SHEA
The Society for Healthcare Epidemiology of America

May 23, 2022

Douglas L. Parker
Assistant Secretary of Labor for Occupational Safety and Health
Occupational Safety and Health Administration
200 Constitution Ave NW
Washington, DC 20210

RE: Occupational Exposure to COVID–19 in Healthcare Settings – Limited Reopening of the Comment Period for Docket No. OSHA-2020-0004

Dear Assistant Secretary Parker,

On behalf of the Society for Healthcare Epidemiology of America (SHEA), thank you for the opportunity to deliver oral testimony on April 28, 2022, and to submit follow up commentary in response to the public hearings. SHEA represents more than 2,000 physicians and other healthcare professionals globally with expertise in healthcare epidemiology, infection prevention and antibiotic stewardship. SHEA is dedicated to advancing the science and practice of healthcare epidemiology and preventing and controlling morbidity, mortality and the cost of care linked to healthcare-associated infections (HAIs), including those impacting healthcare personnel (HCP).

In brief, SHEA respectfully submits the following comments:

- Obtain the advice of content experts and organizations whose research, clinical and operational expertise is specifically focused on protection of patients and HCP in healthcare settings;
- Collaborate with experts qualified in the protection of HCP at CDC, the premier public health agency;
- Create a permanent COVID-19 standard that is clearly defined in scope and enforceable;
- Apply the up-to-date "hierarchy of controls" to manage source control and respiratory protection while minimizing unintended harms to HCP that may occur through the use of practices above those recommended by public health guidelines;
- Align regulatory requirements with surveillance and outbreak investigations; and
- Limit the permanent standard to COVID-19, because not all pathogens are transmitted the same way.

SHEA is a passionate advocate for patient and HCP safety. Our members and colleagues throughout our professional community work daily to protect HCP and the patients they care for from infectious harms using evidenced-based guidance. SHEA members have been on the frontlines of the pandemic since early 2020, when relatively little was known about the transmission of SARS-CoV-2. The onset of this novel virus came after many years of chronic underfunding for pandemic preparedness resources and infrastructure, despite the dire warnings of the broader public health community. Because of the lack of preparedness and limited resiliency of our nation's healthcare system, frontline personnel across the healthcare continuum were immediately met with suboptimal working conditions as hospitals across the country became overwhelmed. While hospitals and long-term care facilities surged with an unrelenting influx of patients with serious COVID-19 illness, shortages of critical supplies and an unstable medical supply chain already stressed by high global demand moved the standard of care to crisis levels. It was under these conditions that guidance for healthcare facilities published by the Centers for Disease Control and Prevention (CDC) was suboptimal. Due to the limited science and evidence, this chronically under-resourced agency had difficulty keeping pace with the needs of the public health community.

What is known today about the transmission of SARS-CoV-2 and the interventions that minimize the spread has dramatically expanded since March 2020. Although hospitals and other healthcare facilities continue to struggle with resource and staffing shortages, the science of SARS-CoV-2 -- supported by robust epidemiological data -- has evolved, and we have identified strategies that work to prevent transmission of SARS-CoV-2 in healthcare settings. This is in part due to the work of CDC, the National Institutes of Health, the World Health Organization, and a host of other subject matter experts dedicated to preventing the spread of infectious diseases. Allowing divergent recommendations and standards to emerge from various public health entities striving for the same goals will result in a regulation that is difficult to comply with and possibly unenforceable.

Therefore, SHEA believes the Occupational Safety and Health Agency (OSHA) should not endeavor to establish a healthcare personnel safety standard for COVID-19 independent of the CDC. OSHA and CDC, with the support of relevant subject matter experts, must work together to establish a healthcare standard that is clearly defined, enforceable, and harmonized with requirements already established by other regulatory agencies and standard-setting bodies.

Attached is a more detailed response to some of the testimony heard in April. Please do not hesitate to reach out with questions to Lynne Batshon, Director of Policy and Practice, at (703) 684-0761 or lbatshon@shea-online.org.

