BrightSpring – PharMerica Enterprise Outbreak Preparedness Plan

Version 6: August 1, 2020

Update: Summary of Our Response

Since the novel Coronavirus 2019 (COVID-19) pandemic began in early 2020, BrightSpring-PharMerica has focused on implementing best practices in infection control, visitor management, employee screening, and streamlined reporting and triage protocols to optimally support clients, patients, employees, families and communities. To date, we have experienced an overall infection rate of less than one percent, and have reported our preparation plan, tactics, experience and data in numerous peer-reviewed research publications, including the below:

1. Supporting individuals with intellectual and developmental disability during the first 100 days of the COVID-19 outbreak in the USA. *Journal of Intellectual Disability Research* 2020, 64: 489-496. https://doi.org/10.1111/jir.12740
2. An Outbreak Preparedness and Mitigation Approach in Home Health and Personal Home Care During the COVID-19 Pandemic. *Home Health Care Management & Practice* 2020. https://doi.org/10.1177/1084822320933567
3. Hydroxychloroquine Sulfate Prescribing Trends and Pharmacist-Led Outbreak Preparedness in Long Term Care Pharmacy During COVID-19. *Journal of the Medical Directors Association* 2020. https://doi.org/10.1016/j.jamda.2020.06.012
4. Home Based Primary Care Led-Outbreak Mitigation in Assisted Living Facilities in the First One Hundred Days of COVID-19. *Journal of the American Medical Directors Association* 2020. https://doi.org/10.1016/j.jamda.2020.06.014

This plan version has been updated to incorporate evolving public health guidance as well as our own experiential best practices as we enter the seventh month of the COVID-19 pandemic.

Introduction

BrightSpring-PharMerica takes all outbreak threats very seriously. While we have had an organizational disaster and pandemic plan for many years, with the new threat posed by the novel Coronavirus and COVID-19, we have we have adopted additional tactics and committee governance to be able to respond to COVID-19 and other potential outbreaks with agility – to meet both the rapid pace of information being disseminated, and the concerns that people in the community have about COVID-19.

Outbreak Preparedness and Action Committee

We have leveraged the cross-functional expertise of a diverse set of medical, clinical, risk management, human resources, legal, communications and operations leaders throughout our organization and have formed an Outbreak Preparedness and Action Committee. The mission of the Committee is to prepare for potential outbreaks and to act when necessary to protect, support and serve our patients, clients and employees. The Committee embodies the principles of preparation, reassurance, evidence-based action, coordination, communication and support. The Committee works with operators and stakeholders to identify areas of patient, client and employee outbreak risk and prepares the organization for such threats. The Committee also serves as a means of

consolidating internal and external communications regarding COVID-19 and other potential outbreaks.

Situation Summary

The virus is named "SARS-CoV-2" (*Figure 1*) and the disease it causes has been named "coronavirus disease 2019" (abbreviated "COVID-19"). Early on, many of the patients in the COVID-19 outbreak in Wuhan, China, had some link to a large seafood and live animal market, suggesting animal-to-person spread. Since, a growing number of patients reportedly did not have exposure to animal markets, indicating person-to-person spread. After implementing travel restrictions and robust infection control, the number of new daily cases of COVID-19 in Wuhan decreased significantly (*Figure 2*).

Figure 1. This transmission electron microscope image shows SARS-CoV-2, the virus that causes COVID-19—isolated from a patient in the U.S. Virus particles are shown emerging from the surface of cells cultured in the lab. The spikes on the outer edge of the virus particles give coronaviruses their name, crown-like. National Institute of Allergy and Infectious Diseases.

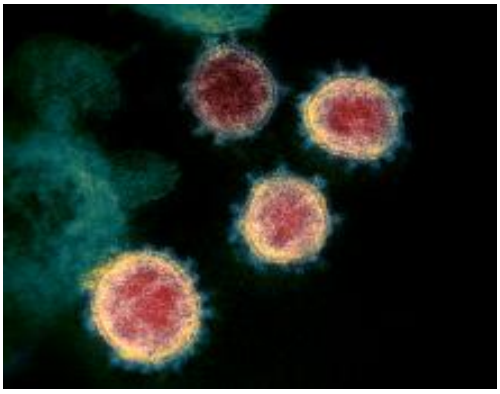
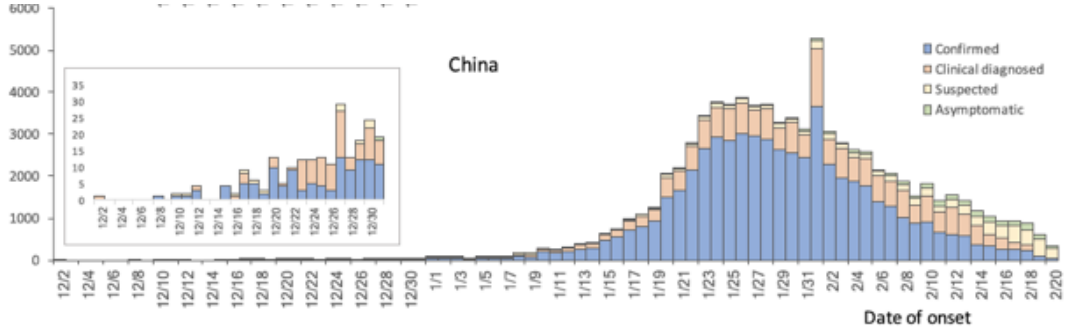
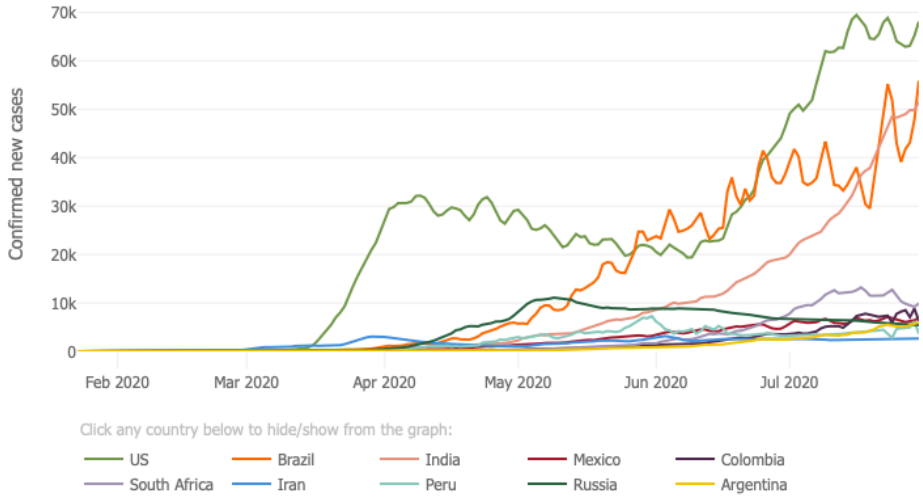


Figure 2. Number of new daily cases of COVID-19 in China steadily decreased since infection control measures and travel restrictions were implemented.



Our organization is using the data that illustrate that the infection control measures taken in China and other countries are working, to sharpen our focus on our own efforts on best practices in infection control and prevention. We are also following the incidence of new daily cases in a number of countries to help inform our trajectory estimate and planning for the situation in the US (*Figure 3*).

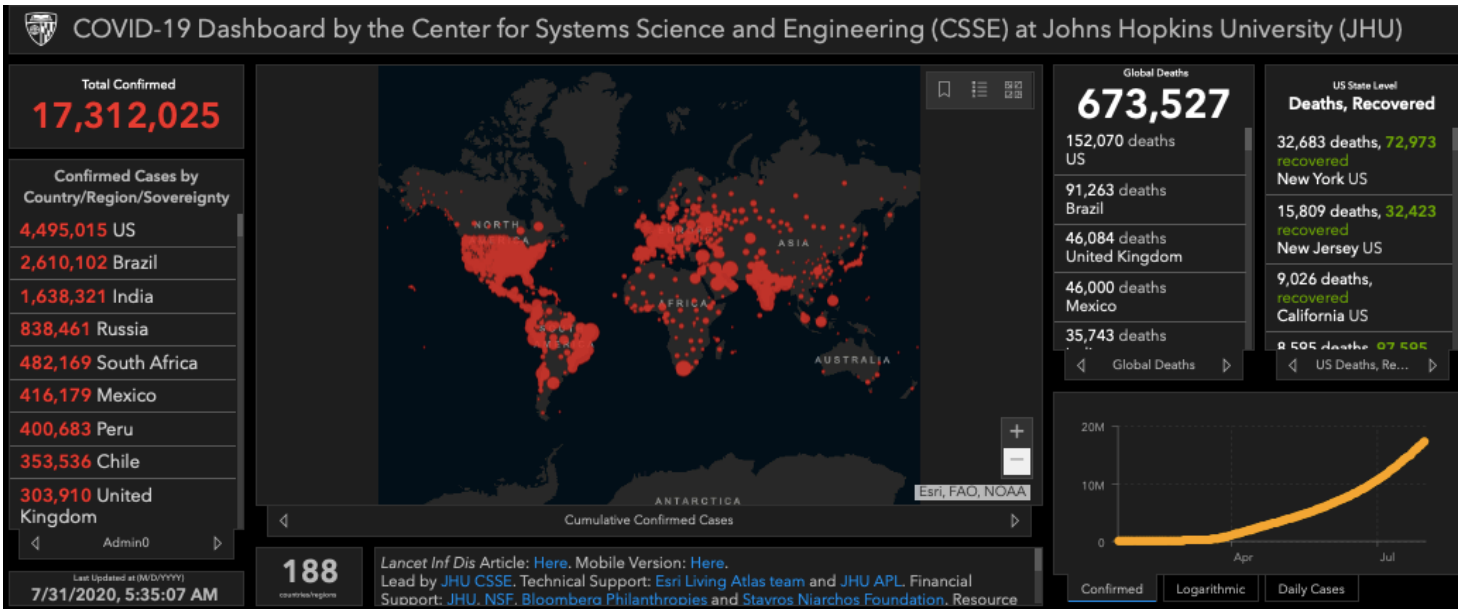
Figure 3. New daily cases of COVID-19 between January 21, 2020 and July 30, 2020.



