

# Crisis Standards of Care and Employer Duty to Supply PPE During COVID-19

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## Introduction

In times of crisis, demand frequently exceeds supply and employers must quickly make difficult decisions to triage rapidly depleting resources—often with incomplete data. COVID-19 has caused rolling shortages of essential personal protective equipment (PPE) forcing employers to reduce, replace, or reuse PPE for frontline essential workers. Crisis standards of care<sup>1</sup> permit flexibility and liability protection for some, but not all, creative alternatives to PPE.<sup>2</sup> These deviations from conventional standards of care must be navigated carefully by employers to avoid liability for breach of one, or more, duty of care.

## I. Employer Duty to Provide Personal Protective Equipment (PPE) and Pre-Pandemic Standards of Care

Employers must “assess the workplace to determine if hazards are present, . . . which necessitate the use of [PPE]” and if present they must “[s]elect, and have each affected employee use, the type(s) of PPE that will protect the affected employee from the hazards identified.”<sup>3</sup> The employer is responsible for ensuring that PPE is maintained in a sanitary condition.<sup>4</sup> Employers must train employees on the selection, donning, doffing, care, maintenance, useful life, and disposal of PPE.<sup>5</sup>

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1. John L. Hick, Joseph A. Barbera & Gabor D. Kelen, *Refining Surge Capacity: Conventional, Contingency, and Crisis Capacity*, 3 DISASTER MED. & PUB. HEALTH PREPAREDNESS (SUPP. 1/2) S59, S59–60 (2009).

2. Brent Ibata, *Improvising Personal Protective Equipment during COVID-19*, AM. COLL. OF HEALTHCARE EXECs. (Apr. 27, 2020), <http://blog.ache.org/2020/04/27/improvising-personal-protective-equipment-during-covid-19> [perma.cc/9UAX-G9ZT].

3. 29 C.F.R. § 1910.132(d)(1) (2019).

4. *Id.* § 1910.132(a)–(b).

5. *Id.* § 1910.132(f).

Retraining is required when there are changes in the types of PPE to be used or if there are inadequacies in an employee's knowledge or use of assigned PPE.<sup>6</sup>

The Occupational Safety and Health Administration (OSHA) is not the only agency contributing to standards-of-care for PPE. The U.S. Food and Drug Administration (FDA) regulates PPE that qualify as medical devices.<sup>7</sup> The U.S. Centers for Disease Control and Prevention (CDC) publishes detailed transmission-based isolation precautions.<sup>8</sup> The National Institute for Occupational Safety and Health (NIOSH) regulates N95 respirators.<sup>9</sup> The Centers for Medicare & Medicaid Services (CMS) regulates hospitals and, by extension, infection prevention and control programs within regulated hospitals.<sup>10</sup>

Employers may adopt PPE standards from governmental<sup>11</sup> or non-governmental<sup>12</sup> organizations, and they may supplement these standards with on-the-job standard work with detailed job breakdowns.<sup>13</sup> Together, these safety standards—including industry, federal,<sup>14</sup> and state<sup>15</sup> standards—comprise the baseline (non-crisis) standard of care due to an employee from an employer and can be admitted as evidence of said duty.<sup>16</sup>

## II. COVID-19 Occupational Hazards

In the initial phases of a pandemic, the epidemiology of a novel virus is highly speculative, and high-quality, peer-reviewed, well-controlled

6. *Id.* It should be noted that a change from conventional to contingency or crisis capacity use of PPE would most likely qualify as a change requiring retraining.

7. The FDA defines a *device* to include those intended for use in the prevention of disease in man. See 21 U.S.C. § 321(h) (2018). PPE that makes a “prevention of disease” claim and is regulated by the FDA include isolation gowns (FDA Product Code OEA); surgical gowns (FDA Product Code LYU); surgical caps (FDA Product Code FYF); surgical masks (FDA Product Codes FXX/OUK); and medical N95 respirators (FDA Product Codes MSH/ONT). Facemasks that do not make claims of filtration efficiency are subject to enforcement discretion (FDA Product Code QKR).

