attached disciplinary order have been complied with and is respectfully requesting: (circle one)

1. An order issued reflecting that compliance; or

2. An order issued reflecting that compliance and lifting a previously ordered suspension or probation; or

Note – You must enclose all documents necessary to prove your request including a copy of the original order. If any of the proof you are relying upon to show compliance is the testimony of any individual, including yourself, you must enclose signed statements from every individual you intend to rely upon attesting, under oath, to the compliance. The Commission's staff, in its discretion, may require such signed statements to be notarized. No documentation or testimony other than that submitted will be considered in making an initial determination on, or a final order in response to, this petition.

Respectfully submitted the ____ day of _____ , 20___.

_____

By: _____
Name of Individual Signing on behalf of petitioner

Authority: T.C.A. §§ 68-11-207, 68-11-213, and 68-11-2206.

0720-46-.08 Penalties

(1) Civil Penalties

(a) Purpose - The purpose of this rule is to set out a schedule designating the minimum and maximum civil penalties which may be assessed.

(b) Schedule of Civil Penalties

1. A Type A civil penalty may be imposed whenever the Commission finds the person who is required to be registered by the Commission is guilty of a willful and knowing violation of the Temporary Healthcare Staffing Registry Act, or regulations promulgated pursuant thereto, to such an extent that there is, or is likely to be an imminent substantial threat to the health, safety, and welfare of the public. For purposes of this section, a Type A penalty shall include, but not be limited to, a person who willfully and knowingly operates

a staffing registry without registration from the Commission.

2. A Type B civil penalty may be imposed whenever the Commission finds the person required to be registered by the Commission is guilty of a violation of the Temporary Healthcare Staffing Registry Act or regulations promulgated pursuant thereto in such manner as to impact directly on the care of patients received in a licensed healthcare facility or the public.

3. A Type C civil penalty may be imposed whenever the Commission finds the person required to be registered by the Commission is guilty of a violation of the Temporary Healthcare Staffing Agency Registry or regulations promulgated thereto, which are neither directly detrimental to clients or the public, nor directly impact their care, but have only an indirect relationship to client care or the public.

(c) Amount of Civil Penalties

1. Type A civil penalties shall be assessed in the amount of not less than $1000 nor more than $5,000.

2. Type B civil penalties may be assessed in the amount of not less than $500 and not more than $1000.

3. Type C civil penalties may be assessed in the amount of not less than $100 and not more than $500.

(d) Procedures for Assessing Civil Penalties

1. The Commission's staff may initiate a civil penalty assessment by filing a Memorandum of Assessment of Civil Penalty. The Commission's staff shall state in the memorandum the facts and law upon which it relies in alleging a violation, the proposed amount of the civil penalty and the basis for such penalty. The Commission's staff may incorporate the Memorandum of Assessment of Civil Penalty with a Notice of Charges which may be issued attendant thereto.

2. Civil Penalties may also be initiated and assessed by the Commission during consideration of any Notice of Charges. In addition, the Commission may, upon good cause shown, assess a type and amount of civil penalty which was not recommended by the Commission's staff.

3. In assessing the civil penalties pursuant to these rules the Commission may consider the following factors:

(i) Whether the amount imposed will be a substantial economic deterrent to the violator;

(ii) The circumstances leading to the violation;

(iii) The severity of the violation and the risk of harm to the public;

(iv) The economic benefits gained by the violator as a result of non-compliance; and

(v) The interest of the public.

4. All proceedings for the assessment of civil penalties shall be governed by the contested case provisions of T.C.A. Title 4, Chapter 5 and shall be heard by an Administrative Law Judge sitting alone.

Authority: T.C.A. §§ 68-11-2206 and 68-11-2207.

HFC

STATE OF TENNESSEE
HEALTH FACILITIES COMMISSION
665 MAINSTREAM DRIVE, SECOND FLOOR
NASHVILLE, TENNESSEE 37243
TELEPHONE (615) 741-7221
FAX (615) 741-7051

PM 99

Board for Licensing Health Care Facilities

Policy Memorandum

SUBJECT: Home Medical Equipment Disaster Preparedness Waiver Request of Rules 0720-30-.14(1) and 0720-30-.14(2)

DATE: June 5, 2024

POLICY: As a result of "Quinnlee's Law," out-of-state providers are being licensed in Tennessee and may not be able to establish and maintain communication with the Tennessee Emergency Management Agency (TEMA). Additionally, the out-of-state provider who is not able to establish communication with TEMA would not be able to maintain documentation demonstrating that communication and cooperation. Therefore, an out-of-state provider that is not able to establish and maintain communication with TEMA may request a waiver of the above cited rules.

The requestor must:
(1) Provide an explanation, in writing, why these requirements cannot be met.
(2) Provide evidence that no Tennessee resident will suffer deleterious effects by granting this waiver.
(3) Provide any other information requested by the Board/Commission.

This policy will remain in effect until this policy is rescinded by the Board/Commission.

EFFECTIVE: June 5, 2024

APPROVED:

Christopher Wilson, M.D., Chairman
Board for Licensing Health Care Facilities

Caroline Tippens, Esq, CHC
Director, Licensure and Regulation
Board for Licensing Health Care Facilities

State of Tennessee
Health Facilities Commission
502 Deaderick Street, 9th Floor, Nashville, TN 37243
www.tn.gov/hsda Phone: 615-741-2364

SUBJECT: **INTERPRETATION AND TEMPORARY WAIVER OF RULES RELATED TO HURRICANE HELENE**

DATE: **October 23, 2024**

POLICY: **# 100**

EFFECTIVE: **OCTOBER 23, 2024**

The Commission issues this policy to facilitate the recovery from Hurricane Helene and offer regulatory flexibilities for healthcare facilities in the affected counties.