Sincerely,

Sharon B. Wright, MD, MPH, FIDSA, FSHEA
President, SHEA

Obtain the advice of content experts and organizations whose research, clinical and operational expertise is specifically focused on protection of patients and HCP in healthcare settings

SHEA represents a professional community of healthcare epidemiologists and infection preventionists with passion and expertise in translating research into clinical practice and developing smart public policy. SHEA's expertise is sought by healthcare regulatory authorities, including the Centers for Medicare and Medicaid Services, and accrediting agencies, such as The Joint Commission (TJC). The society's scientific voice guides decision-making bodies in developing rational, effective, and cost-conscious public policies. For example, SHEA and six leading healthcare organizations issued a consensus statement in July 2021 on what to consider in developing a policy of COVID-19 vaccination as a condition of employment (CoE). This statement included a thorough overview of current vaccines' safety and efficacy, legal considerations, ways to engage stakeholders and improve vaccination rates before implementing a policy of vaccination as a CoE, and advantages to having a fully vaccinated workforce – including creating a safer work environment for HCP through reduction in the risk of inadvertent COVID-19 exposure from unvaccinated co-workers.[1]

Healthcare epidemiologists directly guided the COVID-19 frontline response, guidance, and other policies intended to protect HCP and patients. They are uniquely skilled in the ability to apply the science of epidemiology to the healthcare setting. They are subject matter experts in many areas, including but not limited to infectious diseases, principles of infection prevention and control, occupational health related to infectious diseases, and quality improvement processes related to HAIs. Additionally, they have expertise in understanding disease exposure and transmission, an understanding of measures of incidence and prevalence (and the distinction between the two), and a basic knowledge of microbiology, bacteriology, virology, and mycology. Beyond their role as healthcare epidemiologists in which they gather, analyze, and act upon data, they also hold diverse responsibilities within hospitals and other healthcare facilities that include regulatory review, patient safety, quality improvement, clinical practice and education, administration and public reporting of infection, and infection process data. Healthcare epidemiologists help meet relevant state, federal, and accrediting organization reporting requirements. Furthermore, they collaborate and maintain relationships with public health entities at the local, state, and national levels, including taking part in emergency response efforts. Their understanding of core emergency preparedness concepts, including emergency response planning, incident command functions, and facility response to emergent events, makes them invaluable partners in policy and response plan development and evaluation for infection-related events, such as bioterrorism or pandemic respiratory pathogens.

SHEA has a shared goal of protecting HCP from exposures to COVID-19 and other infectious diseases in the healthcare setting. The society acknowledges the experiences of frontline HCP throughout the pandemic and the variety of interpretations of the existing science. **SHEA supports the creation of a COVID-19 standard, and we urge OSHA to prioritize recommendations supported by evidence in the peer-reviewed medical literature.**

Collaborate with experts qualified in the protection of HCP at CDC, the premier public health agency

The national and global scientific community has come together as never before to accelerate our understanding of SARS-CoV-2 and COVID-19. While we now know significantly more about this virus and disease than we did two years ago, we are still learning, as evidenced by the regular updating of public health

[1] Weber, D., Al-Tawfiq, J., Babcock, H., Bryant, K., Drees, M., Elshaboury, R., . . . Young, H. (2022). Multisociety statement on coronavirus disease 2019 (COVID-19) vaccination as a condition of employment for healthcare personnel. Infection Control & Hospital Epidemiology, 43(1), 3-11. doi:10.1017/ice.2021.322

guidance for our communities, healthcare, and other settings from CDC and state and local public health authorities. With the rapidly evolving pandemic, the understanding of the virus and its spread was unclear in the beginning. This led to initial guidance under emergent circumstances that, as the science evolved, had to be changed. For example, it was initially thought that asymptomatic transmission of SARS-CoV-2 was not a key driver for the spread of this disease, and this led to advising against universal masking. As the role of asymptomatic transmission became clear, it gave way to appropriate changes in guidance.

