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INFORMATIONAL LETTER #2020-16

DATE: March 31, 2020

TO: ALL IDAHO AMBULATORY SURGICAL CENTERS (ASCS), OUTPATIENT PHYSICAL THERAPY CENTERS (OPTS), AND RURAL HEALTH CLINICS (RHCS)

FROM: DEBBY RANSOM, R.N., R.H.I.T., Chief
Bureau of Facility Standards

SUBJECT: **GUIDANCE FOR INFECTION CONTROL AND PREVENTION OF CORONAVIRUS DISEASE (COVID-19) IN OUTPATIENT SETTINGS: FAQS AND CONSIDERATIONS**

The CMS QSO 20-22-ASC, OPT, and RHC - Guidance for Infection Control and Prevention of Coronavirus Disease (COVID-19) in Outpatient Settings: FAQs and Considerations is being distributed to all ASCs, OPTs, and RHCs in Idaho.

If you have any questions, please contact Dennis Kelly, RN or Nicole Wisenor at 208-334-6626, option 4.

DEBBY RANSOM, R.N., R.H.I.T., Chief
Bureau of Facility Standards

DR/lg
Attachments

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

Ref: QSO-20-22- ASC, CORF, CMHC, OPT, RHC/FQHCs

DATE: **March 30, 2020**

TO: State Survey Agency Directors

FROM: Director
Quality, Safety & Oversight Group

SUBJECT: Guidance for Infection Control and Prevention of Coronavirus Disease (COVID-19) in Outpatient Settings: FAQs and Considerations

Memorandum Summary

- ***CMS is committed*** to taking critical steps to ensure America's healthcare facilities can respond to the threat of COVID-19.
- ***Coordination with the Centers for Disease Control and Prevention (CDC) and local public health departments*** - We encourage all healthcare facilities to monitor the CDC website for information and resources and contact their local health department when needed (CDC Resources for Health Care Facilities).
- ***Guidance for Infection Control and Prevention of COVID-19 and Actions*** - CMS regulations and guidance support Ambulatory Surgical Centers (ASCs), Community Mental Health Centers (CMHCs), Comprehensive Outpatient Rehabilitation Facilities (CORFs), Outpatient Physical Therapy or Speech Pathology Services (OPTs), Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs) taking appropriate action to address potential and confirmed COVID-19 cases. This guidance discusses recommendations to mitigate transmission including screening, restricting visitors, cleaning and disinfection, and possible closures. Supply scarcity guidance and FDA recommendations are also included within this memo.

Background

The Centers for Medicare & Medicaid Services (CMS) is responsible for ensuring the health and safety of patients receiving care, treatment and services in healthcare facilities from the spread of infectious disease, including being committed to taking critical steps to ensure America's healthcare facilities can respond to the threat of COVID-19. This memorandum responds to questions we have received and provides important guidance for outpatient settings other than hospital outpatient departments, specifically ASCs, CMHCs, CORFs, OPTs, and RHCs/FQHCs (herein referred to as healthcare facilities) in addressing the COVID-19 outbreak and minimizing transmission to other individuals.

Guidance

Healthcare facilities should monitor CDC's website (https://www.cdc.gov/coronavirus/2019-ncov/index.html) for up to date information and resources (additional resource links are below). They should contact their local health department if they have questions or suspect a patient or healthcare provider has COVID-19. Healthcare facilities should have plans for monitoring staff 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-assesment-hcp.html

On March 18, 2020, CMS recommended that all elective surgeries, non-essential medical, surgical, and dental procedures be delayed during the COVID-19 outbreak. As increasing numbers healthcare providers are asked to assist with the COVID-19 response, it is critical that providers consider whether non-essential surgeries and procedures can be delayed to preserve personal protective equipment (PPE), beds, ventilators, and other critical resources as applicable. 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, as decisions are made whether to delay non-essential procedures. CMS also strongly encourages facilities with available PPE, bed capacity and ventilators to work closely with their local communities and their respective health departments to redistribute resources when possible. https://www.cms.gov/files/document/31820-cms-adult-elective-surgery-and-procedures-recommendations.pdf

For purposes of this document we use the general term "patients," which includes clients in the CMHC setting as well. "Visitors" is also used generally and could include a wide variety of persons, dependent upon the outpatient setting.