With this same aim, on September 27, 2024, Tennessee Governor, Bill Lee, issued Executive Order No. 105, which suspends certain statutes and rules. *See* Exhibit 1.

On September 28, 2024, President Biden declared a FEMA federal disaster in the counties of Cocke, Hawkins, Washington, Carter, Johnson, and Unicoi Counties. *See* Exhibit 2.

In a letter dated September 30, 2024, the Centers for Medicare and Medicaid (CMS) Secretary Xavier Becerra declared a Public Health Emergency existed in counties included in President Biden's FEMA disaster declaration. *See* Exhibit 3.

On September 30, 2024, CMS suspended certain regulations (known as 1135 waivers) 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* Exhibit 4.

In light of the 1135 waivers, the Commission hereby waives its analogous State rules to allow for the construction of temporary structures related to the treatment of patients in temporary facilities in the affected counties, provided that following criteria are met. The Commission interprets these revised building standards to include the provisions in Attachment 5 – Temporary Structures.

This policy shall remain in effect until the Commission's October 2025 Commission Meeting or whichever date that CMS repeals the 1135 waivers, whichever comes first.

Mr. Rick Chinn, Chair
Health Facilities Commission

Logan Grant, Executive Director
Health Facilities Commission

STATE OF TENNESSEE

EXECUTIVE ORDER

BY THE GOVERNOR

No. 105

AN ORDER TO PROVIDE RELIEF TO VICTIMS OF SEVERE WEATHER AND FLOODING IN TENNESSEE

WHEREAS, on September 26 and 27, 2024, severe weather, including severe rainfall and flash flooding, affected significant portions of the State and caused substantial damage and destruction, and threatened public safety, and these severe weather conditions continue to affect the lives and property of Tennesseans; and

WHEREAS, many people have suffered significant property damage; and

WHEREAS, many residents of the affected areas have evacuated their homes or places of lodging and are seeking temporary refuge in other locations within the State; and

WHEREAS, local, state, and federal agencies and other organizations are engaged in relief efforts throughout the affected regions; and

WHEREAS, in response to the severe weather and flooding, Tennessee has requested an Emergency Declaration from the President of the United States; and

WHEREAS, the severe weather impacts, as well as the relief efforts in response thereto, are expected to persist for several weeks.

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 applicable law including Tennessee Code Annotated § 58-2-107, do hereby declare a major disaster and state of emergency exist and direct and order the following, *nunc pro tunc* to 12:01 a.m., Central Time, on September 27, 2024:

EXHIBIT
1

1. The relevant provisions of Tennessee Code Annotated, Titles 63 and 68, and related rules are hereby suspended 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, if such individual is a health care professional who is assisting victims of the severe weather in Tennessee.

2. The provisions of Tennessee Code Annotated, Section 63-10-207(a) and (c), are hereby suspended to allow a pharmacist to dispense a 30-day supply of a prescription drug without proper authorization to victims of the severe weather in Tennessee, subject to all other provisions of Tennessee Code Annotated, Sections 63-10-207 and 63-1-164.

3. Any provision of the Tennessee Code Annotated and related rules that require Tennessee residency as a condition of eligibility to participate in programs administered by the Department of Health are hereby suspended to allow otherwise eligible evacuees from the severe weather to participate in such programs. These programs include but are not limited to the Special Supplemental Nutrition Program for Women, Infants and Children (Tenn. Comp. R. & Regs. Chapter 1200-15-2-.03), Renal Disease Program (Tenn. Comp. R. & Regs. Chapter 1200-11-1-.03), Hemophilia Program (Tenn. Comp. R. & Regs. Chapter 1200-11-2-.03), Children's Special Services (Tenn. Comp. R. & Regs. Chapter 1200-11-3-.03), and the Child Safety Fund (Tenn. Comp. R. & Regs. Chapter 1200-11-4-.04).

4. The relevant provisions of Tennessee Code Annotated, Title 56, and related rules are hereby suspended to give the Commissioner of Commerce and Insurance the discretion to direct Tennessee-licensed insurance companies to make reasonable efforts to assist policyholders who have experienced losses as a result of the severe weather in Tennessee. Specifically, where a delay in premium payment appears to be the result of a disruption to the mail delivery system or the policyholder's displacement due to the severe weather in Tennessee, the Department of Commerce and Insurance requests that insurers work with policyholders and take those circumstances into account before cancelling a policy and that insurers suspend cancellations or non-renewals of policies for non-payment of premiums for a period of at least sixty (60) days from the effective date of this Order for those policyholders who have suffered property damage, injuries, or loss of life as a result of these catastrophic events. The Commissioner of Commerce and Insurance has the discretion to allow an insurance professional who is licensed in another state and who would otherwise be subject to licensing requirements under Title 56 to engage in the practice of such individual's profession, if the individual is assisting victims of the severe weather in Tennessee.

5. The provisions of Tennessee Code Annotated, Section 55-50-323, and related rules are hereby suspended to the extent necessary to give the Commissioner of Safety and Homeland Security the discretion to waive fees for duplicate driver licenses or

photo identification licenses issued to persons affected by the severe weather in Tennessee.