Public health guidance evolves along with these learnings and changing epidemiology of SARS-CoV-2, and CDC guidance must and continues to evolve with it. Of note, all CDC guidance related to infection prevention, occupational health, and vaccination for COVID-19 are considered "interim," therefore acknowledging the evolving nature of science.[2,3,4] In applying these guidance documents over the course of the pandemic, healthcare facilities around the United States have ensured the safety of HCP, patients, and visitors. A rigid standard that does not allow alterations due to emerging science will place HCP at increased risk by relying on and requiring practices that could be later found unhelpful or even harmful.

OSHA should not create clinical definitions for occupational exposure or other similar terms independent of CDC and other public health agencies for the purpose of establishing compliance with the standard. These responsibilities and expertise lie with the country's leading public health and infection prevention experts at CDC, and the language in the standard should refer to CDC-created definitions. In particular, the National Institute of Occupational Safety and Health (NIOSH) at CDC has developed COVID-19 guidance with a dedicated focus on protecting healthcare workers. As the preeminent public health institution in this country and around the world, the CDC and its guidelines and guidance have long been considered the gold standard to safely protect HCP and their patients for decades. The CDC expertise and guidance has been used across the world as the basis for other public health and infection prevention standards, and in the U.S., the CDC guidance is one of the core anchors by which regulatory agencies, such as CMS and TJC, assess and survey the safety of healthcare facilities for patients and HCP. The suggestion that CDC guidance is weak, unreliable, or even dangerous runs counter to the decades-long experience and opinions of most experts in healthcare and infection prevention across the globe.

To ensure our shared goal of safety of all healthcare workers, **SHEA recommends OSHA ensure the language of the permanent standard allows for healthcare facilities to demonstrate compliance through activities that are aligned with the guidance issued by the CDC and WHO.** As expressed in our oral testimony, we raise concerns that the forthcoming standard may conflict with the most current public health guidance and, as a result, may undermine HCP confidence in such guidance and create unnecessary burden for all HCP and healthcare facilities. **We further suggest that OSHA work with the CDC to inform the evolving guidance instead of developing a separate set of standards.** More complexity (e.g., different definitions) means less standardized implementation and understanding of guidance, resulting in more infections as well as undermining faith in these agencies.

<u>Create a permanent standard that is clearly defined in scope and enforceable</u>

[2] "Infection Control: Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-COV-2)." Centers for Disease Control and Prevention, https://www.cdc.gov/coronavirus/2019-ncov/hcp/infection-control-recommendations.html.
[3] "Interim Guidance for Managing Healthcare Personnel with SARS-COV-2 Infection or Exposure to SARS-COV-2." Centers for Disease Control and Prevention, https://www.cdc.gov/coronavirus/2019-ncov/hcp/guidance-risk-assesment-hcp.html.
[4] "Clinical Guidance for Covid-19 Vaccination." Centers for Disease Control and Prevention, 20 May 2022, https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html.

Some of the testimony of other stakeholders during the hearing was based on the conditions that existed at the beginning of the pandemic when most hospitals were operating under crisis standards and contingency strategies, particularly with respect to availability of staffing and personal protective equipment (PPE). Many expressed valid concerns over the confusing guidance that changed rapidly during that early phase.

SHEA agrees that healthcare facilities should not be permanently operating from or implementing local policies based upon outdated CDC crisis standards guidance issued in early 2020. CDC's provision of crisis and contingency strategies for staffing are based on surges in healthcare needs together with shortages of resources including staff and PPE. Studies found no increased risk of infection in HCP compared to the general public (and some showed a lower risk), and the majority of infections were acquired in the community through household and other exposures[5][6]. Once the medical supply chain was stabilized and risk mitigation strategies informed by a greater understanding of COVID-19 transmission were implemented, the risk to HCP was reduced, in some instances to levels lower than in the general public and other occupations.

Crisis standards of care were never intended, nor should they be used, as a cost-cutting measure for facility operating expenses. In creating a standard that is enforceable, **OSHA must utilize the full scope of scientific evidence** (both laboratory as well as those studies done in the field) combined with public health and infection prevention expertise and principles. **The OSHA final rule should also allow healthcare facilities to establish compliance standards aligned with local public health agency that oversees their jurisdiction**, as they currently do for all other infection prevention and control requirements. The ETS may have contributed to the reduction in risk, emphasizing the importance of a permanent standard that prioritizes evidence-based policies. However, if OSHA were to codify public health guidance that is unable to accommodate evolving science within a final rule, it would quickly become outdated, compelling healthcare facilities to comply with obsolete and potentially unsafe protocols.