Global Situation Summary

BrightSpring-PharMerica is actively monitoring the global situation daily, in order to understand transmission patterns, rate of spread, mitigation tactics, and to highlight geographies that represent high risk travel for employees or family members of employees. Our primary monitoring source is the Johns Hopkins University Coronavirus Resource Center (*Figure 4*), in addition to the Centers for Disease Control and Prevention (CDC) and World Health Organization's (WHO) COVID-19 situation rooms.

Figure 4. Johns Hopkins University Coronavirus Resource Center Dashboard.



Situation in U.S.

The Outbreak Committee monitors the situation rooms from Johns Hopkins University daily, and utilizes "Heat Maps" updated so we can best direct our local operations in markets. These trackers are shown below, for illustrative purposes (*Figure 5a-5b*).

Figure 5a. U.S. State "Heat Map", which shows the new daily COVID-19 case incidence trends by state. The line represents the three day moving average of new cases, and the background color represents the overall trend of new cases in a state (green=downward trend; red=upward trend).

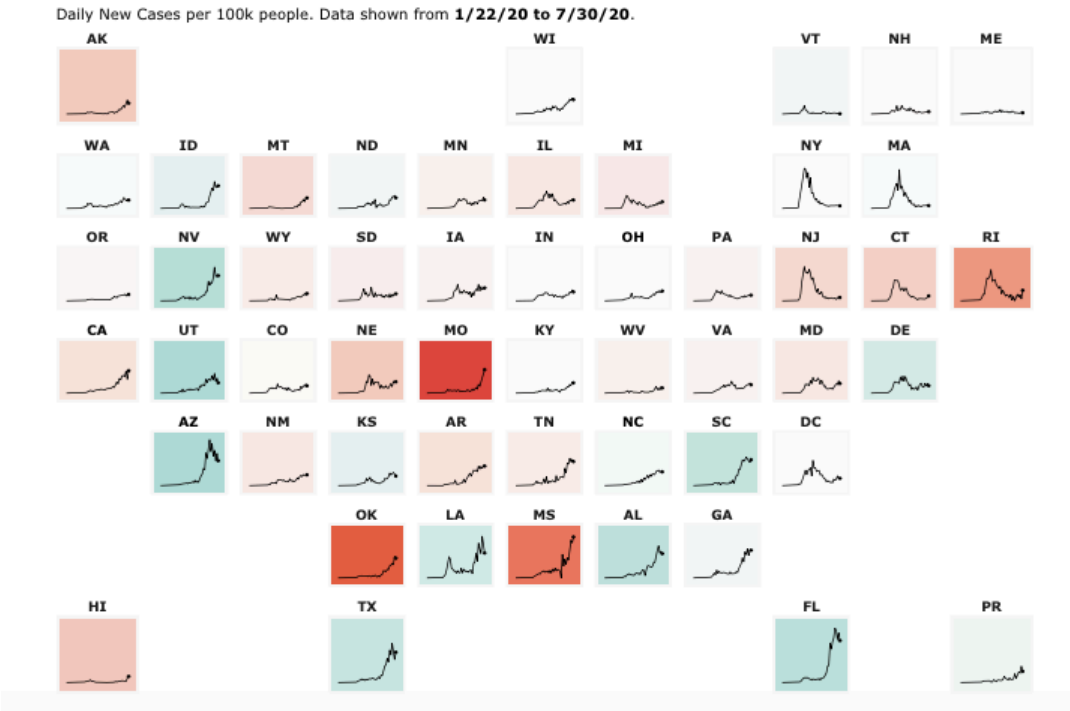
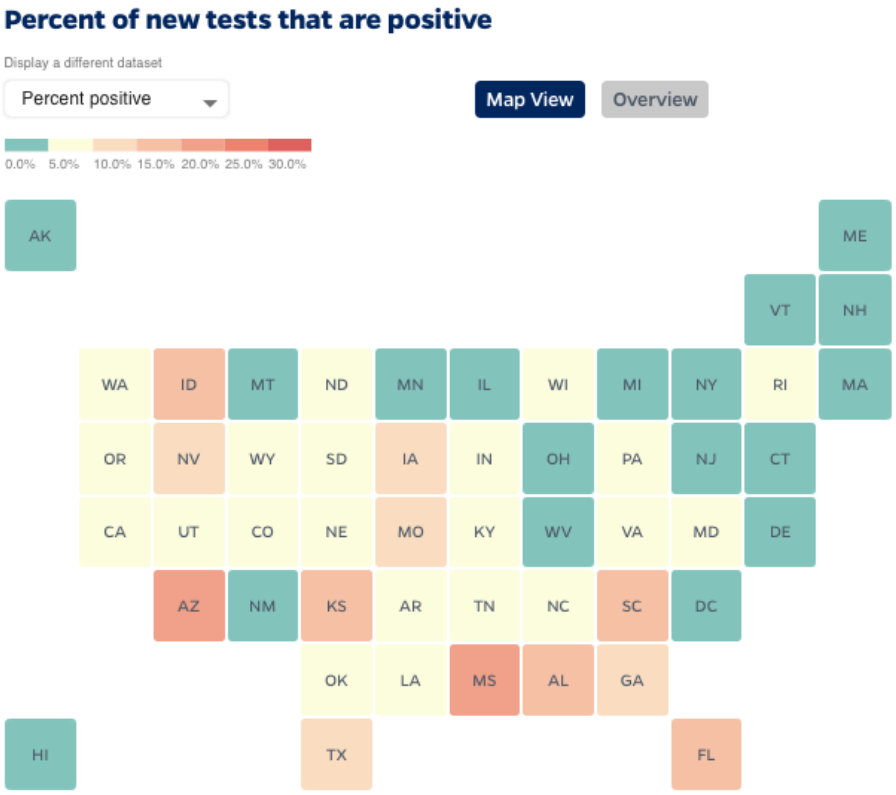


Figure 5b. [Percent of new tests that are positive by state], which shows the COVID-19 positivity rate. This tracker can be used to view transmission trends, which can support social distancing and infection control measures decision making.



Assessment and COVID-19 Case Definition

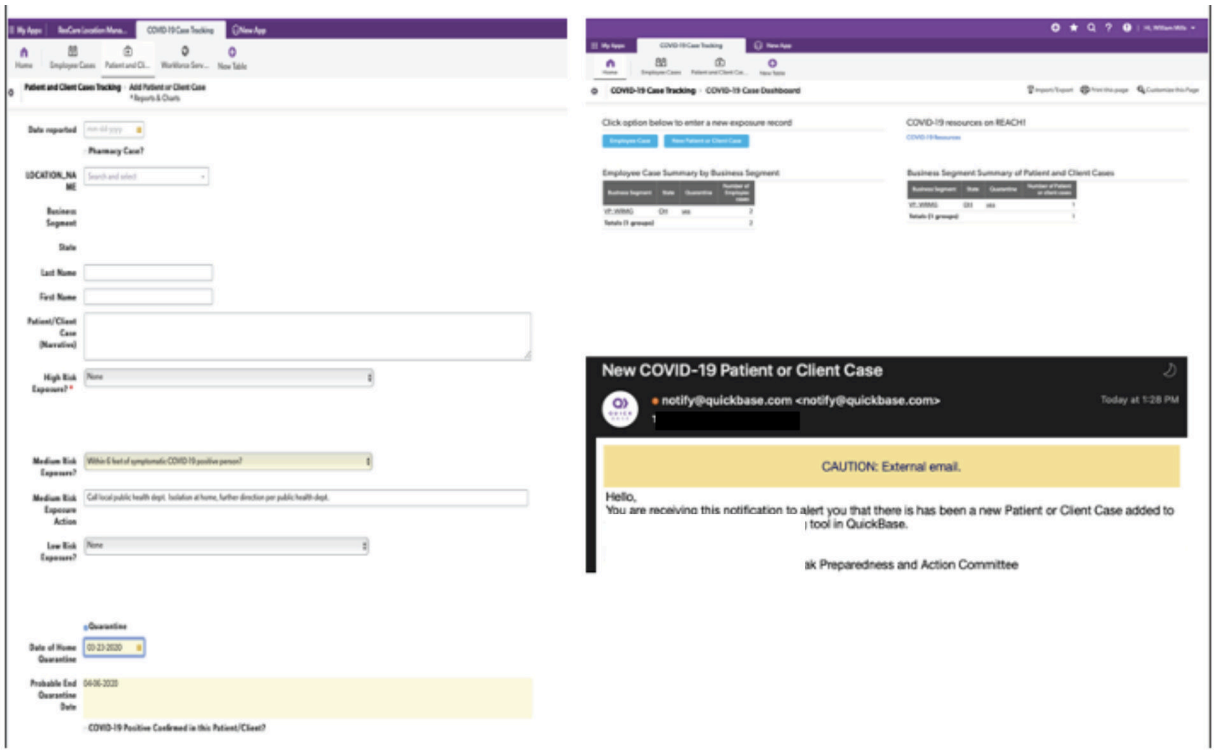
When assessing individuals with a fever and lower respiratory symptoms, such as coughing or shortness of breath, or asymptomatic individuals with potential exposures, [we utilize CDC testing and isolation algorithms.] A positive case is defined as a positive nucleic acid swab / polymerase chain reaction test for SARS-coV-2 RNA.