6. The relevant provisions of Tennessee Code Annotated, Title 62, Chapter 6, Part 1, and related rules are hereby suspended to allow the Board for Licensing Contractors to temporarily license a person otherwise qualified to be licensed as a contractor without examination if the person provides sufficient proof, in the discretion of the Board or the Board's designee, that the issuance of the license is to assist victims of the severe weather in Tennessee and that the person to be licensed has sufficient experience and knowledge in the field of contracting in which the license will be issued to provide for the protection of the health, safety, and welfare of the public. Any applicable fees shall be prorated. Any such license shall not be eligible for renewal and shall expire six (6) months from the date of issuance.

7. The provisions of Tennessee Code Annotated, Sections 55-6-101(a)(4) and 55-6-104(a)(4), are hereby suspended to waive the fees due to the State and county clerk for the issuance of a duplicate title to replace a motor vehicle title that is lost or mutilated, pursuant to Tennessee Code Annotated, Section 55-3-115, for persons affected by the severe weather in Tennessee.

8. In accordance with Tennessee Code Annotated, Section 47-18-5103, it is hereby declared that the severe weather in Tennessee has resulted in an abnormal economic disruption, and therefore, persons are prohibited from charging any other person a price for the goods or services listed in Tennessee Code Annotated, Section 47-18-5103(a)(1), 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 9 of this Order shall remain in effect until 11:59 p.m., Central Time, on October 11, 2024.

9. 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 weight, height, length, and width limitations are hereby suspended in the case of vehicles providing relief efforts in response to the severe weather in Tennessee, subject to the following conditions:

   a. A vehicle must be transporting emergency supplies, equipment, or mobile housing units to the impacted 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 highways and roads as may be required to respond to the severe weather emergency, 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. Vehicles transporting FEMA or other mobile housing units exceeding ten feet (10') in width, but not exceeding fourteen feet, six inches (14' 6") in width, may travel seven (7) days per week during daylight or nighttime hours without any time restrictions except as follows:

   i. To promote public safety by avoiding "rush hour" traffic, vehicles shall not transport any load authorized herein between the hours of 7:00 a.m. to 9:00 a.m. and 4:00 p.m. to 6:00 p.m. (local time) Monday through Friday in Knox, Hamilton, Davidson, Williamson, and Shelby Counties.

h. Vehicles are responsible for ensuring that they have proper oversize load signs, markings, flags, and escorts as required by the Tennessee Department of Transportation's rules and regulations for overdimensional movements on Tennessee's roads, except that a contracted FEMA carrier may use a single escort to escort up to three (3) overdimensional loads.

i. This Executive Order shall serve as a special permit for transporting any load authorized herein. Transporters shall keep appropriate identification as designated by FEMA or their state of origin in their vehicle while transporting any load permitted by this Order and shall reference this Order as permitting such transports.

j. 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.

10. Any request by vehicles carrying appropriate identification designated by FEMA or their state of origin that are transporting emergency supplies, equipment, or mobile housing units in response to the severe weather in Tennessee for a special permit to transport loads in excess of the foregoing weight, height, length, and width limits or other restrictions shall be given expedited consideration and may be approved within the discretion of the Tennessee Department of Transportation's Oversize and Overweight Permit Office. The Commissioner of Transportation shall have the authority to waive any otherwise applicable permit fees related to such a request.

11. 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 the severe weather in Tennessee, 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.

12. The provisions of Tennessee Code Annotated, Section 62-35-115, and related rules are hereby suspended to the extent that they would otherwise apply to non-resident security guards or security officers properly registered or licensed in another jurisdiction providing support to the areas affected by the severe weather in Tennessee; provided, that the following conditions are met:

a. Such non-resident registered or licensed security guards or security officers are employed only within the areas affected by the severe weather in Tennessee; and

b. The employers of the non-resident licensed security guards or security officers provide to the Commissioner of Commerce and Insurance a list of the names, addresses, and social security numbers of all non-resident licensed security guards or security officers utilized under the terms of this Order.

13. The relevant provisions of Tennessee Code Annotated, Sections 62-6-102(4)(A)(i), 62-6-103(a)(1), and 62-6-502, and related rules are hereby suspended in the case of persons engaging solely in storm damage cleanup resulting from the severe weather in Tennessee, provided that the person has sufficient experience and knowledge in the field to provide for the protection of the health, safety, and welfare of the public.

14. The provisions of Tennessee Code Annotated, Sections 62-13-104(b)(l)(C), 62-13-103(a), and 62-13-301, are hereby suspended only to the extent necessary to permit vacation lodging services licensed pursuant to Tennessee Code Annotated, Section 62-13-104(b), to engage in the business of providing the services of management, marketing, booking and rental of residential units owned by others as sleeping accommodations furnished for pay to persons providing relief services to persons affected by the severe weather or who are victims of the severe weather periods longer than fourteen (14) days without the requirement that such vacation lodging services hold any other license with the Tennessee Real Estate Commission, be under the supervision of a licensed real estate broker, or hold a real estate firm license; provided, that sufficient proof of the status of each person providing relief services or who is a victim is maintained by the vacation lodging service and made available to the Tennessee Real Estate Commission upon request. All other provisions applicable to vacation lodging services, real estate firms, and real estate brokers remain in effect.

15. All state agencies are encouraged to work with persons adversely affected by a disruption to the mail delivery system or displacement due to the severe weather in Tennessee and to take those circumstances into account with respect to giving notice and providing state services.

Any law, order, rule, or regulation that would otherwise limit the enforceability of this Order is hereby suspended, pursuant to Tennessee Code Annotated, Section 58-2-107.

