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

Ref: QSO-20-18-HHA REVISED 4/23/2020

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) and Religious

Nonmedical Healthcare Institutions (RNHCIs)

Revised to include RNHCI Guidance on COVID-19

Memorandum Summary

CMS is committed to protecting American patients and residents by ensuring health care facilities have up-to-date information to 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 (HHAs) 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; additional information about CMS waivers and regulations, and CDC guidance are added for optimizing personal protective equipment and return to work criteria for healthcare personnel with confirmed or suspected COVID-19.
- Recommendations for Visitation in Residential Facilities not Certified by Medicare: CMS is providing recommendations to home health care personnel who care for patients in residential settings such as assisted and independent living facilities.
- Medicare Participating Religious Nonmedical Healthcare Institutions (RNHCIs) and Actions- CMS is providing additional guidance for RNHCIs related to addressing potential and confirmed COVID cases and mitigating transmission including screening, treatment, and transfer to higher level care (when appropriate).

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) *and Religious Nonmedical Healthcare Institutions (RNHCIs) in* addressing the COVID-19 outbreak and minimizing transmission to other individuals.

Guidance

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

RNHCIs by nature only furnish nonmedical nursing items and services to beneficiaries who choose to rely solely upon a religious method of healing, and for whom the acceptance of medical services would be inconsistent with their religious beliefs. CMS recognizes this setting to be different from other providers. However, CMS believes that general guidance for screening and detection, and potential transfer to a healthcare setting that can provide medical care to potential or positive COVID-19 patients, if requested by the patient, may be appropriate. While CMS understands that in the RNHCI settings, screenings and examination to determine diagnosis are generally not performed, we still encourage and recommend that medical professionals within this healthcare setting closely monitor the patient population for potential symptoms or exposure to COVID-19 to prevent the spread of COVID-19 to other patients within this setting.

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 *and RNHCI* providers.

HHA and RNHCI 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 *and RNHCIs* screen patients for COVID-19?

When making a home visit, HHAs and RNHCIs 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 shortness of breath.
- 3. In the last 14 days, has had contact with someone with or under investigation for COVID-

- 19, or who is ill with respiratory illness.
- 4. Residing in a community where widespread community-based transmission of COVID-19 is occurring.

For individuals within the RNHCI setting, CMS expects religious nonmedical nursing personnel and nonmedical nursing personnel who are experienced in caring for the physical needs of nonmedical patients to identify those who may be at risk for having COVID-19 and following the same process outlined above for HHAs. RNHCIs are generally responsible for caring for the physical needs of patients, such as assistance with activities of daily living; assistance in moving, positioning, and ambulation; nutritional needs; and comfort and support measures. Additionally, RNHCIs must provide basic screening to reduce the risk of exposure to the virus that causes COVID-19 and report potential infected patients to their local health departments.

For ill patients *in both settings*, both HHAs and RNCHIs should 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 or *RNHCI charge nurse or management*, and local and state public health authorities about the presence of a person under investigation (PUI) for COVID-19. Additional guidance for evaluating patients in the U.S. for COVID-19 infection can be found on the CDC COVID-19 website.

CMS regulations require 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 alcohol-based hand sanitizer (ABHS) with greater than 60% ethanol or 70% isopropanol. 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.

RNHCIs are expected to provide care in a safe setting, which includes following current standards of practice for patient environmental safety, and may also include infection control), worker safety, and security measures). Additionally, the RNHCI's emergency preparedness program must include an all-hazards approach to their risk assessment, including emerging infectious diseases (refer to Appendix Z of the State Operations Manual). Therefore, the RNHCI should follow their emergency preparedness program to ensure that care continues in a safe setting.