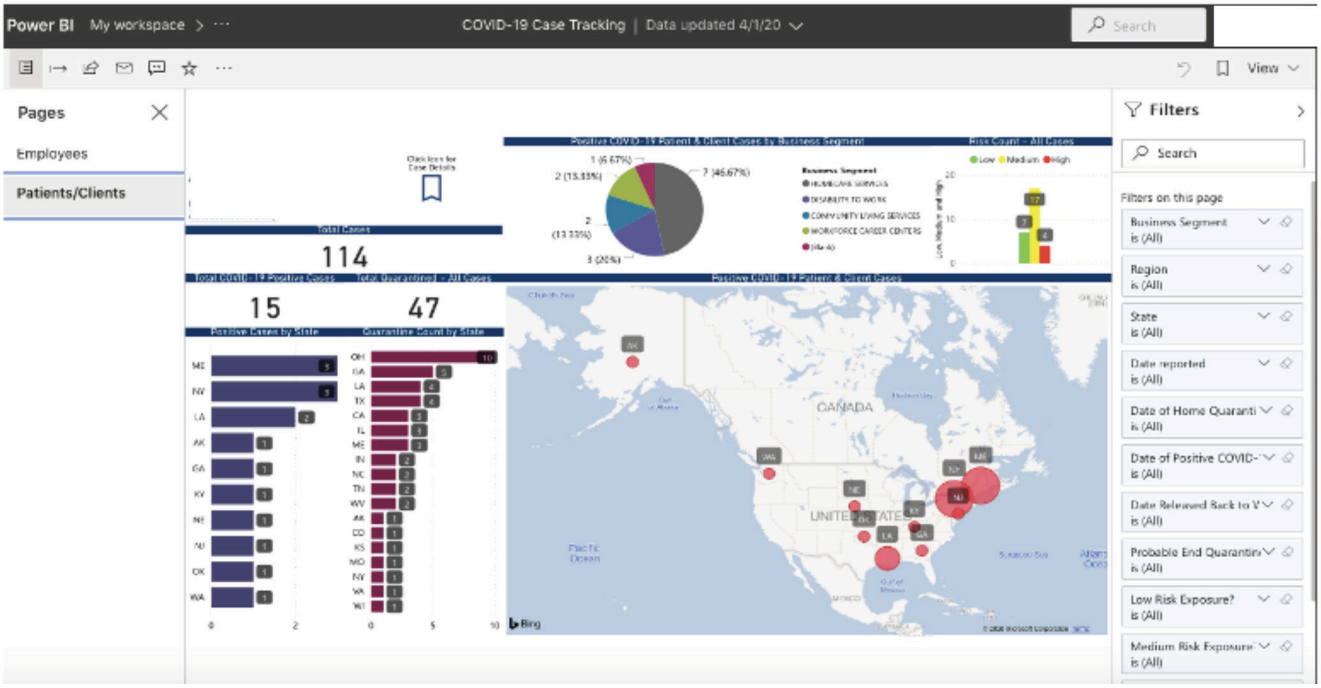
COVID-19 Case Tracking and Visualization Application

In order to streamline COVID-19 case and exposure triage and reporting, we built a secure, cloud-based web application. The application leverages a QuickBase (QuickBase, Inc., Cambridge, MA) data structure to quickly capture confirmed cases as well as potential exposures from our operations sites across the U.S (Figure 6, Panel A). Entry of new patient cases auto-notified of our team of nurses. The nurses then advised the operations team at our local and regional sites to assist with triage and planning. The clinical and operational plan included reinforcement and training on necessary quarantine and isolation procedures, as well as ordering additional personal protective equipment (PPE) supply. Entry of new employee cases or exposures triggered an auto-notification to that location's human resources partner, who then worked with the clinical team and the employee to support triage and assessment. To optimize our ability to visualize COVID-19 positive patients, clients and employees by business segment and geography, we also developed a business intelligence application, leveraging Power BI (Microsoft Corp, Redmond, WA) Figure 6, Panel B. The

clinical, operations, human resources, and executive teams use the visualization tool throughout the day as a “situation room” that enabled us to deploy specific mitigation tactics as cases emerged.

Figure 6. COVID-19 Case Tracking and Data Visualization Application.
Panel A. COVID-19 tracking application that stratifies risk using CDC guidance.
Panel B. COVID-19 case visualization application.

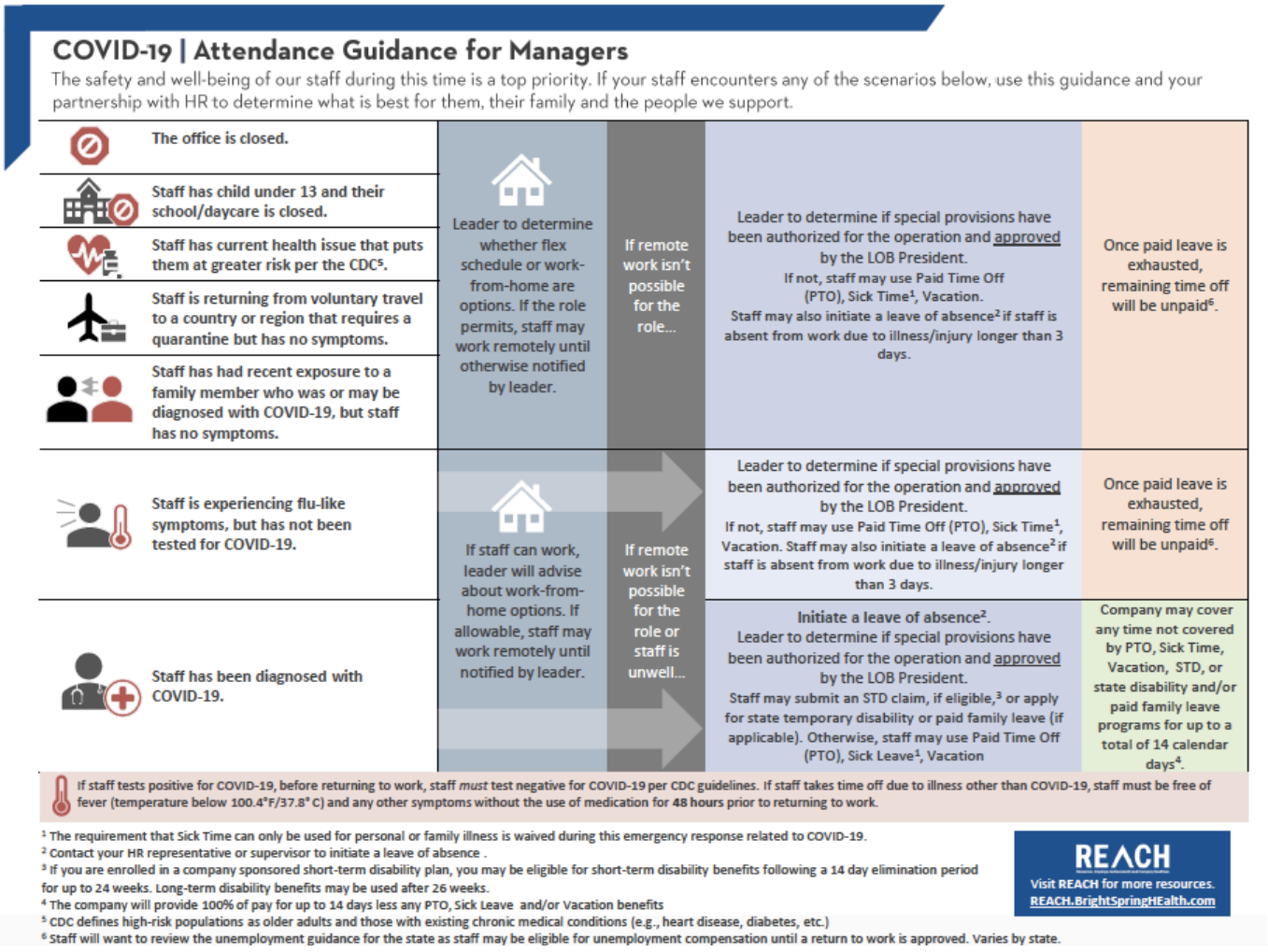




Employee Attendance Policy

To standardize support of employee cases and exposures identified through the above app, our human resources leadership has developed the below COVID-19 attendance policy (*Figure 7*).