This Order shall remain in effect until 11:59 p.m., Central Time, on November 10, 2024, at which time the suspension of any state laws and rules shall cease and be of no further force and effect.

IN WITNESS WHEREOF, I have subscribed my signature and caused the Great Seal of the State of Tennessee to be affixed this 27th day of September, 2024.

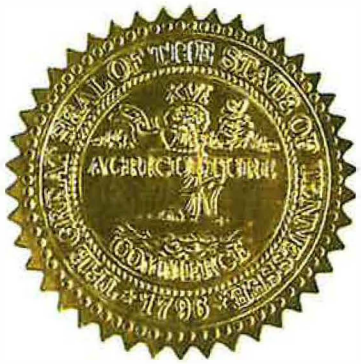
Bill Lee

GOVERNOR

ATTEST:

Tre Hargett

SECRETARY OF STATE



President Joseph R. Biden, Jr. Approves Emergency Declaration for Tennessee

Release Date: September 28, 2024

WASHINGTON -- FEMA announced today that federal disaster assistance is available to the state of Tennessee to supplement response efforts due to emergency conditions resulting from Tropical Storm Helene beginning Sept. 26 and continuing.

The President's action authorizes FEMA to coordinate all disaster relief efforts to alleviate the hardship and suffering caused by the emergency on the local population and to provide appropriate assistance to save lives, to protect property, public health and safety and to lessen or avert the threat of a catastrophe.

Federal funding is available to state and eligible local governments and certain private nonprofit organizations on a cost-sharing basis for emergency protective measures limited to direct federal assistance and reimbursement for mass care including evacuation and shelter support for Cocke, Hawkins and Washington counties.

Federal funding is available for emergency protective measures including direct federal assistance for Carter, Johnson and Unicoi counties.

Darryl L. Dragoo has been named the Federal Coordinating Officer for federal recovery operations in the affected area.?

EXHIBIT 2

FEMA

THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

DETERMINATION THAT A PUBLIC HEALTH EMERGENCY EXISTS

As a result of the consequences of Hurricane Helene on the States of South Carolina and Tennessee, on this date and after consultation with public health officials as necessary, I, Xavier Becerra, Secretary of Health and Human Services, pursuant to the authority vested in me under section 319 of the Public Health Service Act, do hereby determine that a public health emergency exists and has existed since September 25, 2024, in the State of South Carolina and since September 26, 2024, in the State of Tennessee.

September 30, 2024
Date

Xavier Becerra

EXHIBIT
3

2024 Hurricane Helene Available Waivers for Affected Counties in the States of South Carolina and Tennessee Health Care Providers

CMS is empowered to take proactive steps to help providers through waivers issued pursuant to section 1135 of the Social Security Act (the Act). In addition, the statute provides for discretionary SNF coverage authority under section 1812(f) of the Act, and extended coverage until December 2024 for certain telehealth services. The following blanket waivers and other flexibilities are in effect through the end of the Hurricane Helene public health emergency declaration of the State of South Carolina signed 09/30/2024, retroactively from 09/25/24, and the State of Tennessee signed 09/30/2024, retroactively from 09/26/2024 for the geographic area covered by the President's declaration in both states or when no longer needed. Despite the availability of blanket waivers, suppliers and providers should strive to return to their normal practice as soon as possible.

Blanket waivers DO NOT need to be submitted via the CMS 1135 Waiver Portal (https://cmsqualitysupport.servicenowservices.com/cms_1135) or via notification to the CMS Survey & Operations Group and are applied automatically by surveyors.

Hospitals, Psychiatric Hospitals, and Critical Access Hospitals (CAHs), including Cancer Centers and Long-Term Care Hospitals (LTCHs)

- **Emergency Medical Treatment & Labor Act (EMTALA).** CMS is waiving the enforcement of section 1867(a) of the Act to allow hospitals, psychiatric hospitals, and critical access hospitals (CAHs) to screen patients at a location offsite from the hospital's campus, so long as it is not inconsistent with a state's emergency preparedness plan or pandemic plan.

- **Medical Staff.** CMS is waiving requirements under 42 CFR §482.22(a)(1)-(4) to allow for physicians whose privileges will expire to continue practicing at the hospital and for new physicians to be able to practice before full medical staff/governing body review and approval to address workforce concerns. CMS is waiving §482.22(a)(1)-(4) regarding details of the credentialing and privileging process.

- **Physical Environment.** CMS is waiving **certain** physical environment requirements under the hospital, psychiatric hospital, and critical access hospital conditions of participation at 42 CFR §482.41 and 42 CFR §485.623 to allow increased flexibilities for surge capacity. CMS will permit facility and non-facility space that is not normally used for patient care to be utilized for patient care, provided the location is approved by the state (ensuring that safety

EXHIBIT 4

and comfort for patients and staff are sufficiently addressed) and is consistent with the state's emergency preparedness or pandemic plan. States are still subject to obligations under the integration mandate of the Americans with Disabilities Act, to avoid subjecting persons with disabilities to unjustified institutionalization or segregation[1].

- **Telemedicine.** CMS is waiving the provisions related to telemedicine at 42 CFR §482.12(a)(8)– (9) for hospitals and §485.616(c) for CAHs, making it easier for telemedicine services to be furnished to the hospital's patients through an agreement with an off-site hospital. This allows for increased access to necessary care for hospital and CAH patients, including access to specialty care.