8. JANE D. SIEGEL, EMILY RHINEHART, MARGUERITE JACKSON & LINDA CHIARELLO, HEALTHCARE INFECTION CONTROL PRACTS. ADVISORY COMM., CTRS. FOR DISEASE CONTROL & PREVENTION, 2007 GUIDELINE FOR ISOLATION PRECAUTIONS: PREVENTING TRANSMISSION OF INFECTIOUS AGENTS IN HEALTHCARE SETTINGS (2019), <https://www.cdc.gov/infectioncontrol/pdf/guidelines/isolation-guidelines-H.pdf>.

9. 42 C.F.R. pt. 84 (2019).

10. *Id.* § 482.42.

11. For example from the U.S. Centers for Disease Control and Prevention.

12. For example from the American Industrial Hygiene Association.

13. PATRICK GRAUPP & MARTHA PURRIER, GETTING TO STANDARD WORK IN HEALTH CARE 29–50 (2012).

14. “The existence and content of applicable standards [including OSHA standards] should have been admitted as evidence of the standard of care due [to the employee] from his employer.” *Donovan v. Gen. Motors*, 762 F.2d 701, 705 (8th Cir. 1985).

15. See *Schroeder v. C.F. Braun & Co.*, 502 F.2d 235, 243 (7th Cir. 1974).

16. *Donovan*, 762 F.2d 701.

studies are lacking.<sup>17</sup> For COVID-19, it quickly became evident that SARS-CoV-2 could be transmitted via aerosolized droplets<sup>18</sup> from symptomatic<sup>19</sup> and asymptomatic<sup>20</sup> individuals, and, early in the pandemic, the “weight of combined evidence support[ed] airborne precautions for the occupational health and safety of health workers treating patients with COVID-19.”<sup>21</sup> SARS-CoV-2 can be transmitted via everyday aerosol-generating activities, including talking,<sup>22</sup> eating,<sup>23</sup> singing,<sup>24</sup> and possibly toileting.<sup>25</sup>

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17. See generally DAVID L. SACKETT, SHARON E. STRAUS, W. SCOTT RICHARDSON, WILLIAM ROSENBERG & R. BRIAN HAYNES, *EVIDENCE-BASED MEDICINE—HOW TO PRACTICE AND TEACH EBM* 29–66 (2d ed. 2000) (describing how to find the current best evidence to manage pressing clinical problems).

18. Parham Azimi, Zahra Keshavarz, Jose Guillermo Cedeno Laurent, Brent R. Stephens & Joseph G. Allen, *Mechanistic Transmission Modeling of COVID-19 on the Diamond Princess Cruise Ship Demonstrates the Importance of Aerosol Transmission*, MEDRXIV (July 15, 2020), <https://www.medrxiv.org/content/10.1101/2020.07.13.20153049v1.full.pdf> (preprint not yet subject to peer review); Joshua L Santarpia et al., *The Infectious Nature of Patient-Generated SARS-CoV-2 Aerosol*, MEDRXIV (July 21, 2020), <https://www.medrxiv.org/content/10.1101/2020.07.13.20041632v2/full.pdf> (preprint not yet subject to peer review); Lidia Morawska & Donald K Milton, *It Is Time to Address Airborne Transmission of Coronavirus Disease 2019 (COVID-19)*, CLINICAL INFECTIOUS DISEASES (Sept. 19, 2020), <https://academic.oup.com/cid/advance-article-pdf/doi/10.1093/cid/ciaa939/33772734/ciaa939.pdf>; Renyi Zhang, Yixin Li, Annie L. Zhang, Yuan Wang & Mario L. Molina, *Identifying Airborne Transmission as the Dominant Route for the Spread of COVID-19*, 117 PROC. NAT'L ACAD. SCI. (2020), 14857, 14857; Neeltje van Doremalen et al., *Letter to the Editor: Aerosol and Surface Stability of SARS-CoV-2 as Compared with SARS-CoV-1*, 382 N. ENG. J. MED. 1564, 1566 (2020).