Guidance for Limiting the Transmission of COVID-19, Recommendations, and Supply Shortages Guidance

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

Based upon CDC data (https://www.cdc.gov/coronavirus/2019-ncov/specific-groups/high-risk-complications.html), older adults and people of any age with underlying chronic medical conditions or immunocompromised state may be most at risk for severe outcomes due to COVID-19. This information should be considered in the decision to conduct visits or provide services, surgical procedures or treatment to patients in the outpatient setting.

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

When possible, as recommended by CDC, facility staff should proactively communicate about COVID-19 with scheduled and potential patients. Healthcare facilities should provide patients with updates about changes to policies and procedures regarding appointments, the potential for coordinating non-urgent patient care by telephone, and any visitor restrictions. One consideration could be to use the facility's website or social media platforms to share updates. Healthcare facilities should identify visitors and patients at risk for having COVID-19 infection before or immediately upon arrival to the healthcare facility.

Before or immediately upon arrival for appointments, healthcare facilities should ask 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 CDC Level 3 risk 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;
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:

- At the time the appointment is scheduled, ask patients to call ahead to report fever or respiratory symptoms so the healthcare facility can be prepared for their arrival or triage them to a more appropriate setting (e.g., an acute care hospital). If capacity allows, call patients shortly before their appointment to ask if they have a fever or respiratory symptoms.
- Healthcare facilities should establish limited entry points for all patients and visitors and/or establish alternative sites for screening prior to entry.
- Healthcare facilities should identify those with fever or signs and symptoms of respiratory infections before they enter the waiting and treatment areas. Patients with fever or 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 healthcare facility should provide the facemask if one is needed and available.
- Healthcare facilities should post signs at entrances with instructions (in appropriate languages) to patients with fever or symptoms of respiratory infection to alert staff who can implement appropriate precautions.
- Healthcare facilities should have the following supplies available to ensure adherence to hand and respiratory hygiene, and cough etiquette: tissues, no-touch receptacles for disposal of tissues, and hand hygiene supplies (e.g., alcohol-based hand sanitizer (ABHS))

How should healthcare facilities monitor or restrict their staff?

The same screening performed for patients and visitors should be performed for healthcare facility staff.

- 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 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 professional/preventionist (or leadership/administrator if no infection professional is available), 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).

Healthcare facilities should contact their local health department for questions, and frequently review the CDC website dedicated to COVID-19 for healthcare professionals (https://www.cdc.gov/coronavirus/2019-nCoV/hcp/index.html). Additional resources related to PPE and worker safety are located in the resources section of this memo.

What is the return to work criteria for health care staff?

Occupational health programs and public health officials making decisions about return to work for health care personnel (HCP) with confirmed COVID-19, or who have suspected COVID-19 (e.g., developed symptoms of a respiratory infection, e.g., cough, sore throat, shortness of breath, fever, but did not get tested for COVID-19) should be made according to the CDC guidelines https://www.cdc.gov/coronavirus/2019-ncov/healthcare-facilities/hcp-return-work.html.

Should healthcare facilities restrict patients from bringing visitors with them to appointments?

Healthcare facilities should set limitations on visitation. For example, limitations may include restricting the number of visitors per patient, or limiting visitors to those that provide assistance to the patient, participate in a joint treatment session (i.e. counseling session) or limiting visitors under a certain age. For additional guidance on visitation, visit CMS: https://www.cms.gov/files/document/qso-20-20-allpdf.pdf-0

Note: If a state implements actions pursuant to their authorities that exceed CMS requirements, (e.g., a ban on all visitation through a governor's executive order) a healthcare facility would not be out of compliance with CMS' requirements.

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

During environmental cleaning procedures, personnel should wear appropriate PPE to prevent exposure to infectious agents or chemicals (PPE such as gloves, gowns, masks, respirators, and eye protection). Environmental surfaces in patient care areas should be cleaned and disinfected, using an appropriate Environmental Protection Agency (EPA)-registered disinfectant on a regular basis (e.g., daily), when spills occur and when surfaces are visibly contaminated. Healthcare facilities should use disinfectants on List N of the EPA website for EPA-registered disinfectants that have qualified under EPA's emerging viral pathogens program for use against SARS-CoV-2 (the cause of COVID-19) or other national recommendations.