Figure 7. BrightSpring-PharMerica COVID-19 Attendance Policy.



Enterprise Infection Control and Prevention Policy

BrightSpring-PharMerica effectuated a new Enterprise-Wide Infection Control and Prevention Policy, aimed at providing enhanced protection for the patients, clients and employees we serve (*Exhibit A*). Adoption of the policy is optimizing our ability to prevent and control outbreaks in all business segments. Training on the policy has been deployed through a combination of intranet resources as well as on-site and web-based live meetings. The Company has implemented nurse-leader hosted infection control and isolation protocol web meetings, occurring regularly, open to all employees. Hundreds of employees are currently attending these sessions per week.

Supplies

The organization has aggressively acquired PPE in utilizing its large procurement team and approaching many potential global suppliers, attempting to identify reliable sources of PPE. To enable consolidated ordering and distribution of PPE to our 2,400 community living sites, we formed a new Central Supply distribution center (*Figure 8*). Full PPE kits were assembled and shipped to all locations, in addition to extra allotments of surgical masks, hand sanitizer, cleaning materials, and other items required to effectuate optimal infection. We have implemented the recent recommendations by CDC and the Centers for Medicare and Medicaid Services to use surgical masks for respiratory droplet precautions in non-aerosol-generating situations until the N95 supply chain is restored (*Exhibit B*). We have set up a dedicated email address to streamline requests at PPEsupplyrequests@brightspringhealth.com. Current PPE inventory and order status is communicated daily between Procurement and the Outbreak Committee. PPE kits have been assembled and shipped to locations out of our new Central Supply (*Figure 9*), which has been set up in Louisville as a collaborative effort between the Outbreak Committee and Procurement. All locations have received full PPE kits, and none are currently undersupplied based use scenarios outlined in our Infection Control Policy.

Figure 8. BrightSpring employees sorting PPE for placement into kits for shipping to all locations.

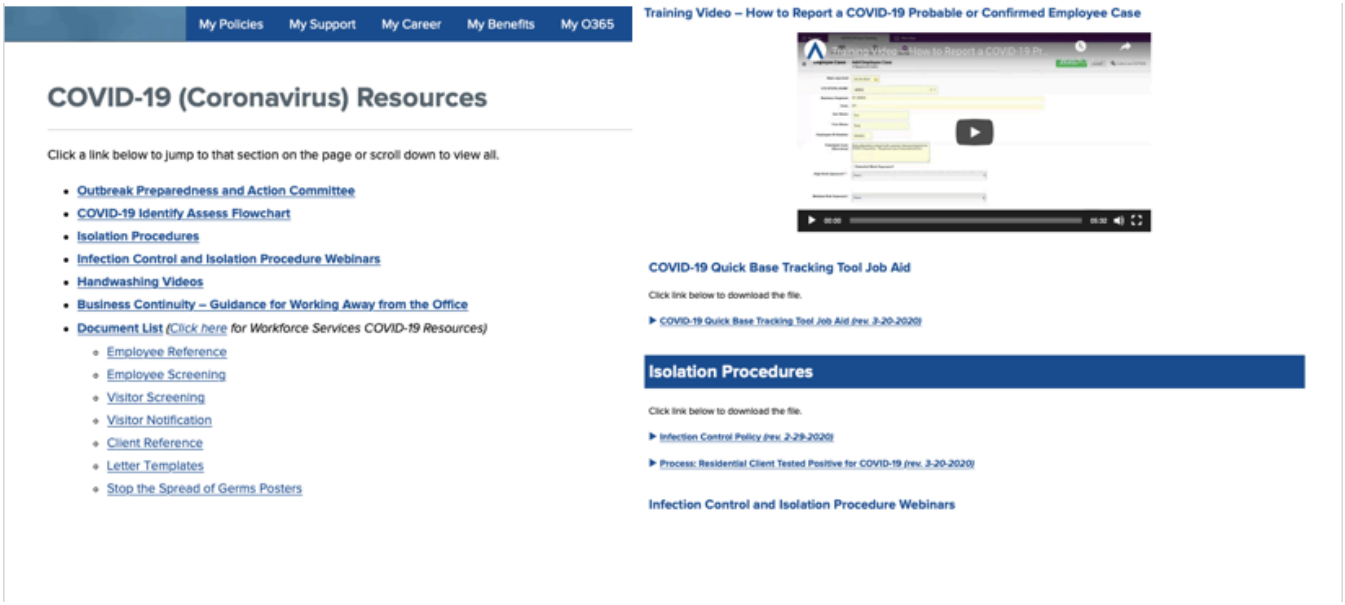
Personal Protective Equipment Conservation

To optimize our supply of PPE, we have provided materials and training to our employees on appropriate steps to conserve equipment where possible. Materials and educational resources are available on our company intranet, and our nurse-led training programs reiterate PPE conservation in real time, daily.

Educational Resources

To enable employees across all locations to have access to the most current information, policies and training materials, we developed and deployed over one hundred COVID-19 and outbreak prevention and action resource materials for employee use. This resource library is available on our organizational intranet (Figure 9), and updates are also communicated by email to the organization three times per week.

Figure 9. BrightSpring-PharMerica Intranet COVID-19 Educational and Practical Resources.



Return to Work Practices and Restrictions

In July, 2020, the CDC updated its guidance regarding return to work for health care workers who have confirmed or suspected (e.g., developed symptoms, but were not tested) COVID-19 infection. In addition to the guidance below, decisions about return to work should consider local circumstances (e.g., rate of new infections in the community), and whether the employee is at high risk, living with or caring for vulnerable persons at high-risk for illness and death if infected.

Except for rare situations, a test-based strategy is no longer recommended in determining when to return to work because in most cases, this results in excluding workers who are no longer infectious. The guidance for return to work falls into one of four categories:

1. Employees with **no symptoms** and who are **not seriously immunocompromised**
2. Employees who experienced **mild to moderate symptoms** and who are **not severely immunocompromised**
3. Employees who experienced **severe or critical illness/symptoms**, or who **are severely immunocompromised**
4. Employees who have **not experienced any symptoms** but who **are severely immunocompromised**

Return to work guidance for each of these scenarios is outlined below. Per the CDC, "Severely immunocompromised" includes:

- Receiving chemotherapy for cancer, untreated HIV infection, combined primary immunodeficiency disorder, and conditions treated with Prednisone (in doses greater than 20mg) for more than 14 days
- Note: factors such as advanced age, diabetes mellitus, or end-stage renal disease may pose a lower degree of immunocompromise
- Ultimately, if there is a question, the employees' treating health care provider will determine whether the employee is immunocompromised

Determination of whether symptoms are "Mild, Moderate, Severe or Critical" is based on the severity of symptoms experienced. This may also be determined by the employees' healthcare provider. Your Director, Clinical Practice can help determine whether there is a need to contact the employee's health care provider

1. Employees with **no symptoms** and who are **not seriously immunocompromised** may return to work when:
    - At least 10 days have passed since the date of their first positive test
2. Employees with **mild to moderate symptoms** and **who are not** severely immunocompromised may return to work when:
    - 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

3. Employees with **severe or critical illness or symptoms,** or **who are** severely immunocompromised may return to work
    - 20 days after symptom onset
    - 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

4. Employees who **are** severely immunocompromised but have **not had any symptoms** throughout their infection may return to work:
    - 20 days after the date of their first positive viral diagnostic test (e.g., the "swab" or PCR test).

Return to Work Practices: Upon return to work per the above, employees will:

- Wear a surgical facemask for source control at all times while at work until all symptoms are completely resolved
- After all symptoms have resolved, the employee can revert to using a cloth facemask (per company policy)
- A facemask for source control does not replace the need to wear an N95 mask when caring for clients and patients with suspected or confirmed COVID-19 infection
- Self-monitor for symptoms, and notify their manager if symptoms recur or worsen

Additional information regarding Quarantine

Please note that recommendations for discontinuing isolation in persons known to be infected with COVID-19 (above) may appear to be in conflict with recommendations for when to discontinue quarantine for workers known to have been *exposed* to COVID-19.

The CDC recommends 14 days of quarantine *after an exposure* based on the time it takes to develop illness if infected. It is possible that a person *known* to be infected could leave isolation earlier than a person who is quarantined because of the *possibility* they are infected.
Please contact your Director, Clinical Practice or the Outbreak Committee with questions.

Visitor Management

BrightSpring-PharMerica understands that visitors to care sites represent a potential vector of SARS-CoV-2 transmission. We have enacted a policy that limits visits by people who are sick, and have posted signs, near the entrance of our sites to remind visitors that if they are sick they should not visit until they are free of fever, cough, and shortness of breath for at least 48 hours, and are performing visitor screening at congregate living locations. We have developed letters to inform patients, clients, guardians of the visitor management policy, and have initiated mandatory visitor logs.