19. John A. Lednický et al., *Viable SARS-CoV-2 in the Air of a Hospital Room with COVID-19 Patients*, MEDRXIV (Aug. 4, 2020), <https://www.medrxiv.org/content/10.1101/2020.08.03.20167395v1.full.pdf> [perma.cc/S2VC-BC4R] (preprint not yet subject to peer review).

20. Seungjae Lee et al., *Clinical Course and Molecular Viral Shedding Among Asymptomatic and Symptomatic Patients With SARS-CoV-2 Infection in a Community Treatment Center in the Republic of Korea*, JAMA INTERNAL MED. (Aug. 6, 2020), <https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2769235> [perma.cc/QLY5-HCZP]; Daniel P. Oran & Eric J. Topol, *Prevalence of Asymptomatic SARS-CoV-2 Infection*, 173 ANNALS INTERNAL MED. 362, 362–63 (2020).

21. Prateek Bahl, Con Doolan, Charitha de Silva, Abrar Ahmand Chughtai, Lydia Bourouiba & C. Raina MacIntyre, *Airborne or Droplet Precautions for Health Workers Treating Coronavirus Disease 2019?*, J. INFECTIOUS DISEASES (Apr. 16, 2020), <https://doi.org/10.1093/infdis/jiaa189> [perma.cc/4Z8R-V9G3].

22. Valentyn Stadnytskyi, Christina E. Bax, Adriaan Bax & Philip Anfinrud, *The Airborne Lifetime of Small Speech Droplets and Their Potential Importance in SARS-CoV-2 Transmission*, 117 PROC. NAT'L ACAD. SCI. 11875, 11875 (2020); Shin Young Park et al., *Coronavirus Disease Outbreak in Call Center, South Korea*, 26 EMERGING INFECTIOUS DISEASES 1666, 1666–67 (2020).

23. Jianyun Lu et al., *COVID-19 Outbreak Associated with Air Conditioning in Restaurant, Guangzhou, China*, 26 EMERGING INFECTIOUS DISEASES 1628, 1629 (2020).

24. Lea Hamner et al., *High SARS-CoV-2 Attack Rate Following Exposure at a Choir Practice—Skagit County, Washington*, 69 MMWR MORBIDITY & MORTALITY WKLY. REP. 606, 606 (2020).

25. Min Kang et al., *Probable Evidence of Fecal Aerosol Transmission of SARS-CoV-2 in a High-Rise Building*, 173 ANNALS INTERNAL MEDICINE \_\_\_\_ (forthcoming 2020).

Rigorous application of infection control measures is known to minimize the risk of COVID-19 in frontline essential workers.<sup>26</sup> Physical distancing, face masks,<sup>27</sup> and eye protection quickly emerged as the most effective combination of administrative controls and PPE to prevent person-to-person transmission of SARS-CoV-2.<sup>28</sup> Conversely, lack of physical distancing and lack of recommended PPE have been associated with increased risks of occupational COVID-19 infection.<sup>29</sup> Front-line essential workers in hospitals and nursing homes are at the greatest risk.<sup>30</sup> “Among front-line health-care workers, reuse of PPE or inadequate PPE were each associated with an increased risk of COVID-19.”<sup>31</sup> Protocols requiring universal masking for healthcare workers were associated with significantly lower rates of SARS-CoV-2 infections.<sup>32</sup>

### III. COVID-19 Crisis Standards of Care

During the COVID-19 public health emergency, the CDC has issued crisis capacity standards for PPE;<sup>33</sup> the FDA has issued emergency-use

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26. Chanu Rhee et al., *Incidence of Nosocomial COVID-19 in Patients Hospitalized at a Large US Academic Medical Center*, 3 JAMA NETWORK OPEN (Sept. 9, 2020), <https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2770287>; Joshua L Santarpia et al., *Aerosol and Surface Contamination of SARS-CoV-2 Observed in Quarantine and Isolation Care*, 10 SCI. REPS. 12732 (2020), <https://www.nature.com/articles/s41598-020-69286-3>; Roger Chou et al., *Epidemiology of and Risk Factors for Coronavirus Infection in Health Care Workers*, 173 ANNALS INTERNAL MED. 120, 120–22 (2020); Daniel H.T. Wong et al., *Risk Stratification Protocol to Reduce Consumption of Personal Protective Equipment for Emergency Surgeries During COVID-19 Pandemic*, 26 HONG KONG MED. J. 252, 253 (2020).

