December 22, 2014

Dr. David Michaels
Assistant Secretary for Occupational Safety and Heath
U. S. Department of Labor
200 Constitution Avenue, NW
Washington, DC 20210

Dear Dr. Michaels:

The Small Business Advocacy Review Panel (Panel), established in accordance with the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA), is transmitting to you this report on the Occupational Safety and Health Administration's (OSHA's) draft regulatory framework for Occupational Exposure to Infectious Diseases in Healthcare and Other Related Work Settings.

The Panel consisted of representatives of OSHA, the Department of Labor's Office of the Solicitor (SOL), the Office of Information and Regulatory Affairs (OIRA) of the Office of Management and Budget, and the Office of Advocacy (Advocacy) within the U.S. Small Business Administration (SBA). The Panel was chaired by Robert Burt, director of the OSHA's Office of Regulatory Analysis - Safety. Staff from the Agencies and SOL who participated in development of the Panel's report include: Charles Maresca (Advocacy), Bruce Lundegren (Advocacy), Jonathan Porat (Advocacy), Cortney Higgins (OMB/OIRA), Andrew Levinson (OSHA Directorate of Standards and Guidance (DSG)), Val Schaeffer (DSG), Tom Nerad (DSG), Margy Lambert (DSG), Sharon Carr (DSG), Lauren Goodman (SOL), Lee Grabel (SOL), Anne Ryder (SOL), Jessica Stone (ORA), Charles McCormick (ORA), Bryan Lincoln (ORA), Robert Stone (ORA), and LaJuane Paige (OSHA/DSG/SBREFA Coordinator).

On October 14, 2014, the Panel was officially convened by OSHA. On November 12, 13, 14 and 20, 2014, the Panel members, along with the Small Entity Representatives (SERs), participated in four conference calls providing the opportunity for an open discussion regarding the draft regulatory framework. In addition to the conference calls, the SERs provided the Panel with their written comments.

The Panel Report is attached, which includes the Panel's major findings and recommendations. Also included as appendices to that report are a listing of participating SERs, the SERs' written comments, and the basic documents provided to the SERs (the SER Background document and the draft regulatory framework). SBREFA requires that this Panel Report and its attachments become part of the rulemaking record, which Mr. Burt will arrange by posting the report in the docket at http://www.regulations.gov, the Federal eRulemaking portal.

The Panel wishes again to thank the SERs for their participation in the early stages of the rulemaking process. The Panel particularly appreciates the time that the

SERs took from their busy schedules to read the considerable SBREFA materials sent to them and provide comments to the Panel.

Sincerely,

Robert E. Burt
Chairperson
Small Business Advocacy Review Panel
Occupational Safety and Health Administration
U.S. Department of Labor

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Report of the Small Business Advocacy Review Panel on a Possible OSHA Rule on Occupational Exposure to Infectious Diseases in Healthcare and Other Related Work Settings

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1. Introduction

This report has been developed by the Small Business Advocacy Review Panel (the Panel) for the Occupational Safety and Health Administration's (OSHA's) potential rule on Occupational Exposure to Infectious Diseases in Healthcare and Other Related Work Settings. The Panel included representatives of OSHA, the Office of the Solicitor of the Department of Labor, the Office of Advocacy within the U.S. Small Business Administration, and the Office of Information and Regulatory Affairs of the Office of Management and Budget. On October 8, 2014, the Panel Chairperson, Robert Burt of OSHA, convened the Panel under Section 609(b) of the Regulatory Flexibility Act (RFA) as amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA) (5 U.S.C. 601 *et seq.*). A list of the Panel members and staff representatives is included in Appendix A. The Panel chose small entity representatives (SERs) from potentially regulated industries where workers perform tasks that may expose them to infectious diseases. The SERs reviewed the regulatory framework for an Infectious Diseases rule and offered their advice and recommendations to the Panel. The Panel is deeply indebted to the SERs for taking the time to assist the Panel in examining this potential rule.

This report consists of four parts: Part 1 is this introduction; Part 2 provides reasons why action is being considered by the Agency; Part 3 summarizes the oral and written comments received from the SERs; and Part 4 presents the Panel's findings and recommendations. A list of the SERs is included in Appendix B of this report, and a complete copy of all of the written comments submitted by the SERs is included as Appendix C. In addition, the principal documents sent to the SERs are included as Appendix D to this document.

