Trinity Health

April 19, 2022

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

Re: OSHA-2020-0004; Occupational Exposure to COVID-19 ETS

Submitted electronically via http://www.regulations.gov

Dear Assistant Secretary Parker-

Trinity Health appreciates the opportunity to comment on policies set forth in OSHA-2020-0004. Our comments and recommendations reflect a strong interest in public policies that support better health, better care and lower costs to ensure affordable, high quality, and people-centered care for all.

Trinity Health is one of the largest not-for-profit, Catholic health care systems in the nation. It is a family of 115,000 colleagues and nearly 26,000 physicians and clinicians caring for diverse communities across 25 states. Nationally recognized for care and experience, the Trinity Health system includes 88 hospitals, 131 continuing care locations, the second largest PACE program in the country, 125 urgent care locations and many other health and well-being services. Based in Livonia, Michigan, its annual operating revenue is $20.2 billion with $1.2 billion returned to its communities in the form of charity care and other community benefit programs.

Trinity Health has 17 Clinically Integrated Networks (CINs) that are accountable for approximately 1.5 million lives across the country through alternative payment models. Our health care system participates in 14 markets with Medicare Shared Savings Program (MSSP) Accountable Care Organizations (ACOs), which includes eleven markets partnering in one national MSSP Enhanced Track ACO, Trinity Health Integrated Care. Two of the 14 markets also participate in CPC+. In addition, we have 33 hospitals participating in the Bundled Payments for Care Improvement Advanced (BPCIA) initiative, and three hospitals in the Comprehensive Care for Joint Replacement (CJR) program. Our work—and experience in value-based contracting—also extends beyond Medicare as illustrated by our participation in 123 non-CMS APM contracts.

General Comment on the OSHA ETS

Trinity Health is opposed to the establishment of new regulations that are not aligned with the Centers for Disease Control and Prevention's (CDC) evidence-based guidance. CDC guidance and recommendations have long been the national standard for safe operations during public health crises and have been utilized by health care providers since the beginning of the COVID-19 public health emergency (PHE). Hospitals and health care systems are already held to those standards by Centers for Medicare & Medicaid Services (CMS)

regulators. Notably, all healthcare facilities that provide services to beneficiaries of Medicare and Medicaid are required to assure their healthcare personnel have received primary prevention against COVID-19 by being vaccinated against this infection. This was an element of OSHA's ETS on Vaccination issued last November that is no longer needed given this CMS requirement. One of Trinity Health's core values is safety and as such, we were one of the first large national health systems to implement a COVID-19 vaccination requirement. While Trinity Health supports vaccinations to keep our employees safe, we do not believe OSHA should be the governing body for these requirements.

Creating new standards, separate and distinct from CDC's, will only serve to sow doubt and confusion about the guidance provided by CDC, something that would be particularly dangerous as hospitals continue to struggle with the stresses of the ongoing PHE. It is essential to a well-functioning health care system that only one set of science-based requirements be applied to health care providers, and that these standards be aligned across federal agencies.

Below are Trinity Health's responses to targeted questions.

A. Potential Changes from the ETS – policies that may departs from provisions in ETS

A.1 - Alignment with CDC Recommendations for Healthcare Infection Control Practices

We agree that HCP and hospital leaders have struggled with implementing strategies and tactics to prevent transmission in healthcare facilities given the unpredictable nature of variants of this virus as well as frequent changes to recommendations from CDC, CMS, and OSHA. As stated, understanding and adherence with infection prevention and control (IPC) recommendations from a single federal agency is ideal. While OSHA's ETS for Healthcare did incorporate by reference several CDC recommendations on preventing COVID-19 as well as their existing CDC/HICPAC *Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings (2007)*, the ETS fixed on a point in time that was not able to reflect more contemporary updates to CDC recommendations – especially critical and needed during the recent surge of Omicron variant. Healthcare facilities and its HCP leaders need flexibility in responding to the course of this pandemic. Therefore, we recommend OSHA, should it issue a proposed rule, word incorporated references that permits flexibility and alignment with CDC as the CDC releases updates. Healthcare facilities can document and refer to prior versions of recommendations that might have been in place should a specific situation or concern arise in which OSHA is notified that preceded the updates.

A.2 - Additional Flexibility for Employers

Trinity Health supports a "safe harbor" enforcement policy for employers who are in compliance with CDC guidance applicable during the period at issue, as this will provide important flexibility. The ETS as published in June 2021 was very specific and detailed in requirements of employers that limited the flexibility needed to respond to surges. During the Delta and Omicron surges in particular from October 2021 – February 2022, many of our member hospitals encountered significant challenges in navigating through the conflicts between the ETS and CDC updates and limitations imposed by ETS such as returning essential personnel to work following close contact exposure. As states in our comments in A.1, flexibility is essential should OSHA finalize the ETS, and OSHA must walk the delicate balance between clear requirements that also provide flexibility.