Employee Travel

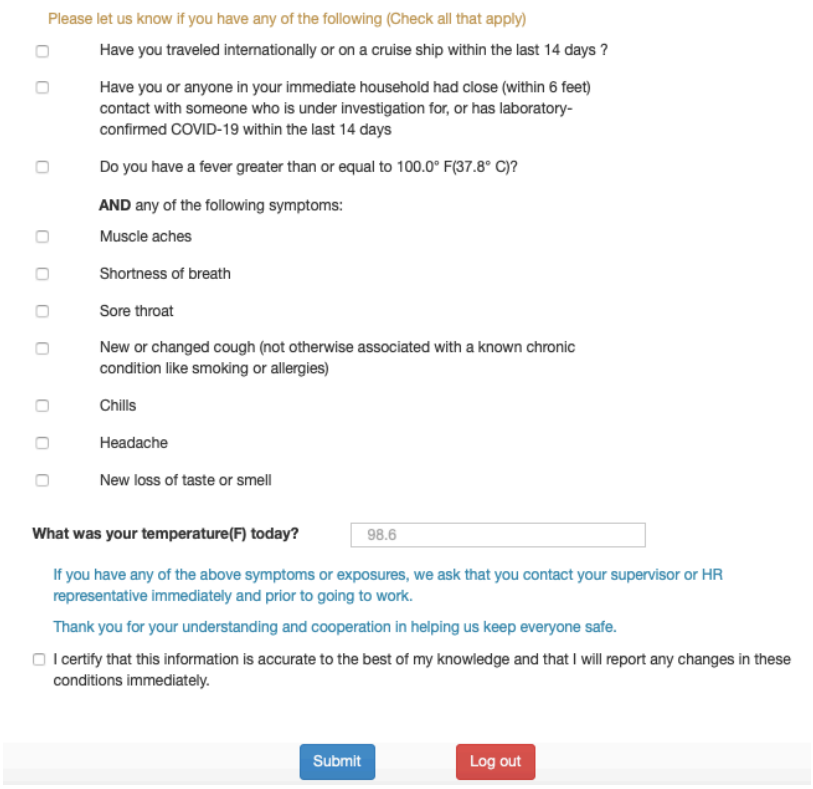
We feel it is our organizational responsibility to do our part in minimizing the spread of the virus for the protection of our patients, clients, those we support, our communities and each other. All non-essential travel has been restricted. Essential travel has been narrowly defined, and requires Executive Committee member approval. In addition, we have provided the following guidance to our employees:

- We have restricted any work-related international travel. Additionally, we strongly discourage any employee from traveling outside of the U.S. for any reason. If an employee or someone who lives in an employee's home still chooses to travel to a destination with significant community transmission of COVID-19 on personal time, the employee is asked to self-quarantine at home for 14 days.
- In-person group meetings are conducted, where possible, via WebEx, phone or video conference. Training and orientation is essential for our business, so when small group in-person meetings are required, we practice social distancing and the meeting space is regularly disinfected.

Employee Screening App Developed

In order to prevent well-intentioned, but ill employees from coming to work sick, BrightSpring-PharMerica developed deployed a symptom-screening app, that can be used on any device – desktop, laptop or mobile (*Figure 10*). All employees are asked to take their own temperature and answer simple screening questions as shown. The app better enables sick employees to stay home, as well as instills confidence in patients, clients, senior communities and referral sources – that we have an organized, scalable, and reportable model for screening employees for illness.

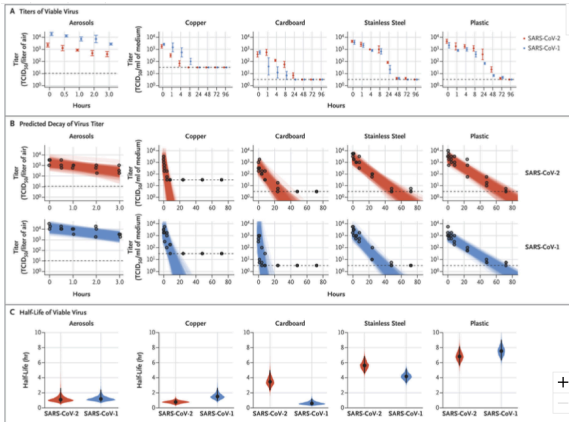
Figure 10. BrightSpring-PharMerica Employee Symptom Screening App.



Cleaning and Disinfection

Current evidence suggests that COVID-19 may remain viable for hours to days on surfaces made from a variety of materials – longer on plastics and steel, and shorter viability on cardboard and copper. (*Figure 11*). Cleaning visibly dirty surfaces followed by disinfection is a best practice measure for prevention of COVID-19 and other viral respiratory illnesses in households, clinics, offices and community settings. BrightSpring-PharMerica has implemented additional cleaning and disinfection protocols to limit the spread of COVID-19, and has a number of instructional resources available on our Company intranet.

Figure 11. Doremalen N et al found that SARS-coV-2 is viable for up to 72 hours on plastics, 48 hours on stainless steel, 24 hours on cardboard, 4 hours on copper, and is detectable in aerosols for up to 3 hours. *New England Journal of Medicine, March 17, 2020.*



Potential Therapeutics

We are actively following scientific advancements in potential therapeutics for COVID-19. We have evaluated several early studies of agents with potential activity against COVID-19, including the recent report by the National Institutes of Health, of a placebo-controlled, randomized controlled trial of the investigational antiviral drug remdesivir in COVID-19 positive, hospitalized patients. Preliminary results indicate that patients who received remdesivir had a 31% faster time to recovery than those who received placebo ($p<0.001$). Specifically, the median time to recovery was 11 days for patients treated with remdesivir compared with 15 days for those who received placebo. Results also suggested a survival benefit, with a mortality rate of 8.0% for the group receiving remdesivir versus 11.6% for the placebo group ($p=0.059$).

We follow the Regulatory Affairs Professional Society's therapeutics tracker, which is updated on a weekly basis. As the COVID-19 pandemic continues, researchers and manufacturers are moving potential therapeutics into clinical trials quickly. The search is on to find treatment candidates that lower mortality rates and lessen the severity of COVID-19. To date, three therapeutics are approved to treat COVID-19: dexamethasone in the United Kingdom and Japan; Avigan (favilavir) in China, Italy and Russia; and Veklury (remdesivir) in Japan and Australia. Potential therapies are being examined in several large international trials. The largest, SOLIDARITY, is led by the World Health Organization (WHO). More than 100 countries have joined SOLIDARITY to evaluate high-profile treatment candidates for COVID-19.

The pandemic has created unprecedented public/private partnerships. Operation Warp Speed is a collaboration of several US federal government departments including Health and Human Services and its subagencies, Agriculture, Energy and Veterans Affairs and the private sector. Within this effort, the US National Institutes of Health (NIH) has partnered with more than 18 biopharmaceutical companies to accelerate development of drug and vaccine candidates for COVID-19 in a collaboration dubbed Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV).

The European Medicines Agency (EMA) is building procedures for accelerated drug and vaccine development, promising to offer rapid reviews for scientific advice, compliance, market authorization, extensions beyond indications and market authorizations, and compassionate use for

COVID-19 related initiatives.

Once a leading candidate, hydroxychloroquine/chloroquine has been removed from the tracker due to evidence it can cause more harm than benefit in patients with COVID-19. It will be reinstated if evidence to the contrary arises.

Vaccine Development

The Outbreak Committee follows the Regulatory Affairs Professionals Society COVID-19 Vaccine Tracker. Researchers worldwide are working around the clock to find a vaccine against SARS-CoV-2, the virus causing the COVID-19 pandemic. Experts estimate that a fast-tracked vaccine development process could speed a successful candidate to market in approximately 12-18 months – if the process goes smoothly from conception to market availability.

The pandemic has created unprecedented public/private partnerships. Operation Warp Speed (OWS) is a collaboration of several US federal government departments including Health and Human Services and its subagencies, Agriculture, Energy and Veterans Affairs and the private sector. Within OWS, the US National Institutes of Health (NIH) has partnered with more than 18 biopharmaceutical companies to accelerate development of drug and vaccine candidates for COVID-19 (ACTIV). The COVID-19 Prevention Trials Network (COVPN) has also been established, which combines clinical trial networks funded by the National Institute of Allergy and Infectious Diseases (NIAID): the HIV Vaccine Trials Network (HVTN), HIV Prevention Trials Network (HPTN), Infectious Diseases Clinical Research Consortium (IDCRC), and the AIDS Clinical Trials Group.

The US government is choosing three vaccine candidates to fund for Phase 3 trials under Operation Warp Speed: Moderna's mRNA-1273 in July, The University of Oxford and AstraZeneca's AZD1222 in August, and Pfizer and BioNTech's BNT162 in September. Members of ACTIV have suggested developing safe controlled human infection models (CHIMs) for human trials could take 1-2 years. A sponsor would need to provide data from placebo-controlled trials indicating their vaccine is at least 50% effective against COVID-19 in order to be authorized for use, according to FDA guidance issued and effective 30 June.