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

- Health care personnel (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:
 - o Immediately stop work, put on a facemask, and self-isolate at home;
 - o Inform the HHA clinical manager of information on individuals, equipment, and locations the person came in contact with; and
 - o 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
health care personnel from reporting to work (https://www.cdc.gov/coronavirus/2019-ncov/hcp/guidance-risk-assesment-hcp.html)

Since RNHCIs provide nonmedical services in a residential care setting, CMS recommends that RNHCI staff follow the similar procedures to those outlined above for HHAs, due to the possible community transmission. We also recommend that RNHCIs review the guidance related to visitation at https://www.cms.gov/files/document/qso-20-20-allpdf.pdf-0.

HHAs *and RNCHIs* 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

**The guidance above would not apply to RNHCIs

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

Initially, symptoms may be mild and not require transfer to a hospital as long as the individual with support of the HHA *or RNHCI* 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 should 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.

We also recognize that in some cases RNHCI patients may wish to not seek medical care. Therefore, we recommend that individuals who return to a home setting or remain in the RNHCI follow all necessary recommendations related to isolation to ensure the health and safety of others. In home and community-based settings, health care providers should advise patients with COVID- 19 of the CDC guidance to mitigate transmission of the virus. This includes isolating at home during illness, restricting activities except for medical care, using a

separate bathroom and bedroom if possible, and prohibiting visitors who do not have an essential need to be in the home. The certified Medicare/Medicaid provider is expected to share this information with patients with the COVID-19 virus and his/her caregiver. RNHCIs should follow the guidance located at https://www.cdc.gov/coronavirus/2019-ncov/hcp/guidance-prevent-spread.html.

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) require that the 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 the implications for discharge planning within RNHCIs for patients with suspected COVID-19?

RNHCIs must have in effect a discharge planning process that applies to all patients. The process must assure that appropriate post-institution services are obtained for each patient, as necessary. Since many of those residing in a RNHCI may fall into a high-risk category for COVID-19, the RNHCI must assess the need for a discharge plan for any patient identified as likely to suffer adverse consequences if there is no planning as required by existing regulations.

For suspected COVID-19 patients, the RNHCI staff should communicate any relevant patient information to the receiving service provider and the healthcare transport personnel prior to the discharge/transfer of the patient(s).

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 HHAs *and RNHCIs* 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?

HHA 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.

RNHCIs should follow the same guidelines considering that this setting often provides non-clinical services, including care related to daily activities. Additionally, existing regulations at 42 CFR §403.748 require RNHCIs to have an emergency preparedness program, which should include an all-hazards approach. In addition, in 2019, CMS required providers to also include potentially emerging infectious diseases to their programs (State Operations Manual, Appendix Z). RNHCIs should follow current standards of practice, including infection control practices as annotated for HHA and outlined by CDC at https://www.cdc.gov/coronavirus/2019-ncov/infection-control/control-recommendations.html.

Should HHA staff be restricted from accessing patients in assisted and independent living facilities?

CMS does not regulate these facilities, as they are subject to state jurisdiction. HHAs are encouraged to coordinate with assisted living/independent living facilities to assure services related to direct clinical care can be provided in an appropriate and safe manner.

HHAs serve an important role in providing essential healthcare services in a variety of community-based settings, including assisted and independent living facilities. However, if the HHA staff are appropriately wearing PPE, and do not meet criteria for restricted access, they should be allowed to enter and provide services to the patient. Visit CMS guidance at: https://www.cms.gov/files/document/qso-20-20-allpdf.pdf-0. HHA personnel should participate in any screening activity that the facility requires.

If access is restricted, HHAs should communicate with the facility administration, including the state or local health department when indicated, on the nature of the restriction and timing for gaining access to HHA patients. This communication is essential for maintaining surveillance and preventing the spread of infection while also ensuring access of patients to essential home care services.