2. Reasons Why Action by the Agency is Being Considered

Infectious agents can cause occupationally-acquired infections in healthcare workers (HCWs) and workers involved in certain tasks ancillary to direct patient care. Some of these infections are very serious (e.g., Methicillin-resistant *Staphylococcus aureus* (MRSA) bacteremia, Norovirus Gastroenteritis) and some can be fatal (e.g., Tuberculosis, Bacterial Meningitis).

Infectious agents can also cause healthcare-associated infections (HAIs) in patients. HAIs are recognized as a serious and costly problem in the U.S. healthcare system. According to the Centers for Disease Control and Prevention (CDC), there are 1.7 million HAIs leading to approximately 99,000 patient deaths and $20 billion in additional healthcare costs in the U.S. system each year. OSHA currently lacks data on the exact

number of HCWs and other ancillary workers that contract infectious diseases at work because there are no centralized surveillance systems that specifically track all occupationally acquired infections; however, OSHA plans to develop and model this data to inform its rulemaking. Preventing the spread of infectious diseases in healthcare and related settings benefits both workers and patients. Patient safety and healthcare worker safety are inherently linked. Integration of patient and worker safety initiatives has been shown to improve both patient outcomes and worker protection.

Infectious agents pose a unique occupational hazard because, unlike chemical hazards: 1) each infectious agent replicates within infected workers (increasing risk to the infected individual); and 2) infected workers can transmit the agent to other individuals (increasing risk to others). Transmission of infectious agents from infected individuals to other individuals (e.g., workers, patients, and the public) has the potential to result in an ever-widening circle of infection that can lead to an infectious disease outbreak.

OSHA does not have a standard that addresses occupational exposure to infectious agents transmitted by contact, droplet and airborne routes. OSHA's Bloodborne Pathogens standard (29 CFR 1910.1030) covers occupational exposure to infectious agents transmitted by the bloodborne route. Precautions used for bloodborne pathogens (termed universal precautions) are not sufficient in some sectors to protect workers from infectious agents transmitted by the contact, droplet, and airborne routes. Protection of workers from exposure to agents transmitted by these other routes requires implementation of transmission-based precautions (i.e., contact, droplet and airborne precautions) in addition to universal precautions (universal precautions is also referred to as standard precautions in healthcare settings). The Agency is concerned about occupational exposure to infectious diseases not addressed by the Agency's Bloodborne Pathogens standard.

This concern is shared by stakeholders who support an OSHA standard that addresses occupational exposure to infectious diseases. In 2005, the American Federation of State, County & Municipal Employees (AFSCME) petitioned OSHA for a rule addressing pandemic influenza. And in 2009, AFSCME petitioned OSHA for a rule addressing occupational exposure to infectious diseases. More recently, the American Industrial Hygiene Association urged OSHA to quickly move forward with an Infectious Diseases rule. In addition, a December 2014 report issued by the Federal Experts Security Advisory Panel (FESAP) on laboratory biosafety and biosecurity in the U.S. recommended that the development and implementation of an OSHA Infectious Diseases standard be supported and made a high priority.

OSHA evaluated many peer-reviewed journal articles relating to occupational exposure to infectious agents. The evidence thus far examined shows that there is a sustained prevalence of work-related infectious diseases in healthcare, laboratory, and associated work settings, and that these infectious diseases are caused by agents that are transmissible to humans by different routes, including the contact, droplet and airborne routes. The peer-reviewed literature also suggests that HCWs and workers involved in certain tasks ancillary to direct patient care (e.g., laboratorians) are especially susceptible

to occupational exposures to emerging infectious diseases (e.g., SARS, Ebola virus disease) and that healthcare facilities and associated settings are not always prepared to rapidly develop and implement contingency plans that address these unexpected exposures.

OSHA maintains that because HCWs and workers involved in ancillary tasks are exposed to infectious diseases in a variety of settings, it is important for employers in all such settings to implement infection control practices. Good infection control practices are laid out in a number of non-mandatory guidelines (e.g., CDC/Healthcare Infection Control Practices Advisory Committee (HICPAC) guidelines) and are recognized and generally accepted by the industry. When these practices are consistently and rigorously followed, they have proven effective at preventing the spread of infections. OSHA believes that the evidence shows, however, that many employers do not consistently adopt or rigorously enforce these guidelines, leaving both workers and patients at risk of contracting infectious diseases. OSHA believes that a rule as outlined in the regulatory framework would reduce risk to workers who would be covered by the rule. In addition, the Agency believes that effective enforcement by OSHA would result in more consistent and rigorous adherence to recognized and generally accepted good infection control practices, which would, in turn, result in safer environments for both workers and patients.