A.3 - Removal of Scope Exemptions (e.g., ambulatory care facilities where COVID-19 patients are screened out; home healthcare):

As we mention earlier, this virus is one that can be widespread in the community and even perfect adherence with PPE by HCP during patient care may not prevent exposure once personnel leave work and return to their household or other public spaces in the community. Therefore, the application of significant risk rather than grave danger is appropriate as OSHA standards do not apply to persons outside of workplace settings and with effective vaccines risk of severe disease, hospitalization and mortality from COVID-19 is considerably less. Our nationwide integrated delivery network includes a large number of primary care services and the work practices to prevent exposure of HCP in all settings is clearer and more straightforward. The layered strategies of administrative and engineering controls and use of PPE therefore is applicable and appropriate to all healthcare settings.

A.4 - Tailoring Controls to Address Interactions with People with Suspected or Confirmed COVID-19:

CDC's current IPC recommendations do offer the option for HCP to remove facemasks in well-defined areas (WDAs) where neither patients nor the general public are anticipated to be present. This option has been generally well received by our system's HCP and we would support this option. As indicated by OSHA, we recommend the wording of this avoid overly prescriptive requirements and permit the employer to define and document operational aspects of use of WDAs. For these spaces we support the concept of including an ''outbreak provision'' to ensure that healthcare employers would still have a duty to address an outbreak quickly if one occurs among staff in the areas normally subject to fewer requirements. However, Trinity Health urges OSHA not to establish its own definition of "outbreak". Rather, OSHA should reference existing CDC definitions of cluster/outbreaks and let hospitals make this determination.

A.5 – Vaccination

A.5.1 - Booster Doses

OSHA is considering how the Advisory Committee on Immunization Practices (ACIP) and CDC recommendations might impact the requirements in the ETS that take account of individuals' vaccination status (e.g., fully vaccinated, up to date) and seeks comment on this issue. Trinity Health established a vaccination requirement for all our HCP that was implemented in July 2021. Our policy is to require HCP be fully vaccinated and strongly encourage booster(s) as recommended by CDC's ACIP and consistent with FDA approvals. As indicated, healthcare facilities already must comply with CMS vaccination requirements, and it is likely there would be confusion and potential for conflicts if OSHA promulgated additional vaccination requirements. Under its vaccination requirement regulation, CMS can address booster doses for HCP and make any future updates based on ACIP and FDA actions. Therefore, we do not support any inclusion of vaccination requirements in a new standard on COVID—19 issued by OSHA.

However, should OSHA decide to address the COVID-19 vaccines, we recommend they follow the precedent established under its Bloodborne Pathogens (BBP) Standard and limit any reference to vaccination that it be offered by employers to its HCP at no cost to employees. Note, Trinity Health's vaccination requirement does include a process for colleagues to request an exemption for medical or religious reasons and this would fulfill the declination option that is part of the BBP Standard.

A.5.2 - Employer Support of Employee Vaccination

The Healthcare ETS included a provision requiring employers to educate employees on vaccines and provide reasonable time and paid leave for vaccination. OSHA is considering adjusting this requirement to include paid time up to 4 hours, including travel time, for employees to receive a vaccine and paid sick leave to recover from side effects and seeks comment on the approach.

While we support flexibility from employers for the workforce, we do not think OSHA should dictate how employers provide benefits. These decisions should be left to employers and should not be included in OSHA regulation.

A.5.3 - Requirements for Vaccinated Workers

Stakeholders raised questions about whether the Healthcare ETS requirements should be relaxed/eliminated based on vaccination status. OSHA is considering that requirements be relaxed for certain circumstances.

The experience with the Omicron variant has found that even persons who are up to date with vaccination can be infected following exposure. Further, distinction of precautions based on vaccination status are problematic from an operations perspective for employers. Instead, we support adjusting precautions based on community transmission rates as is currently recommended by CDC. While current CDC recommendations do offer some different strategies based on vaccination status, the ongoing change in how many and optimal timing for boosters precludes detailed specifications for this in a new federal OSHA standard.

As stated earlier, Trinity Health strongly urges OSHA rely on CMS and CDC vaccine recommendations and requirements for HCP. However, should OSHA seek to include COVID-19 vaccination requirements in the ETS, Trinity Health recommends language be patterned after the existing OSHA BBP standard (i.e. employers are required to offer vaccine and employees are permitted to submit documentation requesting an exemption).