Government Relations and Advocacy

BrightSpring-PharMerica is leveraging its outstanding Government Relations team to advocate for the Company continually being deemed a vital, essential service through our diversified, community-based businesses which provide clinical care, support, medication management, and rehabilitation of the most medically, behaviorally, and socially complex individuals in society. Specific to our outbreak preparedness work, Government Relations has undertaken many initiatives, including:

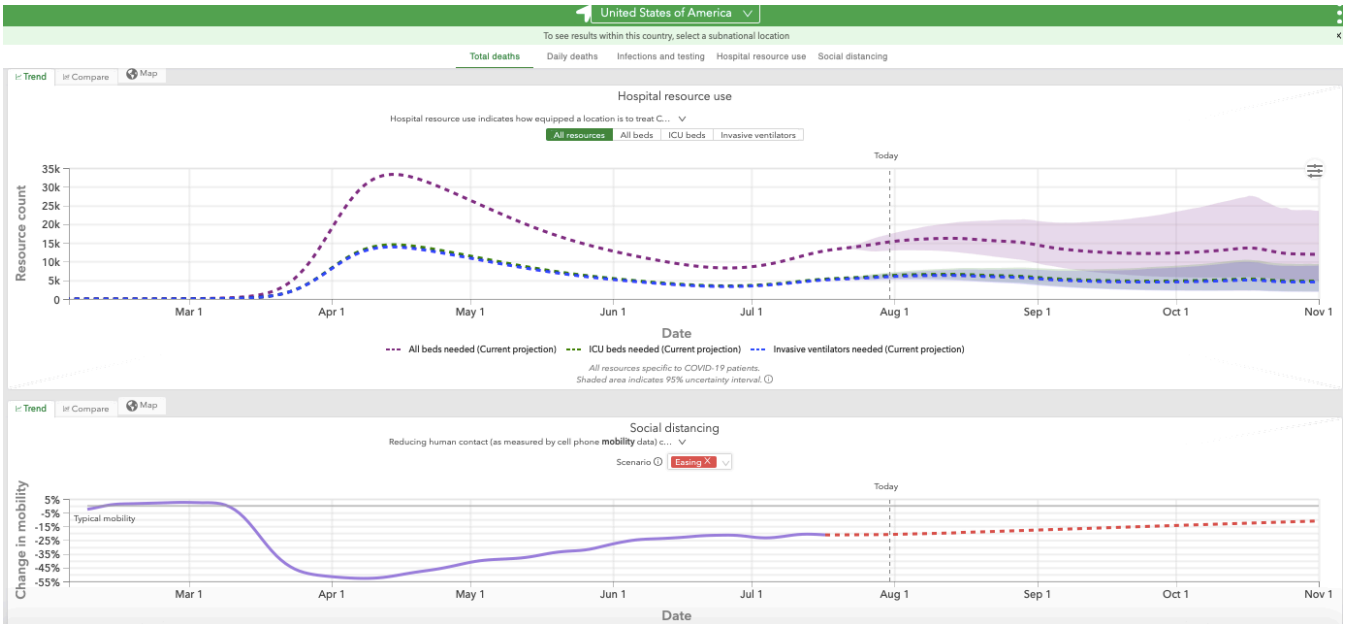
- Holding a seat on the Company's Outbreak Committee to advise and report on local, state and federal developments impacting the Committee's work;
- Lobbying state and federal lawmakers and appointed officials, including CMS, for the funding, regulatory structures, and flexibility the Company needs to be equipped to answer the challenges of our response to this outbreak;
- Ensuring our services and are workforce are deemed "essential" during any government ordered Stay at Home or business closure periods; and

- Being a leading voice with numerous state and national associations, among other external stakeholder groups, to make our response priorities have broad support.

Business Continuity Planning

BrightSpring-PharMerica has leveraged technology enablers to facilitate remote work for positions that can be effectively performed remotely. The Company has regular executive meetings where census data, COVID-19 cases, and PPE supply and demand are reviewed by business segment. Operational, human resources and governmental relations issues are also discussed. To date, the company has experienced a modest decrease in referrals to some service lines due to the pandemic, and has been working with stakeholders to mitigate effects of the outbreak. We use several COVID-19 case forecast models to best enable national and state-level planning by business segment, including the University of Washington's Institute for Health Metrics and Evaluation predictive model shown below (*Figure 12*).

Figure 12. US-level COVID-19 related resource utilization predictive model (Institute for Health Metrics and Evaluation, University of Washington).



Webinars to Support Our Families

The overall well-being of our team members and their families is very important to us. To help alleviate some of these stressors and provide solutions and support, we are lending the expertise of our Workforce Services division.

Our workforce industry internal experts share information through a series of webinars hosted exclusively to support impacted family members of BrightSpring/PharMerica employees. Attendees find out how to access resources, find replacement income opportunities and learn coping skills for dealing with job loss.

Conclusion

BrightSpring-PharMerica's Outbreak Committee reviews COVID-19 epidemiologic data in real time, linking the company's stakeholders to this Plan to ensure optimal preparedness and action. The plan is updated frequently, and is adjusted to best serve the needs and safety of the patients, clients, employees and communities we serve.

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<tr><th colspan="3">EXHIBIT A</th></tr>
<tr><td>PROCEDURE: Isolation Precautions and PPE</td><td colspan="2">SUBJECT: Infection Control</td></tr>
<tr><td rowspan="3">PERFORMED BY: DSP, LPT, LVN, LPN, RN, All direct care and support staff</td><td colspan="2">Prepared By: E. Shauen Howard DHA, MSN, RN; VP Clinical Services</td></tr>
<tr><td colspan="2">Approved By: Outbreak Preparedness and Action Committee</td></tr>
<tr><td>Date Written: February 2019
Last Updated February 29, 2020</td><td>Reviewed annually: See below</td></tr>
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GENERAL: When individuals we serve have a known infection, staff must follow specific precautions to reduce the risk of cross contamination to other clients.

World Health Organization—Recommendations for standard precautions:

1. Hand hygiene technique:

- Hand washing (40–60 sec): Wet hands and apply soap; rub all surfaces; rinse hands with warm water and dry thoroughly with a single use towel; use towel to turn off faucet.
- Hand rubbing (20–30 sec): Apply enough hand sanitizer product to cover all areas of the hands; rub hands until dry.

Summary indications:

- Before and after direct individual contact and between individuals we serve; whether or not gloves are worn
- Immediately after removing gloves
- Before handling an invasive device
- After touching blood, body fluids, secretions, excretions, non-intact skin, and contaminated items, even if wearing gloves
- During care, before moving from a contaminated to a clean body site
- After contact with inanimate objects in the immediate vicinity of the individual

2. Gloves:

- Wear when touching blood, body fluids, secretions, excretions, mucous membranes, or non-intact skin.
- Change between tasks and procedures on the same individual, after contact with potentially infectious material.
- Remove after use, before touching non-contaminated items and surfaces, and before going to another individual. Perform hand hygiene immediately after removal.

3. Facial protection (eyes, nose, and mouth):

- (1) Wear a surgical or procedure mask and eye protection (eye visor, goggles)

OR

(2) Wear a face shield to protect mucous membranes of the eyes, nose, and mouth during activities likely to generate splashes or sprays of blood, body fluids, secretions, and excretions.

4. Gown:

- Wear to protect skin and prevent soiling of clothing during activities that are likely to generate splashes or sprays of blood, body fluids, secretions, or excretions.
- Remove a soiled gown as soon as possible and perform hand hygiene.

5. Prevention of needle stick and injuries from other sharp instruments:

- Use care when:
  - Handling and disposing needles and other sharp instruments or devices.
  - Cleaning used supplies.

6. Respiratory hygiene and cough etiquette. Persons with respiratory symptoms should apply control measures:

- Cover the nose and mouth when coughing/sneezing with tissue or mask, dispose of used tissues and masks, and perform hand hygiene after contact with respiratory secretions.

In aggregate care settings:

- With acutely febrile (100.4° F [37.8° C] or greater using an oral thermometer), respiratory symptomatic individuals we serve, place individuals we serve at least 6 feet away from others in common areas, if possible.
- Post signs instructing persons to practice respiratory hygiene/cough etiquette.
- Make hand hygiene resources, tissues, and masks available.

7. Environmental cleaning:

- Provide routine cleaning and disinfection of environmental and other frequently touched surfaces.

8. Linens:

Handle, transport, and process used linen in a manner which:

- Prevents skin and mucous membrane exposure and contamination of clothing.
- Avoids transfer of pathogens to other individuals we serve, staff, or the environment.

9. Waste disposal:

- Ensure waste handling and disposal occurs in a manner, including PPE, which protects staff and individuals we serve from exposure to pathogens.

10. Patient care equipment:

- Handle equipment soiled with blood, body fluids, secretions, and excretions in a manner that prevents skin and mucous membrane exposure, contamination of clothing, and transfer of pathogens to others or the environment.
- Clean and disinfect reusable equipment before used by another individual

PURPOSE: To protect employees and individuals we serve from the spread of infection through contact with blood and/or body fluids in the routine or non-routine course of their job; to practice Standard Precautions in accordance with the State Department of Health rules and OSHA Standards.

