August 4, 2010

U.S. Department of Labor
Occupational Safety and Health Administration (OSHA)
29 CFR Part 1910
Docket No. OSHA-2010-0003
RIN No. 1218-AC46

Re: OSHA Request for Information on Infectious Agents in Healthcare Settings

On behalf of Trust for America's Health (TFAH), a nonprofit nonpartisan public health advocacy organization, I am pleased to offer these comments on OSHA's request for information regarding occupational exposure to infectious agents in healthcare settings.

TFAH believes that the federal government should do what is necessary to protect the public from needless transmission of infectious diseases (IDs). Healthcare personnel (HCP) are at particular risk for transmission, as both potential victims and vectors of disease. In the event that OSHA proceeds with a rulemaking process, we respectfully request that it considers the public health implications writ large of its regulations.

The following comments address several questions contained within the request for information (RFI), and will also provide general views on the overall need for a rulemaking.

II.A.7 - Need for Rulemaking

TFAH urges OSHA to proceed with a rulemaking, with some parameters, for several reasons. First, previous OSHA rulemaking related to infection has been successful in changing behaviors of employers and employees. OSHA's promulgation of bloodborne pathogen regulations, which required the Hepatitis B vaccine to be offered free of charge to certain HCPs with an informed refusal, resulted in a significant increase in the number of workers accepting the Hepatitis B vaccine.[1] Yet, there are significant risks posed to personnel from airborne, droplet, and contact transmissible diseases, due to higher rates of infectious illness among patients. This is especially the case during a pandemic, since, healthcare workers are considered at particular risk for exposure to infectious disease. [2]

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[1]Deobbeling et al, "The Impact of OSHA's Bloodborne Pathogens Rule on Institutional Hepatitis B Vaccination Rate." *AHSR FHSR Annu Meet Abstr Book.* 1996; 13: 127-8. Available from: http://gateway.nlm.nih.gov/MeetingAbstracts/ma?f=102222303.html

[2] Kosk-Bienko, Joanna, EU-OSHA's Risk Observatory, "OSH risks related to global epidemics and drug-resistant micro-organisms," Presented to EU-OSHA Seminar, *Occupational risks from biological agents: Facing up the challenges,* June 5, 2007. Available from: http://osha.europa.eu/en/seminars/occupational-risks-from-biological-agents-facing-up-the-challenges/speech-venues/speeches/osh-risks-related-to-global-epidemics-and-drug-resistant-micro-organisms

OSHA's participation in the prevention of infections could lead to a culture change within healthcare settings around infectious disease prevention. Before the development of the bloodborne pathogen standard, there was a pervasive fear of HIV/hepatitis among healthcare personnel. Given that these health conditions can be fatal with specific risks to healthcare workers, there was a demand for regulation. Currently, few patients or providers would expect to see a provider drawing blood without wearing gloves.

Such a culture shift is necessary for airborne/droplet infectious diseases. For example, 36,000 individuals die every year from seasonal influenza and 226,000 are hospitalized, yet healthcare personnel often do not think they are at risk for infection.[3] An urgent change in culture and practice is needed in healthcare settings so that employers and providers better understand and respond to the threat of safety from airborne, contact, and droplet pathogens.

While we acknowledge the role that other regulatory bodies have in regulating infectious disease prevention practices in healthcare settings, these agencies do not specifically have a focus on the protection of employees. Oversight of infectious disease programs already occurs within the contexts of accreditation or reimbursement, such as through the Centers for Medicare & Medicaid Services (CMS) or The Joint Commission. Both of these activities are patient-centered approaches to quality assurance. Furthermore, existing oversight has not done enough to encourage best practices in occupational prevention of communicable disease.

Despite the presence of CMS or other oversight, some infection control practices continue to lag. For example, even with well-over 20 years of Healthcare Infection Control Practices Advisory Committee (HICPAC) and the Advisory Committee on Immunization Practices (ACIP) recommendations regarding vaccine coverage for HCPs, the latest numbers indicate that vaccination of HCPs against influenza has only recently surpassed 50 percent.[4] Clearly, a more rigorous regulation is needed to compel healthcare facilities to protect their employees.

Finally, OSHA should move forward with regulations because the healthcare industry is not confined to facilities regulated by CMS or The Joint Commission. As OSHA points out in the RFI, healthcare is increasingly being provided in non-hospital settings. Unfortunately, many individual clinician offices are not inspected by CMS or other regulatory bodies until there is a complaint. As a growing number of practitioners and some outpatient facilities do not accept Medicare[5] or Medicaid[6] reimbursement, there may soon be more facilities without other federal or national organizations overseeing the infection-control practices of these settings.