Additional guidance related to appropriate cleaning and disinfection is available at CDC's Guideline for Disinfection and Sterilization in Healthcare Facilities (2008) for more information: https://www.cdc.gov/infectioncontrol/guidelines/disinfection/index.html.

Are Medicare-participating healthcare facilities, such as ASCs, CMHCs, CORFs, OPTs, and RHCs/FQHCs required to remain open during this outbreak?

The CMS health and safety requirements (i.e., the conditions of participation/conditions for coverage/certification) do not contain specific requirements for outpatient setting healthcare facilities to remain open during certain hours (e.g., Medicare-certified ASCs do not have the same statutory requirement of a hospital to provide 24 hour care). Therefore, if it is in the best interest of the facility's patients to cancel appointments and temporarily close the facility during an outbreak, that may be acceptable. Facilities should follow their emergency preparedness program policies and procedures to determine whether closure of the facility is appropriate and ensure patients receiving services are notified. Facilities should follow guidance of State and local health departments as conditions change in their state and area. CMS will not take administrative actions with respect to facilities who need to temporarily close during the outbreak, however, facilities are expected to resume operations or voluntarily terminate their Medicare enrollment within 30 days of the public health emergency being lifted.

If a Medicare-participating healthcare facility decides to voluntarily close temporarily or is asked to close by a state or federal recommendation, would that constitute a cessation of business/voluntary termination?

As a result of the ever evolving COVID-19 pandemic, CDC guidelines currently recommend delaying and rescheduling all elective and non-urgent visits/admissions to preserve staff, PPE, and patient care supplies (https://www.cdc.gov/coronavirus/2019-ncov/healthcare-facilities/index.html). Additionally, CMS released a statement on March 18, 2020 recommending that all elective surgeries, non-essential medical, surgical and dental procedures be delayed during the COVID-19 outbreak.

If a healthcare facility temporarily closes because it only provides elective cases/non-emergency treatment or appointments consistent with CDC and CMS recommendations, CMS would not view this as a cessation of business; therefore, would not be deemed as a voluntary termination of the Medicare agreement under 42 C.F.R. §489.52 or §416.35(a)(3). Facilities needing to temporarily shut down or limit operations should post notices at their business as well as on public facing websites and social media platforms during this emergency.

Any healthcare facility that temporarily closes or limits operations are strongly encouraged to reach out to their local community and state health department for possible partnerships, as the conservation and sharing of critical resources such as ventilators and PPE is essential during a national emergency.

Will CMS issue waivers of certain health and safety requirements related to COVID-19?

The Secretary of the Department of Health and Human Services (HHS) is authorized to waive certain Medicare, Medicaid, and Children's Health Insurance Program (CHIP) program requirements and health and safety requirements pursuant to Section 1135 of the Social Security Act once the President declares an emergency through the Stafford Act or National Emergency Act, and the Secretary declares a Public Health Emergency (PHE). Under this authority, CMS has activated various blanket waivers, which will ease certain requirements for impacted providers. CMS will also temporarily modify certain requirements. For more information on such waivers and modifications that CMS has granted, visit: www.cms.gov/emergency.

We note there is no standardized waiver application form or template that is required for a state or individual provider to submit a request for a section 1135 waiver. We have assembled a national team to assist with monitoring, retrieving and responding to all 1135 waiver requests and-related questions as soon as possible. Therefore, we ask that any 1135 waiver questions or requests be submitted to the mailboxes provided below in the contact information of this memorandum. For more information on submitting a waiver, visit: https://www.cms.gov/About-CMS/Agency-Information/Emergency/EPRO/How-We-Can-Help/How-We-Can-Help-page

Supply Scarcity Guidance

CMS is aware that there is a shortage of some medical supplies in certain areas of the country. State and Federal surveyors should not cite healthcare facilities for not having certain supplies (e.g., PPE such as gowns, N95 respirators, surgical masks and ABHS) if they are having difficulty obtaining these supplies for reasons outside of their control. However, CMS does expect healthcare facilities to take actions to mitigate any supplies shortages and show they are taking all steps to obtain the necessary supplies as soon as possible. For example, if there is a shortage of ABHS 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) shortages, 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, and if needed, identify safe alternatives for patient care based on CDC guidelines (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 Office.