- **CAH Staff Licensure.** CMS is deferring staff licensure, certification, or registration to state law by waiving 42 CFR §485.608(d) regarding the requirement that staff of the CAH be licensed, certified, or registered in accordance with applicable federal, state, and local laws and regulations.

Temporary Expansion Locations. CMS is waiving certain physical environment requirements under 42 CFR §482.41 and §485.623 (as noted elsewhere in this waiver document) and the provider-based department location requirements at §413.65(e)(3) to allow hospitals to establish and operate as part of the hospital any location meeting those conditions of participation for hospitals, including any existing provider-based departments of the hospital. This extends to any entity operating as a hospital so long as the relevant location meets the conditions of participation and other requirements not waived by CMS.

Expanded Ability for Hospitals to Offer Long-term Care Services ("Swing-Beds") for Patients Who do not Require Acute Care but do Meet the Skilled Nursing Facility (SNF) Level of Care Criteria as Set Forth at 42 CFR 409.31. Under section 1135(b)(1) of the Act, CMS is waiving the eligibility requirements at 42 CFR 482.58(a)(1)-(4), *"Special Requirements for hospital providers of long-term care services ('swing-beds')"* to allow hospitals to establish SNF swing beds payable under the SNF prospective payment system (PPS) to provide additional options for hospitals with patients who no longer require acute care but are unable to find placement in a SNF.

[1] Please note that consistent with the integration mandate of Title II of the ADA and the *Olmstead vs LC* decision, States are obligated to offer/provide discharge planning and/or case management/ transition services, as appropriate, to individuals who are removed from their Medicaid home and community based services under these authorities during the course of the public health emergency as well as to individuals with disabilities who may require these services in order to avoid unjustified institutionalization or segregation. Transition services/ case management and/or discharge planning would be provided to facilitate these individuals in their return to the community when their condition and public health circumstances permit.

In order to qualify for this waiver, hospitals must:

- Not use SNF swing beds for acute level care.
- Comply with all other hospital conditions of participation and those SNF provisions set out at 42 CFR 482.58(b) to the extent not waived.
- Be consistent with the state's emergency preparedness or pandemic plan.

- **CAH Status and Location.** CMS is waiving the requirement at 42 CFR §485.610(b) that the CAH be located in a rural area or an area being treated as being rural, allowing the CAH flexibility in the establishment of temporary surge site locations. CMS is also waiving the requirement at §485.610(e) regarding the CAH's off-campus and co-location requirements, allowing the CAH flexibility in establishing temporary off-site locations. In an effort to facilitate the establishment of CAHs without walls, these waivers will also suspend restrictions on CAHs regarding their location relative to other hospitals and CAHs consistent with a state's emergency preparedness or pandemic plan.

- **CAH Length of Stay.** CMS is waiving the requirements that CAHs limit the number of beds to 25, and that the length of stay be limited to 96 hours (per patient, on an annual average basis) under the Medicare conditions of participation for number of beds and length of stay at 42 CFR § 485.620.

Housing Acute Care Patients in the Inpatient Rehabilitation Facility (IRF) Excluded Distinct Part Units

Flexibility for Inpatient Rehabilitation Facilities Regarding the "60 Percent Rule"

- CMS is allowing IRFs to exclude patients from the freestanding hospital's or excluded distinct part unit's inpatient population for purposes of calculating the applicable thresholds associated with the requirements to receive payment as an IRF (commonly referred to as the "60 percent rule") if an IRF admits a patient solely to respond to the emergency and the patient's medical record properly identifies the patient as such. In addition, during the applicable waiver time period, we would also apply the exception to facilities not yet classified as IRFs, but that are attempting to obtain classification as an IRF.

Housing Acute Care Patients in the Inpatient Psychiatric Facility (IPF) Excluded Distinct Part Units

Housing Acute Care Patients In Excluded Distinct Part Units

- CMS is allowing acute care hospitals to house acute care inpatients in excluded distinct part units, where the distinct part unit's beds are appropriate for acute care inpatient. The Inpatient Prospective Payment System (IPPS) hospital should bill for the care and annotate

the patient's medical record to indicate the patient is an acute care inpatient being housed in the excluded unit because of capacity issues related to the disaster or emergency.

Long-Term Care Facilities and Skilled Nursing Facilities (SNFs) and/or Nursing Facilities (NFs)

- **Reporting Minimum Data Set (MDS).** CMS is modifying the requirements at 42 CFR §483.20(b)(2) to provide relief to SNFs on the timeframes in which they must conduct a comprehensive assessment and collect MDS data. CMS is not waiving the requirements for facilities to conduct the assessment and collect MDS data at 42 CFR 483.20(b)(1).

- **Waive Pre-Admission Screening and Annual Resident Review (PASARR).** CMS is waiving 42 CFR § 483.20(k), allowing nursing homes to admit new residents who have not received Level 1 or Level 2 Preadmission Screening. Level 1 assessments may be performed postadmission. On or before the 30th day of admission, new patients admitted to nursing homes with a mental illness (MI) or intellectual disability (ID) should be referred promptly by the nursing home to State PASARR program for Level 2 Resident Review.

Supporting Care for Patients in Long-Term Care Acute Hospitals (LTCHs)

- CMS has determined it is appropriate to issue a blanket waiver to long-term care hospitals (LTCHs) where an LTCH admits or discharges patients in order to meet the demands of the emergency from the 25-day average length of stay requirement at § 412.23(e)(2), which allows these hospitals to participate in the LTCH PPS.