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[3] "I don't need it" is considered among the most common reasons healthcare personnel do not get the seasonal influenza vaccine. See Knox, R. "N.Y. Mandates Flu Shots for Health Care Workers," NPR, October 14, 2009. Available from: http://www.npr.org/templates/story/story.php?storyId=113776378

[4] CDC, *Interim Results: Influenza A (H1N1) 2009 Monovalent and Seasonal Influenza Vaccination Coverage Among Health-Care Personnel --- United States, August 2009--January 2010*, April 2, 2010 / 59(12);357-362 Available from: http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5912a1.htm

[5] Connelly, Julie, "Doctors Are Opting Out of Medicare." New York Times, April 1, 2009. Available from: http://www.nytimes.com/2009/04/02/business/retirementspecial/02health.html

Parameters of Rulemaking – Public Health Standards

If OSHA proceeds with these regulations, it is important that they are written in coordination with the Centers for Disease Control and Prevention (CDC) and the AdACIP to ensure the policies do not conflict with existing or future public health guidance. TFAH believes that CDC, ACIP, and CDC/HICPAC should continue to be the public health lead in all infection prevention and control guidance, and OSHA's rules should make clear that public health and scientific experts have a leading role in this effort. CDC and ACIP have the requisite expertise, science base, and access to ID experts to develop guidance that best reflects a worker and patient protection mission. OSHA must, therefore, consider what its role would be as an enforcement body and how its enforcement activities would interact, but not interfere, with ongoing oversight by CMS and other organizations.

Furthermore, given the length of time of an average OSHA rulemaking and the evolution of the science behind infection control, it is important that flexibility be specified in the regulations to allow for future revisions to HICPAC guidance, emerging infectious disease, or scientific breakthrough. We suggest language that requires employers to have an occupational health program that adheres to current CDC/ACIP guidelines, rather than pointing to a specific HICPAC guideline that might be revised numerous times during and following the rulemaking. As part of the rulemaking process, we ask that you include public health stakeholders in each stage.

Finally, any regulations should acknowledge the growing focus on healthcare-associated infection (HAI) prevention and should make every effort not to interfere with those efforts. As part of the *Patient Protection and Affordable Care Act*, there will be an increase in reporting on HAIs and tying reporting to payment policies. In addition, states have also submitted HAI plans to HHS to qualify for Preventive Health and Health Services Block Grant funds.[7] Many states also have mandates to require individual facilities to report HAI rates and other data.[8] OSHA should ensure that its regulations do not supersede state or federal law regarding HAI prevention.

Responses to Request for Data, Information, and Comments

The following comments address other specific questions posed by OSHA within the second section of the RFI.

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[6]Boukus et al, Center for Studying Health System Change. "A Snapshot of U.S. Physicians: Key Findings from the 2008 Health Tracking Study Physician Survey," Data Bulletin No. 35, September 2009. Available from: http://www.hschange.com/CONTENT/1078/?words=Medicaid+physicians#top

[7]HHS Office of Public Health and Science, "State Healthcare-Associated Infection Prevention Plans," Available from: http://www.hhs.gov/ophs/initiatives/hai/statelevel/state_level_act.html

[8]CDC, *First State-Specific Healthcare-Associated Infections Summary Data Report: CDC's National Healthcare Safety Network (NHSN),* January-June 2009. p. 10. Available from: http://www.cdc.gov/hai/pdfs/stateplans/SIR_05_25_2010.pdf

II.A.1 - If OSHA proceeds, it could consider following California's CAL/OSHA format that applied different standards for various types of facilities.[9] The technical capacity of a private practitioner versus a large hospital to develop and implement an infectious disease prevention strategy will vary widely.

II.A.3 – OSHA should not attempt to limit its rulemaking to only certain personnel under specific circumstances that put them at risk of exposure to infectious diseases. Unlike bloodborne pathogens, airborne and droplet infectious agents cannot be contained to one type of personnel or one department of a hospital or facility. Many infectious diseases can be contagious without the carrier showing symptoms, and therefore exposure risks exist throughout the healthcare system. We urge OSHA, if rulemaking proceeds, to examine the definition of healthcare personnel of other federal agencies, such as HHS,[10] CDC[11] or the Veterans Health Administration, which include contract employees, volunteers, and others who enter healthcare settings. Even laundry, cafeteria, and security personnel who do not do direct patient care are at risk for exposure by the nature of non-bloodborne infection transmission.