In addition, Trinity Health has identified challenges with the physical barrier requirements. These barriers alter the dynamic flow of air and clearance of contaminants provided by a facility's heating, ventilation, and air conditioning (HVAC) system. Therefore, overuse may actually interfere with appropriate ventilation and be an un-intended, negative consequence of over-reliance on this type of engineering control. Flexibility and local facility expertise on determining where and how many barriers to place is best and we continue to recommend avoiding detailed requirements for this element of prevention.

<u>A.6 - Limited Coverage of Construction Activities in Healthcare Settings</u>

Trinity Health does not believe a standard on this business sector is necessary. OSHA should continue to exclude this business sector and its personnel from requirements as almost all facilities are required to conduct an infection control risk assessment and risk mitigation requirements for construction and renovation in healthcare facilities. These typically specify work practices to which contractors and sub-contractors are held and are already therefore addressed. Further, construction personnel are included in CMS vaccination requirement.

A.7 - Recordkeeping and Reporting: New Cap for COVID-19 Log Retention Period

OSHA already has an injury and illness record keeping standard that focuses in part on reporting severe events, including hospitalizations and fatalities. The current requirements for reporting COVID-19 hospitalizations and fatalities regardless of when the work-related exposure occurred place undue additional reporting and tracking burdens on employers. We do not need a separate COVID-19 requirement; this requirement can be captured in the same way that a sharps injury log is captured in accordance with existing OSHA standards. Trinity Health urges OSHA to rely on existing reporting mechanisms rather than requiring additional reporting.

A.8 - Triggering Requirements Based on the Level of Community Transmission:

OSHA is considering linking regulatory requirements to measures of local risk, such as CDC's community transmission, and seeks comment in this approach. Trinity Health urges OSHA to refer to CDC guidance rather than define what levels in a community trigger CDC's certain infection prevention and control recommendations to ensure total alignment with CDC. CDC requirements offer flexibility for healthcare facilities and its HCP to adjust to and adapt to COVID-19. This flexibility does not compromise protection of personnel nor patients but instead adjusts to the local epidemiology which is tracked by state public health agencies as well as the CDC.

A.9 - Evolution of SARS-CoV-2 into a Second Novel Strain:

OSHA is considering specifying that this final standard would apply not only to COVID-19, but also to subsequent related strains of the virus that are transmitted through aerosols and pose similar risks and health effects and seeks comment on this approach and alternatives to addressing the potential for new strains related to SARS-CoV-2. Trinity Health agrees continued emergence of variants is likely; however, the nature, transmissibility, morbidity and mortality will be unpredictable and therefore we do not support a federal standard to anticipate emergence of these variants. Such as standard may or may not be effective and instead we and other health systems should continue to rely on CDC for recommendations to address such future public health emergencies. There are existing CMS requirements (appendix Z) as well as standards from accreditation agencies like The Joint Commission that require continual focus on emergency preparedness and response and these will naturally incorporate lessons and learnings from this pandemic to better address the future. Others have recently provided recommendations to assure healthcare systems and their personnel are prepared to respond to newly emergent infectious diseases. We recommend OSHA review these as well as others from organizations like the National Academy of Sciences and the Association for Professionals in Infection Control and Epidemiology[1].

B. Additional Information/Data Requested

OSHA requests new studies or data related to the Delta and Omicron variants since the close of the initial comment period in August 2021. Trinity Health urges OSHA not to place new reporting requirements on providers and instead rely on data that is already reporting in the OSHA 300 log, Bureau of Labor and Statistics workplace injury reporting requirements, and annual Injury Tracking Application requirements.

[1] Between Rock and Hard Place: Recommendations for Balancing Patient Safety and Pandemic Response https://apic.org/wp-content/uploads/2022/03/PandemicResponse_WhiteP-FINAL.pdf

Should OSHA choose to use other data, there have been a considerable number of investigations of occupational risk of exposure and transmission of SARS-CoV-2 to HCP throughout this pandemic. The majority of these investigations find that a high proportion of exposure incidents involving HCP were traced to exposures outside of work. Even while at work there is one illustrative study by Fawcett SE, and colleagues, that tested HCP following unprotected exposure to patients with acute SARS-CoV-2 who also required an aerosol generating procedure (AGP).[2] Only 1/160 HCP (0.6%) was infected and the single HCP infected wore neither a respirator nor eye protection because the patient had an undiagnosed infection. The source patient's AGP was high-flow oxygenation and the HCP cared for this patient over 2 consecutive shifts. In addition, the Infection Disease Society of America conducted a comparative analysis of the efficacy of respiratory protection worn by HCP that indicates marginal difference between a well-fitting facemask and a respirator[3].