Skilled Nursing Facilities (SNFs)

- **3-Day Prior Hospitalization.** Using the authority under Section 1812(f) of the Act, CMS may cover SNF stays without a 3-day prior inpatient hospitalization. In addition, for certain beneficiaries who recently exhausted their SNF benefits, it authorizes a one-time renewal of SNF coverage without first having to start a new benefit period (this portion of the waiver will apply only for those beneficiaries who have been delayed or prevented by the emergency itself from commencing or completing the process of ending their current benefit period and renewing their SNF benefits that would have occurred under normal circumstances).

- **Physician Visits in Skilled Nursing Facilities/Nursing Facilities.** CMS is waiving the requirement in 42 CFR 483.30 for physicians and non-physician practitioners to perform in-person visits for nursing home residents and allow visits to be conducted, as appropriate, via telehealth options.

- **Physical Environment.** CMS is waiving requirements under 42 CFR 483.90 to temporarily allow for rooms in a long-term care facility not normally used as a resident's room, to be used to accommodate beds and residents for resident care in emergencies and situations needed to help with surge capacity. Rooms that may be used for this purpose include activity rooms, meeting/conference rooms, dining rooms, or other rooms, as long as residents can be kept safe, comfortable, and other applicable requirements for participation are met. This can be done so long as it is not inconsistent with a state's emergency preparedness or pandemic plan, or as directed by the local or state health department.

Hospice

- **Comprehensive Assessments.** CMS is modifying certain requirements at 42 CFR §418.54 related to updating comprehensive assessments of patients. This modifies the timeframes for updates to the comprehensive assessment found at §418.54(d). Hospices must continue to complete other required assessments (i.e., initial and ad-hoc assessments based on a change in the patient's condition); however, the timeframes for updating the comprehensive assessment may be extended from 15 to 21 days.

Home Health Agencies (HHAs)

- **Reporting.** CMS is providing relief to HHAs on the timeframes related to OASIS Transmission through the following actions below:
    - Extending the 5-day completion requirement for the comprehensive assessment to 30 days.
    - Modifying the 30-day OASIS submission requirement. Delayed submission is permitted during the PHE.

- **Initial Assessments.** CMS is waiving the requirements at 42 CFR §484.55(a) to allow HHAs to perform Medicare-covered initial assessments and determine patients' homebound status remotely or by record review. This will allow patients to be cared for in the best environment for them while reducing the impact on acute care and long- term care facilities. This will allow for maximizing coverage by already scarce physician, and advanced practice clinicians, and allow those clinicians to focus on caring for patients with the greatest acuity.

Intermediate Care Facility for Individuals with Intellectual Disabilities (ICF/IID)

- **Staffing Flexibilities.** CMS is waiving the requirements at 42 CFR §483.430(c)(4), which requires the facility to provide sufficient Direct Support Staff (DSS) so that Direct Care Staff

(DCS) are not required to perform support services that interfere with direct client care. DSS performs activities such as cleaning of the facility, cooking, and laundry services. DSC performs activities such as teaching clients appropriate hygiene, budgeting, or effective communication and socialization skills. During the time of this waiver, DCS may be needed to conduct some of the activities normally performed by the DSS. This will allow facilities to adjust staffing patterns while maintaining the minimum staffing ratios required at §483.430(d)(3).

- **Physical Environment.** CMS is waiving **certain** physical environment requirements under the ICF/IID conditions of participation at 42 CFR §483.470 to allow increased flexibilities for surge capacity. CMS will permit facility and non-facility space that is not normally used for patient care to be utilized for patient care, provided the location is approved by the state (ensuring that safety and comfort for patients and staff are sufficiently addressed) and is consistent with the state's emergency preparedness or pandemic plan. States are still subject to obligations under the integration mandate of the Americans with Disabilities Act, to avoid subjecting persons with disabilities to unjustified institutionalization or segregation[2]

Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS)

- When DMEPOS is lost, destroyed, irreparably damaged, or otherwise rendered unusable, CMS is allowing DME Medicare Administrative Contractors (MACs) to have the flexibility to waive replacements requirements such that the face-to-face requirement, a new physician's order, and new medical necessity documentation are not required. Suppliers must still include a narrative description on the claim explaining the reason why the equipment must be replaced and are reminded to maintain documentation indicating that the DMEPOS was lost, destroyed, irreparably damaged, or otherwise rendered unusable or unavailable as a result of the emergency.

  This also allows CMS to temporarily extend the 10-business day deadline to provide notification of any subcontracting arrangements. During the temporary extension period, affected contract suppliers will have 30 business days to provide notice to the Competitive Bidding Implementation Contractor of any subcontracting arrangements. CMS will notify DMEPOS Competitive Bidding contract suppliers via e-mail when this temporary extension

[2] Please note that consistent with the integration mandate of Title II of the ADA and the *Olmstead vs LC* decision, States are obligated to offer/ provide discharge planning and/or case management/ transition services, as appropriate, to individuals who are removed from their Medicaid home and community based services under these authorities during the course of the public health emergency as well as to individuals with disabilities who may require these services in order to avoid unjustified institutionalization or segregation. Transition services/ case management and/or discharge planning would be provided to facilitate these individuals in their return to the community when their condition and public health circumstances permit.

expires. All other competitive bidding program requirements remain in force. Note: CMS will provide notice of any changes to reporting timeframes for future events.

Replacement Prescription Fills

- Medicare payment may be permitted for replacement prescription fills (for a quantity up to the amount originally dispensed) of covered Part B drugs in circumstances where dispensed medication has been lost or otherwise rendered unusable by damage due to the disaster or emergency.