II.A.9 – While considering the impact of infectious agent exposure on state and local employees, we urge you to consider the protection of public health employees who respond to infectious disease outbreaks. State and local health departments are called upon to investigate, mitigate, and respond to infectious agents, distribute medical countermeasures, and vaccinate the public. If OSHA determines that a rulemaking is needed, employees of health departments, especially those with contact with the public, should be included in such standards.

II.B.10 and II.C.20 – The HICPAC guide mentioned in the RFI, "2007 Guideline for Isolation Precautions," is not the appropriate guideline for worker protection, at least in hospital settings. Most of this guidance is focused on what the healthcare professional can do to protect patients, not what the employer should doto protect the employee. HICPAC has a separate guideline, "Guideline for Infection Control in Hospital Personnel, 1998," which is scheduled to be updated, that applies to hospital workers.[12] CDC and ACIP also publish guidelines related to vaccination of HCP.[13] As has previously been noted, if OSHA promulgates a rule, any standard should comply with *current* CDC guidelines, rather than referring to a specific document or preempting an accepted public health standard.

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[9] California Occupational Safety & Health Standards Board (OSHSB), General Industry Safety Orders Chapter 4, Subchapter 7, Article 109, Section 5199 *Aerosol Transmissible Diseases--Division of Occupational Safety and Health Information Sheets*. Available from: http://www.dir.ca.gov/oshsb/ATD--InfoSheets.html

[10] HHS, Definition of Healthcare Personnel (HCP), March 2008. Available from: http://www.hhs.gov/ophs/programs/initiatives/vacctoolkit/definition.html

[11] CDC, "Interim Guidance on Infection Control Measures for 2009 H1N1 Influenza in Healthcare Settings, Including Protection of Healthcare Personnel," Updated July 15, 2010. Available from: http://www.cdc.gov/h1n1flu/guidelines_infection_control.htm#a

[12] Bolyard et al, CDC, *Guideline for Infection Control in Hospital Personnel, 1998*. Hospital Infection Control Practices Advisory Committee. Available from: http://www.cdc.gov/hicpac/pdf/InfectControl98.pdf

[13] Pearson, et al, CDC, *Influenza Vaccination of Healthcare Personnel*. MMWR February 24, 2006 / 55(RR02);1-16. Available from: http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5502a1.htm

II.B.11 – OSHA should consider who the infection control person would be in small, outpatient settings, such as small group or individual physician practices or geographically isolated communities.

II.C.16 – In many cases, the infection control practice that protects the patient will equally protect workers. For example, isolating contagious patients, hand washing, vaccination, and availability of personal protective equipment (PPE) all have dual benefits for patient and provider. OSHA should consider how the administrative burden on facilities can be reduced in situations where the activity is the same for HAI protection and occupational health.

II.C.17 – While often seen as a labor standard, paid sick leave is also a significant infection control mechanism. For instance, a recent University of Chicago survey found that 55 percent of workers without paid sick days reported going to work sick, whereas 37 percent of those eligible for paid sick leave have gone to work with a contagious disease.[14] Reports have also found that employers with paid sick policies often penalize employees who take sick time. The University of Chicago study found that 12 percent of employees reported that they or their family member had been penalized, fired, or suspended for taking time off for an illness.[15]

Hospitals and other health facilities are also affected by such punitive policies. These findings are particularly worrisome in healthcare settings, where workers and patients may be at higher risk for contracting and transmitting infectious diseases. In HICPAC's Guidelines for Infection Control in Healthcare Personnel, the guidance defines numerous circumstances where workers must be excluded from duty if they are exposed to job-related infectious agents.[16] Yet, many facilities withhold pay, or otherwise penalize workers, who take appropriate sick days.

If OSHA proceeds with rulemaking, it should also consider standards for fair paid sick day policies in healthcare settings that promote the worker protection goals of this *Request for Information*. OSHA should also use its enforcement and oversight capacity to ensure that existing sick leave policies are implemented fairly, without punishing workers who ethically use this important health benefit. To force employees, through intimidation or explicit punishment, to attend work while sick with a communicable disease, is a major public health concern.