HHAs should ensure they follow the CDC guidelines for restricting access for health care workers found at https://www.cdc.gov/coronavirus/2019-ncov/hcp/guidance-risk-assesment-hcp.html https://www.cdc.gov/coronavirus/2019-ncov/hcp/guidance-risk-assesment-hcp.html https://www.cdc.gov/coronavirus/2019-ncov/hcp/guidance-risk-assesment-hcp.html <a href="https://www.cdc.gov/coronavirus/assesmen

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 with greater than 60% ethanol or 70% isopropanol *or washing hands with soap and water for at least 20 seconds*. Please see CDC Statement for Healthcare Personnel on Hand Hygiene during the Response to the International Emergence of COVID-19 https://www.cdc.gov/coronavirus/2019-ncov/hcp/hand-hygiene.html.

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.

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

If unable to remove all PPE outside of the home, it is 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 with greater than 60% ethanol or 70% isopropanol, remove face protection and discard PPE by placing in external trash can before departing location. Perform hand hygiene again.

CDC has issued guidance on strategies for optimizing the supply of PPE available at: https://www.cdc.gov/coronavirus/2019-ncov/hcp/ppe-strategy/index.html.

RNHCIs are also expected to follow current standards of practice for patient environmental safety, worker safety, and security. RNHCIs should also consider the infection control considerations outlined within this guidance as a recommendation. RNHCIs should follow the same procedures in order to provide care in a safe setting as it relates to infection control practices.

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 the virus that causes COVID-19 in respiratory specimens. For more details, please refer to: https://www.cdc.gov/coronavirus/2019-ncov/hcp/disposition-in- home-patients.html.

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

During a home health agency *or RNHCI* 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 *or RNHCI* has the most recent information provided by the CDC.

- The State should notify the appropriate CMS Regional Office of the HHA *or RNHCI* 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 or RNHCI
 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 alcoholbased 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.

Is there flexibility for the use of telehealth in HHAs during the COVID-19 Public Health Emergency (PHE)?

On March 30, 2020, CMS released an interim final rule that expands access to telehealth services in home health agencies during the PHE. For more information, visit the Coronavirus Waivers & Flexibilities website at: https://www.cms.gov/about-cms/emergency-preparedness-response-operations/current-emergencies/coronavirus-waivers

Are waivers to HHA requirements being considered during the COVID-19 PHE? Yes, CMS announced the release of several blanket waivers intended to provide flexibilities for HHAs during the public health emergency for COVID-19. For example, CMS is waiving onsite visits for supervision, and allowing for additional time to complete and submit OASIS data. Individual waiver requests will be reviewed by CMS on a case-by-case basis. For more information, visit the Coronavirus Waivers & Flexibilities website at: https://www.cms.gov/about-cms/emergency-preparedness-response-operations/current-emergencies/coronavirus-waivers.

Important CDC Resources:

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

- CDC Criteria for Return to Work for Healthcare Personnel with Confirmed or Suspected COVID-19: https://www.cdc.gov/coronavirus/2019-ncov/healthcare-facilities/hcp-return-work.html
- 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-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/respirator-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:

Prioritization of Survey Activities: QSO-20-20-All. https://www.cms.gov/files/document/qso-20-20-allpdf.pdf-0 (Includes guidance on visitation.)

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/Manuals/downloads/som107ap_b_hha.pdf

Interpretive Guidelines for Responsibilities of Medicare Participating Religious Nonmedical Healthcare Institutions, https://www.cms.gov/Regulations-and-
Guidance/Guidance/Manuals/downloads/som107ap_u_rnhci.pdf

CMS Current Emergencies Webpage, https://www.cms.gov/About-CMS/Agency-Information/Emergency/EPRO/Current-Emergencies/Current-Emergencies-page

1135 Waiver Information, https://www.cms.gov/About-CMS/Agency-Information/Emergency/EPRO/Resources/Waivers-and-flexibilities.

Coronavirus Waivers & Flexibilities, https://www.cms.gov/about-cms/emergency-preparedness-response-operations/current-emergencies/coronavirus-waivers.

CDC Updates:

For the latest information on COVID-19 see: https://www.cdc.gov/coronavirus/2019-ncov/whats-new-all.html. You can also 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.

Questions related to 1135 waivers should be addressed to 1135waiver@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