Additionally, facilities may review the Executive Order on preventing hoarding of health and medical resources issued by President Trump on March 23, 2020 https://www.whitehouse.gov/presidential-actions/executive-order-preventing-hoarding-health-medical-resources-respond-spread-covid-19/.

Expanded Respirator Guidance

The Food and Drug Administration (FDA) has approved CDC's request for an emergency use authorization (EUA) to allow HCP to use certain filtering facepiece respirators (FFRs) during the COVID-19 outbreak in health care settings by HCP. The FDA concluded that respirators authorized under this EUA may be effective in preventing HCP from airborne exposure during the COVID-19 outbreak. COVID-19 can cause serious or life-threatening disease, including severe respiratory illness.

Under this EUA, certain NIOSH-approved respirators are authorized for use in health care settings by HCP during the COVID-19 outbreak, thereby maximizing the number of respirators available to meet the needs of the U.S. health care system.

FFRs covered under this EUA are posted on the FDA's website:

- A list of NIOSH approved FFRs eligible for authorization can be found here: https://www.fda.gov/media/135764/download

- A list of FFRs authorized for use under this EUA, including ones that were NIOSH-approved but have since passed the manufacturers' recommended shelf-life, can be found here: https://www.fda.gov/media/135921/download

Therefore, any CMS guidance that explicitly, or by reference, indicates N-95 usage will automatically incorporate any FFRs authorized under this EUA. A second EUA concerning respirators was recently released and may be found here: https://www.fda.gov/media/136403/download

What other resources are available for facilities to help improve infection control and prevention?

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 Suspected or Confirmed Coronavirus Disease 2019 (COVID19) https://www.cdc.gov/coronavirus/2019-ncov/infection-control/control-recommendations.html
- CDC Interim Infection Prevention and Control Recommendations for Patients with Suspected or Confirmed Coronavirus Disease 2019 (COVID-19) in Healthcare Settings https://www.cdc.gov/coronavirus/2019-ncov/infection-control/control-recommendations.html

CMS Resources:

CMS has issued additional guidance which may be beneficial to healthcare facilities 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.

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

CMS COVID-19 FAQs: https://www.cms.gov/files/document/03092020-covid-19-faqs-508.pdf

CMS Emergency Preparedness and Response Operations (EPRO): https://www.cms.gov/About-CMS/Agency-Information/Emergency/EPRO/EPRO-Home including https://www.cms.gov/About-CMS/Agency-Information/Emergency/EPRO/Resources/Waivers-and-flexibilities

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, please contact the following CMS Branch Location mailboxes, or 1135waiver@cms.hhs.gov:

> ROATLHSQ@cms.hhs.gov (Atlanta RO): Alabama, Florida, Georgia, Kentucky, Mississippi, North Carolina, South Carolina, and Tennessee.
>
> RODALDSC@cms.hhs.gov (Dallas RO): Arkansas, Louisiana, New Mexico, Oklahoma, and Texas.
>
> ROPHIDSC@cms.hhs.gov (Northeast Division): Delaware, District of Columbia, Maryland, Pennsylvania, Virginia, West Virginia, New York, New Jersey, Puerto Rico, Virgin Islands, Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, and Vermont.
>
> ROCHISC@cms.hhs.gov (Chicago/Kansas City): Illinois, Indiana, Michigan, Minnesota, Ohio, Wisconsin, Iowa, Kansas, Missouri, and Nebraska.
>
> ROSFOSO@cms.hhs.gov (Western Division): Colorado, Montana, North Dakota, South Dakota, Utah, Wyoming, Alaska, Idaho, Oregon, Washington, Arizona, California, Hawaii, Nevada, and the Pacific Territories.

Effective Date: Immediately. This policy should be communicated with all survey and certification staff, their managers and the State/Regional Office training coordinators immediately. This guidance will cease to be in effect when the Secretary of HHS determines there is no longer a Public Health Emergency due to COVID-19. At that time, CMS will publicly notify that this guidance has ceased to be effective via its website.

/s/
David R. Wright

cc: Survey and Operations Group Management