SHEA recommends OSHA continue to encourage employers to recommend employees receive the COVID-19 vaccine and to provide paid time for recovery from associated side effects. To further increase vaccine uptake, SHEA strongly recommends OSHA require employers institute a policy that makes COVID-19 vaccination, including receipt of appropriate booster doses, a condition of employment (CoE) for HCP, with exemptions for medical contraindications and other exemptions as specified by federal or state law.

Apply the up-to-date "hierarchy of controls" to manage source control and respiratory protection.

As no single intervention can completely prevent the spread of infectious agents, **SHEA recommends OSHA follow the "hierarchy of controls," as described by NIOSH and applied across many occupational safety and health situations:** physically eliminating the hazard, replacing the hazard, isolating people from the hazard through engineering controls, changing the way people work through administrative controls, and protecting workers with personal protective equipment.[7] Some levels of control, while seemingly offering more protection, may also have unintended consequences to HCP. For example, while N95 respirators offer more filtration than medical masks, several clinical trials among HCP have noted the very high rate of adverse

[5] Jacob JT, Baker JM, Fridkin SK, et al. Risk Factors Associated With SARS-CoV-2 Seropositivity Among US Health Care Personnel. JAMA Netw Open. 2021;4(3):e211283. doi:10.1001/jamanetworkopen.2021.1283

[6] Howard-Anderson JR, et al. Occupational risk factors for severe acute respiratory coronavirus virus 2 (SARS-CoV-2) infection among healthcare personnel: A 6-month prospective analysis of the COVID-19 Prevention in Emory Healthcare Personnel (COPE) Study. Infect Control Hosp Epidemiol. 2022 Feb 14:1-8. doi: 10.1017/ice.2021.518. Epub ahead of print. PMID: 35156597; PMCID: PMC8886081.

[7] "Hierarchy of Controls." Centers for Disease Control and Prevention, 13 Jan. 2015, https://www.cdc.gov/niosh/topics/hierarchy/default.html.

symptoms among HCP after prolonged wearing of N95, including in a large cluster RCT where HCP had significantly higher reported rates of difficulty breathing, headaches, and discomfort when wearing an N95 respirator vs. a medical mask during patient care[8]. Recently, a study identified that over 80% of HCP developed PPE-related de novo migraine headaches attributed to prolonged wearing of N95 respirators[9]. While SHEA agrees on the requirement for use of respirators for patients suspected or confirmed to have COVID-19, our experience at the frontlines suggests that if required for universal and prolonged use in healthcare settings, such discomfort could lead to less adherence with wearing of respiratory protection, more frequent respirator removal due to discomfort, and possible increased risk of exposures and HCP harm and injury. **SHEA urges OSHA to work with scientists to develop the next generation of comfortable respirators that can be worn safely for prolonged periods.**

Similarly, changing ventilation and engineering controls is difficult and requires substantial time and resources to implement. However, **SHEA supports the enhancement and implementation of ventilation standards** in the longer term to prevent transmission in hospitals, combined with CDC recommended PPE and vaccinations.[10][11,12]

In summary, SHEA acknowledges that intensifying infection prevention policies -- such as wider use of higher-level respiratory protection; distancing; and better ventilation, HEPA filtration, or ultraviolet air disinfection in both clinical and nonclinical spaces -- could help further decrease workplace transmission of COVID-19. However, the potential incremental benefit of doing so needs to be balanced against unintended consequences and costs. This is particularly important in the face of increasing and unmitigated COVID-19 transmission in the community and evidence that only a minority of HCP infections are acquired in the workplace.

Align regulatory requirements with surveillance and outbreak investigations

SHEA believes COVID-19 data reporting should be held to the established standards of infectious diseases reporting to state and federal authorities and align with CDC guidance and existing standards for recordkeeping and exposure evaluation and management for other infectious diseases in healthcare settings.