EQUIPMENT:

- Gloves
- Gowns
- Masks
- Eyewear

AIRBORNE PRECAUTIONS

Airborne precautions- for individuals we serve known or suspected to be infected with pathogens transmitted by the airborne route (e.g., Coronavirus (COVID-19), tuberculosis, measles, chickenpox, disseminated herpes zoster) will be implemented for this and will include:

- Source control: put a mask on the individual.

Ensure appropriate patient placement in an airborne infection isolation room- (AIIR) constructed according to the Guideline for Isolation Precautions.

In settings where Airborne Precautions cannot be implemented due to limited engineering resources, masking the individual and placing them in an individual room with the door closed will reduce the likelihood of airborne transmission until the individual is either transferred to a facility with an AIIR or returned home.

Restrict susceptible healthcare personnel from entering the room of individuals we serve known or suspected to have measles, chickenpox, disseminated zoster, or smallpox if other immune healthcare personnel are available.

Use personal protective equipment (PPE) appropriately, including a fit-tested NIOSH-approved N95 or higher-level respirator for healthcare personnel.

Limit transport and movement of individuals we serve outside of the room to medically-necessary purposes. If transport or movement outside an AIIR is necessary, instruct individual to wear a surgical mask, if possible, and observe Respiratory Hygiene/Cough Etiquette.

Staff transporting individuals we serve who are on Airborne Precautions do not need to wear a mask or respirator during transport if the individual is wearing a mask and infectious skin lesions are covered.

Immunize susceptible persons as soon as possible following unprotected contact with vaccine- preventable infections (e.g., measles, varicella or smallpox).

DROPLET PRECAUTIONS

Droplet precautions will be implemented for Diphtheria, rubella Streptococcal pharyngitis, pneumonia, scarlet fever, Mycoplasma pneumonia or sepsis, meningococcal pneumonia or sepsis.

This will include private room, mask or respirator (N-95 mask), gown and gloves.

- Source control: put a mask on the individual.

Ensure appropriate individual placement in a single room if possible.

Aggregate Care Settings:

Make decisions regarding individual placement on a case-by-case basis considering infection risks to other patients in the room and available alternatives.

Use personal protective equipment (PPE) appropriately. Apply mask upon entry into the individual room or space.

Limit transport and movement of individual outside of the room to medically-necessary purposes. If transport or movement outside of the room is necessary, instruct individual to wear a mask and follow Respiratory Hygiene/Cough Etiquette.

CONTACT PRECAUTIONS

Contact precautions (direct individual or environmental) will be implemented for multidrug resistant organisms which the such as VRE, MRSA, Clostridium Difficile (C-Diff), and other enteric pathogens, major wound infections, herpes simplex, scabies, varicella zoster.

This will include: private room, gloves and gown, eyewear if splashing is expected.

Ensure appropriate individual placement in a single individual space or room if suspected. Once diagnosis is verified, residential or community settings should make room placement decisions balancing risks to other individuals we serve.

For individuals we serve with suspected Clostridium Difficile (C-Diff) immediate isolation measures should be taken, including use of bedside commode or toilet only to be used by infected individual. Once confirmed, maintain contact precautions for at least 48 hours after diarrhea has resolved.

Restrict any unnecessary personnel from entering the home of individuals we serve known or suspected to have C-Diff.

Use personal protective equipment (PPE) appropriately, including gloves and gown. Wear a gown and gloves for all interactions that may involve contact with the individual or their environment. Donning PPE upon room entry and properly discarding before exiting the patient room is done to contain pathogens.

PROCEDURE:

1. Verify resident's/patient's record and physician order for isolation precautions
   a. Identify specific precaution required
2. Post precaution sign on resident's/patient's door.
3. Protective equipment will be outside of resident's/patient's door.
4. Wash hands before entering room and after leaving room

5. Gather all equipment needed in resident's/patient's room, using resident's/patient's own designated equipment when possible. Keep designated equipment in resident's/patient's room
6. Inform individual that you are entering their room before applying PPE.
7. Apply gown, being sure to cover all outer garments, tie securely at neck and waist.
8. Apply mask next if needed, then eyewear if needed, then clean gloves bring glove cuff over edge of gown sleeves, per specific precaution indicated above
9. If stethoscope is reused, clean ear pieces and diaphragm with alcohol swab.
10. When procedure is completed, dispose of all trash in room.
11. Leave room then remove gloves:
    a. Pinch the outside of the glove about an inch or two down from the top edge inside the wrist.
    b. Peel downwards, away from the wrist, turning the glove inside out
    c. Pull the glove away until it's removed from the hand. Hold the inside-out glove with the gloved hand.
    c. With your gloveless hand, slide your fingers under the wrist of the glove, do not touch the outside of the glove.
    d. Repeat step 3. Peel downwards, away from the wrist, turning the glove inside out.
    e. Continue pulling the glove down and over the first glove. This ensures that both gloves are inside out, one glove enveloped inside the other, with no contaminants on the bare hands.
    f. Dispose of the gloves in a proper bin– this may differ depending on company policies.
12. Dispose of all contaminated items.
13. Wash hands.

Limit transport and movement of individuals we serve outside of the room to medically-necessary purposes. When transport or movement is necessary, cover or contain the infected or colonized areas of the resident's/patient's body. Remove and dispose of contaminated PPE and perform hand hygiene prior to transporting individuals we serve on Contact Precautions. Don clean PPE to handle the individuals we serve at the transport location.

Use disposable or dedicated patient-care equipment (e.g., blood pressure cuffs). If common use of equipment for multiple individuals we serve is unavoidable, clean and disinfect such equipment before use on another individual.

Prioritize cleaning and disinfection of the rooms of individuals we serve on contact precautions ensuring rooms are frequently cleaned and disinfected (e.g., at least daily or prior to use by another individual if outpatient setting) focusing on frequently-touched surfaces and equipment in the immediate vicinity of the individual.

<u>For Individuals we serve diagnosed with C-Diff:</u>

- <u>Complete the Personal Waiver Regarding the use of Chlorine Bleach in a Residential Home.</u>
- <u>Carefully and thoroughly clean rooms and equipment used for the individuals we serve care with a C. Difficile sporicidal bleach wipe or spray (EPA List K agent).</u>
- <u>Wash all linens separately with an additive of bleach (EPA List K agent) to the laundry soap in hot water.</u>

TRAINING: All staff will be trained in Infection Control & PPE procedures upon orientation and annually. When identified for use, staff will be fitted and trained on respirator (N-95 mask). Competency will be documented. See attachments.

Training by the RN or designated employee will consist of lecture and return demonstration.

POLICY REVIEW: Isolation Precautions

Review Date	Signature	Title
2/29/20		Chair, Outbreak Preparedness and Action Committee

 Description

Medline N95 Qualitative Fit Test Kit feature one kit tests for approximately 100 staff members. It is available as a kit with refills, and is easy to administer and instructions are found within the kit. The Medline qualitative fit test kit is to be used in conjunction with our N95 particulate respirator mask models, NON27501, NON24505, NON24506 and NON24507 as fit testing is required prior to the initial use of a respirator. It is saccharin based qualitative fit test kit that can be used for up to 100 tests.

- Type: Fit test kit
- Material: Latex-free parts
- One kit tests approximately 100 staff members
- Refills are also available
- Saccharin based fit test kit
- Easy to administer and includes instructions
- Available as a Kit, and refills are also available
- Qualitative Fit Test Kit is to be used in conjunction with our N95 particulate respirator masks (NON27501, NON24505, NON24506 and NON24507)
- Fit testing is required prior to the initial use of a respirator
- Test is easy to administer and instructions are found within the kit

Test Numerous Employees

Your staff members have to go through fit testing before they can use respirators, and this Medline N95 qualitative fit test kit provides you with up to 100 tests, so everyone can get done without the need for refills. The test is easy to administer and instructions are included with this kit. Latex-Free Design

Don't worry about employees having allergic reactions to this test; the parts are all latex-free, so you can be sure they're safe. The saccharin-based fit test kit is the ideal choice for all the tests you have to complete. Fits Specific Respirator Masks

Make sure your fit test will work the first time with the Medline N95 qualitative fit test kit and the right respiratory mask. This kit works with the N95 particulate respirator masks with the stock numbers NON27501, NON24506, NON24505, and NON24507 for an accurate test.