C. Information for Economic Analysis

C.1.1 – Covered Industries C.1.1A/B

OSHA states the Healthcare ETS did not determine how many non-hospital ambulatory care providers will screen patients for COVID-19 infections and symptoms, and therefore might be fully exempt from the standard**.** While OSHA included in the Healthcare ETS Industry Profile several NAICS outside of healthcare where embedded clinics are prevalent, such as schools, OSHA did not include a number of industries that may have settings with embedded clinics (e.g., embedded clinics in manufacturing facilities) in the industry profile. To address this, OSHA is considering including these industries in the final rule.

Trinity Health recommends OSHA treats all clinics as acute care providers and reiterates that consistency leads to better compliance overall and makes it easier for hospitals to provide guidance to HCPs.

C.1.2 Telework Employees

In the ETS OSHA accounted for reduced employee exposure due to telework but did not explicitly account for telework in the number of employees affected by the final rule in the Industry Profile, resulting in an overestimate of several employee-based costs, like the costs of respirators and personal protective equipment.

Trinity Health agrees telework employees should not be counted and support OSHA adjusting the ETS to ensure this population of the workforce is not being included in cost estimates for PPE and other costs.

C.2 Costs

C.2.1 - One-time costs

OSHA requests comments on the extent to which employers and other entities will bear ongoing costs (e.g., ongoing costs associated with training, PPE, respirators and the respiratory protection program, medical

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[2] transmission risk of severe acute respiratory coronavirus virus 2 (SARS-CoV-2) to healthcare personnel following unanticipated exposure to aerosol-generating procedures: Experience from epidemiologic investigations at an academic medical center https://pubmed.ncbi.nlm.nih.gov/34725006/

[3] Infectious Diseases Society of America Guidelines on Infection Prevention for Healthcare Personnel Caring for Patients with Suspected or Known COVID-19 https://www.idsociety.org/practice-guideline/covid-19-guideline-infection-prevention/

removal protection, COVID-19 plan monitoring and modification, and ventilation maintenance) under a final rule.

Trinity Health, like many providers, are experiencing ongoing and significant costs tied to respiratory protection due to additional fit testing requirements for employees that, absent COVID-19, would not have needed to wear respirators because their job duties would not have exposed them to an aerosol such as COVID-19.

Given the additional demand on our labor resources to accommodate thousands of additional fit tests, Trinity Health is evaluating external vendors to provide the medical evaluation and fit testing services in some of our markets. This is expected to cost us conservatively $3,000 per 2-day visit;[4] even with an organization as large as Trinity Health, vendors require a minimum number of days on-site. In addition, overall supply costs have increased compared to pre-pandemic levels do not show any sign of decreasing. On a per case basis, supply costs have increased 16%, including: Drugs 24%, Implants 6%, Other supplies 17%.

Similarly, COVID-related supply chain inconsistency and higher than average employee turnover have increased fit-testing demands in the last two years.

C.2.2B

OSHA will likely update its estimates to reflect the current baseline of vaccinated employees and will likely rely on the most recent CDC COVID-19 data tracker, as it did for the Healthcare ETS and the Vaccination and Testing ETS and may also rely on estimates or data from CMS or other credible sources, to update its estimates.

Trinity Health reiterates OSHA should rely on CDC data and align with CDC when possible.

C.2.3 – Ancillary Costs:

C.2.3B

OSHA is considering updating how it estimates side effects associated with vaccine doses using CDC estimates

Trinity Health supports aligning with CDC estimates and not requiring additional reporting from providers (see earlier responses).

C.3 Benefits Data Sources:

OSHA seeks information and data on cases, illnesses, hospitalizations, and fatalities that are specific to employees that would be subject to the final rule (i.e., those in the healthcare field). OSHA is also considering using all sources of data on which it relied in the Healthcare ETS and the Vaccination and Testing ETS, as well some new data sources it did not previously rely on.

OSHA should rely on OSHA data that is already required for providers to report and should pull from this and existing CDC data. Trinity Health strongly opposes OSHA placing new reporting requirements on providers as

[4] Note, estimated are based on information provided by vendors during an RFP process.

they are unnecessary and the data OSHA seeks for work-related incidents is already captured via the resources identified in Section B above.

Conclusion

Thank you for your commitment to health care worker safety. If you have any questions, please feel free to contact me at jennifer.nading@trinity-health.org or 202-909-0390.

Sincerely,

/s/

Jennifer Nading
Director, Medicare and Medicaid Policy and Regulatory Affairs
Trinity Health