Limit the permanent standard to COVID-19, because not all pathogens are transmitted the same way

Clinical guidance and standards for previous infectious disease outbreaks do not always apply to future emerging infectious diseases. The COVID-19 standard should not apply to all future infectious disease pathogens. Although pathogens may be acquired by a limited number of mechanisms (e.g., inhalation, ingestion, skin penetration, sexual) effective transmission depends on many factors, especially the inoculating dose. For diseases acquired by inhalation (e.g., COVID-19, RSV, influenza, varicella, measles, pertussis, tuberculosis) a number of factors are critical to infection in addition to the inoculating dose, including the

[8] MacIntyre CR, et al. "A cluster randomized clinical trial comparing fit-tested and non-fit-tested N95 respirators to medical masks to prevent respiratory virus infection in health care workers." Influenza Other Respir Viruses. 2011 May;5(3):170-9. doi: 10.1111/j.1750-2659.2011.00198.x. Epub 2011 Jan 27. PMID: 21477136; PMCID: PMC4941587.

[9] Ong, Jonathan J.Y., et al. "Headaches Associated with Personal Protective Equipment – a Cross-Sectional Study among Frontline Healthcare Workers during COVID-19." Headache: The Journal of Head and Face Pain, vol. 60, no. 5, 2020, pp. 864–877., https://doi.org/10.1111/head.13811.

[10] Sickbert-Bennett EE, Samet JM, Clapp PW, Chen H, Berntsen J, Zeman KL, Tong H, Weber DJ, Bennett WD. Filtration Efficiency of Hospital Face Mask Alternatives Available for Use During the COVID-19 Pandemic. JAMA Intern Med. 2020 Dec 1;180(12):1607-1612.

[11] Rutala WA, Jones SM, Worthington JM, Reist PC, Weber DJ. Efficacy of portable filtration units in reducing aerosolized particles in the size range of Mycobacterium tuberculosis. Infect Control Hosp Epidemiol. 1995 Jul;16(7):391-8.

[12] Weber DJ, Babcock H, Hayden MK, Wright SB, Murthy AR, Guzman-Cottrill J, Haessler S, Rock C, Van Schooneveld T, Forde CA, Logan LK, Malani A, Henderson DK; SHEA Board of Trustees. Universal pandemic precautions-An idea ripe for the times. Infect Control Hosp Epidemiol. 2020 Nov;41(11):1321-1322

survival of the pathogen in the air (dependent on the pathogen, temperature, humidity, size/settling, nature of the pathogen, UV/sunlight susceptibility), distribution (dependent on dispersal in the air), and host susceptibility/infectivity. All these factors are taken into account in the CDC/HICPAC Isolation Guidelines[13] that provide guidance on the type and duration of isolation of patients in healthcare settings who have a confirmed or suspected communicable disease. Although, pathogens acquired via inhalation are transmitted via aerosols, the distance between source and infected contact varies (for example, TB and varicella may be transmitted over very long distances; meningococcus and *B. pertussis* are transmitted over very short distances; and, SARS-CoV-2 is generally transmitted over intermediate distances[14].

Conclusion

As we transition from the pandemic to endemic phase of the COVID-19 outbreak, working collaboratively to protect HCP and the patients they care for from infectious harms is paramount. In order to achieve the mutual goals of the stakeholder community, OSHA must ensure that a permanent COVID-19 standard is clearly defined, enforceable, and based on sound scientific evidence from peer-reviewed medical literature sources. Relying on existing guidance like the "hierarchy of controls" will help healthcare facilities employ known and reasonable options for achieving compliance and preventing transmission. SHEA looks forward to future opportunities to partner with OSHA and other interested parties in achieving the best standards for HCP safety.

[13] "Isolation Precautions." Centers for Disease Control and Prevention, 22 July 2019, https://www.cdc.gov/infectioncontrol/guidelines/isolation/index.html.

[14] "Isolation Precautions." Centers for Disease Control and Prevention, 22 July 2019, https://www.cdc.gov/infectioncontrol/guidelines/isolation/index.html.