Practitioner Locations

- CMS is temporarily waiving requirements that out-of-state practitioners be licensed in the state where they are providing services when they are licensed in another state. CMS will waive the physician or non-physician practitioner licensing requirements when the following four conditions are met: 1) must be enrolled as such in the Medicare program; 2) must possess a valid license to practice in the state, which relates to his or her Medicare enrollment; 3) is furnishing services – whether in person or via telehealth – in a state in which the emergency is occurring in order to contribute to relief efforts in his or her professional capacity; and, 4) is not affirmatively excluded from practice in the state or any other state that is part of the 1135 emergency area.

  In addition to the statutory limitations that apply to 1135-based licensure waivers, an 1135 waiver, when granted by CMS, does not have the effect of waiving state or local licensure requirements or any requirement specified by the state or a local government as a condition for waiving its licensure requirements. Those requirements would continue to apply unless waived by the state. Therefore, in order for the physician or non-physician practitioner to avail him- or herself of the 1135 waiver under the conditions described above, the state also would have to waive its licensure requirements, either individually or categorically, for the type of practice for which the physician or non-physician practitioner is licensed in his or her home state.

Provider Enrollment

- Waive the following screening requirements:
  - Application Fee - (to the extent applicable).

    -Criminal background checks associated with fingerprint-based criminal background checks (FCBC) (to the extent applicable) - 42 CFR §424.518.

    -Site visits (to the extent applicable) - 42 CFR §424.517.

- Allow licensed providers to render services outside of their state of enrollment.

CMS-13 Requirements (allowing rehab hospitals the ability to treat medical/surgical patients and receive an exemption from the requirements of CMS13 which requires that 60 percent of the patients treated at a facility paid under the rehab prospective payment system be treated for one of 13 specified conditions)

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 1: 18.2.3.5.1.1 & 18.2.3.5.1.2]

Tents

1. Tents shall be erected and located in accordance with NFPA 101: Section 11.11.

2. All tent fabric shall meet the flame propagation performance criteria contained in Test Method 2 of NFPA 701 [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: 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 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 Ft^2 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]

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 Ft^2. 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]

EXHIBIT 5

TEMPORARY STRUCTURES

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 150 Ft^2 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: 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 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 Ft^2. 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

FOR IMMEDIATE RELEASE
October 9, 2024

CONTACT: Elizabeth Lane Johnson
Elizabeth.L.Johnson@tn.gov

Federal Disaster Declaration Granted to Additional Tennessee Counties Recovering From Flooding

NASHVILLE, Tenn. – Today, Tennessee Gov. Bill Lee announced three more counties have been approved for FEMA's Public Assistance program. The program is now available to eligible jurisdictions and certain private, non-profit organizations in a total of 12 counties following significant flooding from Hurricane Helene that impacted Northeast Tennessee on September 26.

"State and local officials, first responders, and volunteers continue to provide critical support to impacted Tennessee communities following significant flood damage," **said Gov. Lee.** "As Tennesseans continue the rebuilding process, I thank our federal partners for granting resources to further our severe weather response and recovery in Northeast Tennessee."

The three additional counties named in the amendment of the Major Disaster Declaration to receive **Public Assistance**, including direct federal assistance, are **Claiborne, Grainger, and Sullivan** counties.

Jefferson County, who has already been designated for debris removal and emergency protective measures (Category A and B), including direct federal assistance, has been approved to receive **permanent work assistance** (Categories C-G). **Carter, Cocke, Greene, Hamblen, Hawkins, Johnson, Unicoi, and Washington** counties have also received **permanent work assistance** (Categories C-G). This is in addition to the Individual Assistance and Categories A and B Public Assistance, including direct federal assistance, these counties have already been designated to receive.

"Our top priority remains supporting the recovery of our communities in a way that places survivors at the heart of every decision we make," said TEMA Director, Patrick C. Sheehan. "The amendment to the Major Disaster Declaration, expanding to include the permanent categories of Public Assistance, ensures our communities have the resources they need to rebuild. We will continue working hand-in-hand with federal, state, and local partners to deliver aid efficiently and effectively to survivors."

A Major Disaster Declaration was approved on October 2, 2024. This amendment will make federal disaster relief available in the declared counties. To learn more about FEMA's Public Assistance program, visit their website.

Additionally, Individual Assistance registration remains open for survivors in Carter, Cocke, Greene, Hamblen, Hawkins, Johnson, Unicoi, and Washington counties. Individuals can apply:

- Online anytime at www.disasterassistance.gov
- By phone at 1-800-621-3362 between 7 a.m. and 11 p.m. ET. Multilingual operators are available.
- With FEMA at the Multi-Agency Resource Centers located at:
  - **Elizabethton:** 1749 Hwy 19E, Elizabethton, TN 37643
  - **Jonesborough:** 306 Forest Dr., Jonesborough, TN 37659

EXHIBIT 6

Tennessee experienced severe flooding from Hurricane Helene. This weather event has claimed seventeen lives and left significant damage across Northeast Tennessee.

Resources and updates for survivors can be found on the Tennessee Emergency Management Agency's dedicated Helene webpage.

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HFC

STATE OF TENNESSEE
HEALTH FACILITIES COMMISSION
665 MAINSTREAM DRIVE, SECOND FLOOR
NASHVILLE, TENNESSEE 37243
TELEPHONE (615) 741-7221
FAX (615) 741-7051

PM 101

Policy Memorandum

SUBJECT: CHOW Requirement for Limited Liability Company (LLC)

DATE: February 26, 2025

POLICY: This policy shall supplement Policy 93.