II.C.22 – In developing PPE recommendations, it is critical that the public health standard be preeminent. During the H1N1 outbreak, workers were given variable guidance from OSHA, CDC, Department of Homeland Security and their own employers.[17] Although OSHA has jurisdiction over occupational health, it is vital to the public's health and safety that CDC remains the lead agency on all science- and public health-based decisions. Varying from

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[14] Smith, Tom W. and Jibum Kim, *Paid Sick Days: Attitudes and Experiences*, National Opinion Research Center at the University of Chicago for the Public Welfare Foundation, June 2010. Available from: http://www.publicwelfare.org/resources/DocFiles/psd2010final.pdf

[15] Smith and Kim, 2010.

[16] Bolyard, et al, 1998.

[17] See testimony from hearing of House Oversight & Government Reform Subcommittee on Federal Workforce, Postal Service, and the District of Columbia, May 14, 2009. Available from: http://oversight.house.gov/index.php?option=com_content&task=view&id=4132&Itemid=27

science-based guidance under certain circumstances will most likely lead to confusion and a breakdown in compliance.

Moreover, any rulemaking should not focus solely on respiratory protection. PPE is an important component of a comprehensive occupational health program. The science behind the best PPE is evolving and does not always garner consensus, and therefore cannot be the only worker protective measure required of employers. As discussed throughout this document, an immunization program, sick days, and education of workers are all necessary for a comprehensive infection control program for employers.

II.D.25 – Immunizations are an important aspect of any infection control program, which should also include access to personal protective equipment, hand washing, and comprehensive sick leave policies. As has been previously noted, rates for optional vaccines, such as influenza, are far lower than optimal. Of ACIP-recommended vaccines for healthcare personnel, seasonal influenza has proven to be the most problematic for employees to comply with, given that a new vaccine is required every year.

TFAH believes these low immunization rates pose a significant public health risk for the patient population, HCPs, and the general population. According to the CDC, a well-matched vaccine can reduce influenza by 70-90 percent,[18] and other studies have shown even a poorly matched vaccine has a 50 percent effectiveness.[19] By bypassing vaccines, HCPs place themselves, their families and their communities at risk for illness. It also threatens the continuity of operations and financial viability of healthcare facilities. This is a significant worker protection issue because, even if employees believe they are not at risk for influenza and do not get the vaccine, as many as half of those infected can be asymptomatic,[20] and, therefore, they can continue to infect other employees.

We strongly urge OSHA to include a similar standard for all ACIP-recommended vaccines for healthcare personnel as it did for hepatitis B vaccines. Healthcare facilities should make the seasonal influenza vaccine and all other ACIP-recommended vaccines available at no cost to all employees, volunteers, and contract workers every year. These vaccines should be required, unless personnel signs a written, informed refusal in conjunction with year-round and comprehensive vaccine and ID education and other prevention efforts.

All workers in healthcare settings should receive these vaccines. While some argue that only certain personnel have patient contact, a health facility is a closed setting, and infectious agents can be transmitted in the cafeteria, the laundry, or in hallways. Airborne illnesses in particular do not stop at the departmental level. Vaccine policies must do everything possible to protect

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[18] Fiore et al, "Prevention and Control of Influenza : Recommendations of the Advisory Committee on Immunization practices (ACIP), 2008." *MMWR Recomm Rep* 57:160, Aug. 8, 2008.

[19] Jefferson, T.O. et al, "Vaccines for Preventing Influenza in Healthy Adults," Cochrane Database Syst Rev 2:CD001269, April 18, 2007.

[20] Toner, E. "Do Public Health and Infection Control Measures Prevent the Spread of Flu?" *Biosecurity and Bioterrorism: Biodefense Strategy, Practice, and Science*. 2006, 4(1): 84-86. doi:10.1089/bsp.2006.4.84. Center for Biosecurity of the University of Pittsburgh Medical Center.

workers from infectious agents, regardless of whether the contagion comes from their patients, other employees or visitors.

Conclusion

Thank you for the opportunity to comment on OSHA's request for information and for the Agency's effort to protect the wellbeing of healthcare personnel. This is an important opportunity to advance the development of best practices for protection of healthcare personnel in a range of settings. We urge you maintaining a transparent process and to engage stakeholders throughout the proposed rulemaking process. Please feel free to contact Dara Alpert Lieberman at dlieberman@tfah.org if we can be of further assistance.

Sincerely,

Jeffrey Levi, PhD
Executive Director
Trust for America's Health