27. Kimberly A. Prather, Chia C. Wang & Robert T. Schooley, *Reducing Transmission of SARS-CoV-2*, 368 SCI. 1422, 1423–24 (2020)

28. See generally Derek K. Chu et al., *Physical Distancing, Face Masks, and Eye Protection to Prevent Person-to-Person Transmission of SARS-CoV-2 and COVID-19: A Systematic Review and Meta-Analysis*, 395 LANCET 1973 (2020).

29. Amy Heinzerling et al., *Transmission of COVID-19 to Health Care Personnel During Exposures to a Hospitalized Patient—Solano County, California, February 2020*, 69 MMWR MORBIDITY & MORTALITY WKLY. REP. 472 (2020).

30. *Id.* It should be noted that healthcare workers are distinct from other front-line essential workers since they have a duty to care “even when this entails considerable personal sacrifice.” James N. Kirkpatrick, Sarah C. Hull, Savitri Fedson, Brendan Mullen & Sarah J. Goodlin, *Scarce-Resource Allocation and Patient Triage During the COVID-19 Pandemic*, 76 J. AM. COLL. CARDIOLOGY 85, 91 (2020).

31. Long H. Nguyen et al., *Risk of COVID-19 Among Front-Line Health-Care Workers and the General Community: A Prospective Cohort Study*, 5 LANCET PUB. HEALTH e475 (2020).

32. Xiaowen Wang et al., *Association Between Universal Masking in a Health Care System and SARS-CoV-2 Positivity Among Health Care Workers*, 324 JAMA 703 (2020).

33. *Summary for Healthcare Facilities: Strategies for Optimizing the Supply of PPE During Shortages*, CTNS. FOR DISEASE CONTROL & PREVENTION (July 16, 2020), <https://www.cdc.gov/coronavirus/2019-ncov/hcp/ppe-strategy/strategies-optimize-ppe-shortages.html> [<https://perma.cc/HL2X-V5M9>].

authorizations;<sup>34</sup> OSHA has issued enforcement guidance;<sup>35</sup> and CMS has issued COVID-19 waivers.<sup>36</sup> However, despite the CDC and FDA guidance, “there is inconsistency in the application of the guidance to states on the allocation of scarce resources during a time of crisis.”<sup>37</sup>

Despite the inconsistency at the state level and challenges in implementing crisis standards of care at the national level, rapidly depleting PPE forced hospitals to quickly move from conventional to crisis capacity and crisis standards of care. A report from the Office of Inspector General with the U.S. Department of Health and Human Services noted that in March 2020 “[h]ospitals reported that widespread shortages of PPE put staff and patients at risk.”<sup>38</sup>

Recognizing that crisis standards of care may create regulatory and tort liabilities, the Institute of Medicine (IOM), in 2009, recommended adoption of legal protections for healthcare practitioners and institutions in anticipation of resource-depleting public health emergencies.<sup>39</sup> In a 2012 follow-up report, the IOM dedicated a chapter to the legal issues in emergencies, acknowledging the inherent conflict between individual and community interests and “the need to transition rapidly from individual- to population-centric health services to save as many lives as possible and prevent injuries among patients, practitioners, and responders.”<sup>40</sup>

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34. *Coronavirus Disease 2019 (COVID-19) Emergency Use Authorizations for Medical Devices*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/medical-devices/emergency-use-authorizations-medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices> [https://perma.cc/QAD4-L8XE]. “[T]he federal Public Readiness and Emergency Preparedness (PREP) Act (42 U.S.C. § 247d-6d) provides strong liability protections for individuals and entities implementing . . . counter measures that are . . . [FDA]-approved, authorized for investigational use, or authorized by an emergency use authorization.” 1 INST. OF MED., CRISIS STANDARDS OF CARE: A SYSTEMS FRAMEWORK FOR CATASTROPHIC DISASTER RESPONSE 62 (2012).