For all facility types, the following addition shall be made for the Change of Ownership sections.

Transactions which do not constitute a change of ownership include, but are not limited to, the following:

For a member-managed or manager-managed Limited Liability Company (LLC), an equity transfer or sale, even when a controlling interest.

EFFECTIVE: February 26, 2025

APPROVED:

Logan Grant
Executive Director
Health Facilities Commission

HFC

STATE OF TENNESSEE
HEALTH FACILITIES COMMISSION
665 MAINSTREAM DRIVE, SECOND FLOOR
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TELEPHONE (615) 741-7221
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PM 102

Policy Memorandum

SUBJECT: Hospital Exceeding Bed Capacity

DATE: February 26, 2025

POLICY: This policy allows a hospital facility to request a waiver of bed capacity for a period not to exceed three (3) months, if the following information is provided at the time of the waiver request:

- Provide the number of beds requested under the waiver;
- Provide the reason for the increase in bed capacity to include a description of the illness causing the need;
- Provide an attestation that required staffing levels can be met;
- Provide the expected average length of stay;
- Provide an attestation that staffing levels can be maintained if the expected length of stay is exceeded;
- Provide a description of the location and area of the overflow;

In accordance with this policy, Commission staff may:

1. administratively approve the waiver;
2. administratively approve the waiver with conditions to protect the health, safety, and welfare of the patients;
3. deny the waiver and request appearance before the Commission at the next regularly scheduled Commission meeting.

Notification to the Commission shall be made at the next regularly scheduled Commission meeting.

This policy shall remain into effect until the Commission's rules are amended or the Commission rescinds this policy.

EFFECTIVE: February 26, 2025

APPROVED:

Logan Grant
Executive Director
Health Facilities Commission

State of Tennessee
Health Facilities Commission
502 Deaderick Street, 9th Floor, Nashville, TN 37243
www.tn.gov/hsda Phone: 615-741-2364

POLICY MEMORANDUM PM 103

SUBJECT: Waiver of Admissions Regulations from Sister Facilities

DATE: April 23, 2025

This policy allows an assisted care living facility to request a waiver of admissions agreements for residents transferred within the same facility chain, both in-state and out-of-state, and admitted into Tennessee due to a disaster. Division of Licensure and Regulation staff may approve such a waiver of admissions agreements and exceeding bed capacity for a period of not to exceed sixty (60) days, if the following information is provided at the time of the waiver request:

- Provide the number of residents who shall be transferred into the facility from a sister facility from in or out-of-state;
- Provide the reason for the increase in bed capacity (e.g. flood, fire, hurricane, natural disaster, etc.);
- Provide an attestation that required staffing levels can be met;
- Provide an attestation indicating that staff have access to medical records (either in written or electronic form) and medication administration records from the transferring facility;
- Provide the length of stay expected;
- Provide an attestation that the staffing levels can be maintained if the length of stay is exceeded;
- Provide a description of the location and area where residents will reside; and
- Be willing to undergo a health and life safety inspection of the area being used for temporary stay, if staff deem such inspection is necessary.

In accordance with this Policy, Division of Licensure and Regulation staff may:

1. Ask for additional information;
2. Approve the waiver;
3. Condition the waiver with additional requirements necessary to protect the health, safety, and welfare of the patients; or
4. Deny the waiver and request appearance before the Commission at the next regularly scheduled Commission meeting.

If the waiver is administratively approved, Division of Licensure & Regulation staff shall notify the Commission of the approval at the next regularly scheduled Commission meeting.

This policy shall remain in effect until the Commission rescinds this policy.

Effective: April 23, 2025

APPROVED: Logan Grant
Logan Grant, Executive Director
Health Facilities Commission

STATE OF TENNESSEE
HEALTH FACILITIES COMMISSION
502 Deadrick Street, Ninth Floor
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TELEPHONE (615) 741-2364
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PM 104

Health Facilities Commission

Policy Memorandum

SUBJECT: **End Stage Renal Dialysis Clinic Administrator Serving Multiple Locations**

DATE: September 24, 2025

POLICY: This policy grants the staff of the Division of Licensure and Regulation the administrative authority to approve an application by an End Stage Renal Disease (ESRD) facility to appoint an administrator to serve multiple ESRD facilities, not to exceed a total number of five (5) facilities. In evaluating such applications, the staff may consider the following criteria:

- The facilities proposed to be supervised by the administrator each employ a full-time nurse manager consistent with Tenn. Comp. R. & Regs. Rule 0720-33.01(47);
- The appointment to multiple facilities does not impede the administrator's ability to maintain responsibility for the implementation of policies adopted by the governing body as required by Tenn. Comp. R. & Regs. Rule 0720-33.04(1)(d);
- The administrator maintains oversight of the facility-wide performance improvement program and training programs, and responsibility for implementation of corrective action plans consistent with Tenn. Comp. R. & Regs. Rule 0720-33.04(8)(d); and
- The facilities are in reasonable geographic proximity.

Upon satisfactory demonstration that a single administrator serving multiple ESRD facilities will not negatively impact the health, safety, and welfare of patients, the administrative approval shall be placed on the Commission's consent calendar for ratification.

If the Division staff determine that the application should not be approved, the applicant is permitted to submit the request to be placed on the Commission's regular licensure agenda for consideration.

EFFECTIVE: September 24, 2025

APPROVED:

Logan Grant
Logan Grant
Executive Director
Health Facilities Commission