Glove Use in Standard Prec

Wear gloves when anticipating contact wi
a patient's:

- Blood or body substances (i.e., fluids or
- Mucous membranes (e.g., nasal, oral, ge
- Non-intact skin (e.g., wound or surgical i
- Insertion point of a patient's inva
  indwelling device

(Siegel JD, CDC Guidelines for Isolation Precaution, 2007)

CDC
CENTERS FOR DISEASE CONTROL AND PREVENTION

Donning Gloves

Select correct type of glove and size

Extend to cover wrist, over isolation gown i

Sequence of PPE donning, gloves are ofte
item to be put on

(CDC, Sequence for Personal Protective Equipment, https://www.cdc.gov/hai/pdfs

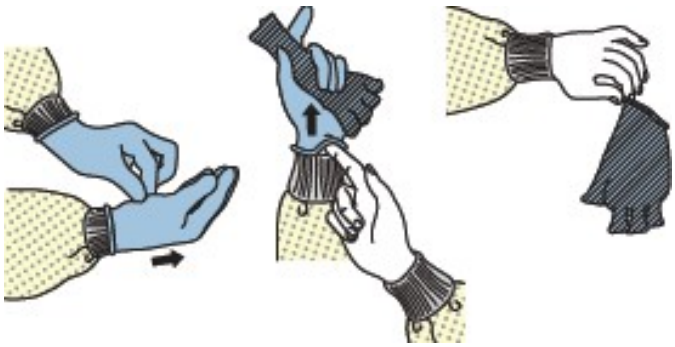
CDC
CENTERS FOR DISEASE CONTROL AND PREVENTION

Doffing Gloves

There are a variety of ways to safely remove gloves

- With the gloved hand, grasp the palm area of t hand and peel off
- Hold removed glove in gloved hand; sli ungloved hand under remaining glove at wris discard

Sequence of PPE doffing, gloves are usually the removed



CDC
CENTERS FOR DISEASE CONTROL AND PREVENTION

sequence.pdf)

Gown Use in Standard Preca

Wear when contact between clothing or skin w
blood or body substances is expected.

For example:

- Contact with patient's non-intact skin (e.g., v
- During procedures likely to generate a splas
of blood or body fluid
- Handling containers or patient fluids like
splash or spill

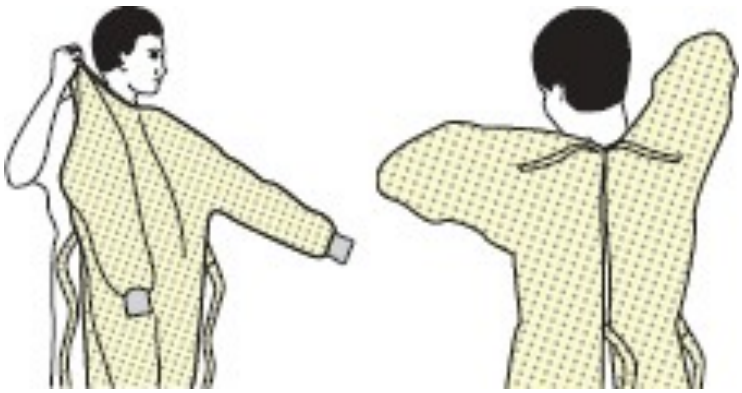
(CDC, Sequence for Personal Protective Equipment, https://www.cdc.go
sequence.pdf)

CDC
Centers for Disease Control and Prevention

Donning Gowns

Gowns should cover the torso, the legs to th
the arms to end of wrist and wrap around the

Slide gowns on with the opening at the b
around the back of the neck and the waist



(CDC, Sequence for Personal Protective Equipment, https://www.cdc.gov/hai/pdfs

CDC
Centers for Disease Control and Prevention

Doffing Gowns

Unfasten gown

Pull away from neck and shoulders, touchi
gown only

Turn gown inside out

Fold or roll into a bundle and discard

Remove gown and perform hand hygiene bef
patient's environment (e.g., exam room)

Do not wear the same gown between patients

(CDC, Sequence for Personal Protective Equipment, https://www.cdc.gov/hai/pdfs

CDC
CENTERS FOR DISEASE CONTROL AND PREVENTION

Face Mask and Eye Protecti
in Standard Precautio

Wear when anticipating potential splashes of blood/body substances during patient c

Face Masks–protect nose and mou

Goggles–protect eyes

Face shields–protect face (i.e., nose, mou

Personal eyeglasses and contact lenses ar considered adequate eye protection

(CDC, Sequence for Personal Protective Equipment, https://www.cdc.gov/hai/pdfs

CDC
CENTERS FOR DISEASE CONTROL AND PREVENTION

Donning a Face Mask or Res

- Secure ties or elastic bands at middle of head
- Flexible band should fit to bridge of nose
- Face mask should fit snug to face and below
- Chin Fit-check respirator

(CDC, Sequence for Personal Protective Equipment, https://www.cdc.gov/hai/pdfs/ppe/ppesequence.pdf)

CDC
CENTERS FOR DISEASE CONTROL AND PREVENTION

Doffing a Face Mask or Res

Grasp bottom ties or elastics of the face mask
then the ones at the top, and remove without t
front

Discard in waste container

(CDC, Sequence for Personal Protective Equipment, https://www
sequence.pdf)

CDC
CENTERS FOR DISEASE CONTROL AND PREVENTION

Donning and Doffing Goggles Face Shield

Don:

- Place over face and eyes and adjust to fit

Doff:

- Remove from t lifting the h over the ear p
- Place in desi for reproc disposal

(CDC, Sequence for Personal Protective Equipment, https://www.cdc.gov/hai/pdfs

CDC
Centers for Disease Control and Prevention

Key Points of PPE

The key for PPE removal is to limit opportunities for environment and self-contamination

Outside front of the PPE is the area most likely to be contaminated

Perform hand hygiene after PPE removal

An example sequence of doffing PPE is as follows:

- Gloves
- Face shield/goggles
- Gown
- Face Mask

(CDC, Sequence for Personal Protective E

EXHIBIT B

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

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

Ref: QSO-20-17-ALL

DATE: March 10, 2020

TO: State Survey Agency Directors

FROM: Director
Quality, Safety & Oversight Group

SUBJECT: Guidance for use of Certain Industrial Respirators by Health Care Personnel

Memorandum Summary

- 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 Coronavirus Disease 2019 (COVID-19) and other respiratory illnesses.
- The memo clarifies the application of CMS policies in light of recent Centers for Disease Control and Prevention (CDC) and Food and Drug Administration (FDA) guidance expanding the types of facemasks healthcare workers may use in situations involving COVID-19 and other respiratory infections.

Background

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 illness. With this announcement, health care workers in providers and suppliers certified by CMS will have a more expansive range of options to protect themselves and those receiving their care. CMS will continue to explore flexibilities and innovative approaches within our regulations to allow health care entities to meet the critical health needs of the country.

Guidance

The Centers for Disease Control and Prevention (CDC) have updated their Personal Protective Equipment (PPE) recommendations for health care workers involved in the care of patients with known or suspected COVID-19. At this time, these recommendations will be considered by CMS surveyors to determine if Medicare and Medicaid providers and suppliers are complying with infection control protocols:

Based on local and regional situational analysis of PPE supplies, facemasks are an acceptable temporary alternative when the supply chain of respirators cannot meet the demand. During this time, available respirators should be prioritized for procedures that are likely to generate respiratory aerosols, which would pose the highest exposure risk to Health Care Providers (HCP).

  - Facemasks protect the wearer from splashes and sprays.
  - Respirators, which filter inspired air, offer respiratory protection.

- When the supply chain is restored, facilities with a respiratory protection program should return to use of respirators for patients with known or suspected COVID-19. Facilities that do not currently have a respiratory protection program, but care for patients infected with pathogens for which a respirator is recommended, should implement a respiratory protection program.
- Eye protection, medical gown, and gloves continue to be recommended.
  - If there are shortages of medical gowns, they should be prioritized for aerosol- generating procedures, care activities where splashes and sprays are anticipated, and high-contact patient care activities that provide opportunities for transfer of pathogens to the hands and clothing of HCP.
- Updated recommendations regarding the need for an airborne infection isolation room (AIIR).
  - Patients with known or suspected COVID-19 should be cared for in a single- person room with the door closed. AIIRs should be reserved for patients undergoing aerosol-generating procedures.
- Updated information based on currently available information about COVID-19 and the current situation in the United States, which includes reports of cases of community transmission, infections identified in HCP, and shortages of facemasks, N95 filtering facepiece respirators (FFRs) (commonly known as N95 respirators), and gowns.
- Increased emphasis on early identification and implementation of source control (i.e., putting a face mask on patients presenting with symptoms of respiratory infection).

Additional information on CDC's recommendations above can be found here: https://www.cdc.gov/coronavirus/2019-ncov/infection-control/control-recommendations.html

Further, the FDA approved the CDC request for an emergency use authorization (EUA) to allow health care personnel to use certain industrial respirators during the COVID-19 outbreak in health care settings. The FDA concluded that respirators approved by the National Institute for Occupational Safety and Health (NIOSH), but not currently meeting the FDA's requirements, may be effective in preventing health care personnel from airborne exposure, including COVID- 19, which can cause serious or life-threatening disease, including severe respiratory illness.

This action allows the NIOSH-approved respirators not currently regulated by the FDA to be used in a health care setting by health care personnel during the COVID-19 outbreak, thereby maximizing the number of respirators available to meet the needs of the U.S. health care system.

PLEASE NOTE: Due to the updated CDC guidance and current supply demands of these devices (and the discards associated with testing), CMS is directing surveyors not to validate the date of the last FIT test for health care workers in Medicare and Medicaid certified facilities, until further notice.

References

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