35. Memorandum from Patrick J. Kapust, Acting Dir., Enf’t Progs., to Reg’l Adm’rs, Enforcement Guidance for Respiratory Protection and the N95 Shortage Due to the Coronavirus Disease 2019 (COVID-19) Pandemic (Apr. 3, 2020), <https://www.osha.gov/memos/2020-04-03/enforcement-guidance-respiratory-protection-and-n95-shortage-due-coronavirus> [https://perma.cc/E759-BD2X].

36. *Coronavirus Waivers & Flexibilities*, CTRS. FOR MEDICARE & MEDICAID SERVS., <https://www.cms.gov/about-cms/emergency-preparedness-response-operations/current-emergencies/coronavirus-waivers> [https://perma.cc/9UFX-NXA5].

37. Douglas Romney, Hannah Fox, Stephanie Carlson, Daniel Bachmann, Donal O’Mathuna & Nicholas Kman, *Allocation of Scarce Resources in a Pandemic: A Systematic Review of US State Crisis Standards of Care Documents*, DISASTER MED. PUB. HEALTH PREPAREDNESS 1, 6 (Apr. 16, 2020), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7198465/pdf/S1935789320001019a.pdf>.

38. CHRISTI A. GRIMM, OFF. OF THE INSPECTOR GEN., U.S. DEP’T OF HEALTH & HUM. SERVS., HOSPITAL EXPERIENCES RESPONDING TO THE COVID-19 PANDEMIC: RESULTS OF A NATIONAL PULSE SURVEY MARCH 23–27, 2020, at 3 (2020), <https://oig.hhs.gov/oei/reports/oei-06-20-00300.pdf>.

39. See generally INST. OF MED., GUIDANCE FOR ESTABLISHING CRISIS STANDARDS OF CARE FOR USE IN DISASTER SITUATIONS: A LETTER REPORT (2009).

40. 1 INST. OF MED., *supra* note 34, at 55.

Anticipating that implementation of crisis standards of care may trigger potential negligence claims, the 2012 IOM report outlines two paths for assessing and resolving these claims: the first path suggests a policy of “adhering to the standards of care as they evolve” with potential negligent claims assessed by “by experts and courts based on what a reasonable practitioner would do under similar circumstances.” The alternative path proposes implementation of legal liability protections from claims of negligence during declared public health emergencies.<sup>41</sup> However, such employer immunity might “create disincentives for even law-abiding employers to protect their workers—producing a race-to-the-bottom for workplace standards.”<sup>42</sup>

### Conclusion

Essential workers make up over half of the workforce, and roughly sixty percent of essential workers are categorized as frontline essential.<sup>43</sup> For these frontline essential workers, there has been limited federal guidance on crisis standards of care for PPE.<sup>44</sup> In the absence of federal directives, some states have filled this regulatory gap by issuing their own PPE requirements for employers within their states.<sup>45</sup>

Against this backdrop of fragmented regulation of PPE for frontline essential workers, employers with workplaces where SARS-CoV-2 is present must select and provide appropriate PPE. Employees must receive training on the appropriate selection, donning, doffing, care, maintenance, useful life, and disposal of the PPE. If local PPE demand exceeds supply, employers must implement appropriate crisis standards of care that comply with all applicable federal, state, and industry standards. Crisis standards of care requiring extended use, reuse, or alternative PPE may trigger required retraining on the temporary crisis standard. All of these spinning plates must be kept in motion by employers large and small struggling to balance economic survival with protection of frontline essential workers.

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41. *Id.* at 57.

42. *Examining Liability During the COVID-19 Pandemic: Hearing Before the S. Comm. on the Judiciary*, 116th Cong. (2020) (statement of Rebecca Dixon, Exec. Dir., Nat'l Emp. L. Project), <https://www.judiciary.senate.gov/imo/media/doc/Dixon%20Testimony.pdf>.

43. James J. Brudney, *Forsaken Heroes: Covid-19 and Frontline Essential Workers*, 48 *FORDHAM URBAN L.J.* (forthcoming 2021), [https://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=3662434](https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3662434).

44. *Id.* (manuscript at 4).

45. *Id.* (manuscript at 20).