3. Summary of SER Comments

The Panel hosted four conference calls for the SERs, on November 12, 13, 14 and 20, 2014, to obtain their input on OSHA's draft regulatory framework for an Infectious Disease rule. A number of SERs also submitted written comments to the Panel (See Appendix C). The following is a summary of the key issues raised during the course of the conference calls and in the written comments.

Need for a Rule and Alternatives, Risk, and Scope

Need for a Rule and Alternatives

Many SERs felt that this rule would overlap with and/or duplicate other relevant guidelines and regulations, including, for example, materials issued by the Centers for Medicare and Medicaid Services (CMS), the Joint Commission and other voluntary accrediting organizations, and state accrediting boards. One SER told the Panel that it was time consuming to coordinate between all of the various guidelines and requirements. Most SERs felt that they were already heavily regulated, and some were concerned that additional rules would not improve infection control or worker safety. One SER pointed out to the Panel that, while CDC infection control recommendations are not mandatory, other regulatory bodies, such as CMS's Clinical Laboratory Improvement Amendments (CLIA) and state agencies, do have mandatory requirements that rely on the CDC recommendations. Similarly, another SER said that if facilities are following CMS guidelines in order to receive Medicare funding, they are following CDC guidelines. One SER stated that "[w]hile the CDC guidelines are not literally regulations they function as

such in the healthcare workplace environment. . . . Additional oversight agencies such as The Joint Commission and DNV require adoption and implementation of CDC and other nationally recognized health agency guidelines." Two SERs representing funeral homes said in their written comments that their industry, "while not subject to third party accreditation, is subject to existing federal and state OSHA standards, as well as random inspections by state health departments, regarding minimal levels of sanitation and procedures designed to effectively protect the general public and funeral home employees." One SER was concerned with a potential conflict with the Patient Safety and Quality Improvement Act. He stated in his written comments that:

> many of the exposure reporting conditions in the framework also conflict with the "Patient Safety and Quality Improvement Act". Patient safety events are protected under that act from regulatory scrutiny if an organization is a partner with a federally certified Patient Safety Organization [(PSO)] and has an approved Patient Safety Evaluation System in place and is reporting patient safety events and incidents to the PSO.

One SER told the Panel that he believed that market forces will do a better job of reducing hospital-acquired infections than more regulations would. In his written comments, this SER elaborated, as follows:

> CMS and other payors are increasingly insisting on transparency of quality data, including data relating to infectious complications. Consumers are increasingly able to access such data and use it to decide where they will go to receive their health care. This is true in even small rural markets where individuals may choose to drive long distances to receive health care if they perceive a lack of quality or safety at their local hospital.
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> [V]arious financial and reputational factors . . . have led to considerable improvement in health care associated infections over the last few years and will continue to drive improvements in the foreseeable future. These are what may be termed market forces and tend to have much more influence on institutional behavior than mere regulatory or rule-based approaches.

Another SER told the Panel that CMS can reduce funding if a facility has a higher-than-average patient infection rate and said that a hospital cannot be successful keeping patient infection rates down if the hospital does not have a good infection control program in place. In his written comments, one SER explained that:

> CMS and other payors have instituted various financial incentives to motivate hospitals to improve care and avoid infectious complications. The CMS Value Based Purchasing initiative track hospitals' performance

> on [catheter-associated urinary tract infections (CAUTI)], [central line-associated bloodstream infections (CLABSIs)], Mortality, Core Measures, etc. Hospitals can lose up to 2% of their total CMS reimbursement for failure to improve and/or perform at very high compliance levels. The CMS Hospital Acquired Condition Program monitors [National Healthcare Safety Network (NHSN)] data on CAUTI, CLABSI and Surgical Site Infections (SSIs) for colon surgeries and hysterectomies. Next year they will add [MRSA] and [*C. difficile*]. Hospitals performing in the lowest quartile on these measures can lose an additional 1% of total CMS payments. A number of private insurers are refusing to pay for "never events" such as central line infections or surgical site infections.

A SER who represented a specialized ambulatory care practice told the Panel that, in her opinion, the interaction between the clinic practitioner and the patient can lead to the risk of passage of communicable diseases.

Many SERs reported that they are already doing all or most of what this rule would require and many reported being subject to regular inspections or audits as a condition of their accreditation. Because of this, some questioned the need for the standard. One SER stated that if the regulated community is already doing the things included in OSHA's regulatory framework, then a standard is unnecessary; another SER said in her written comments that, "given the adequacy of current precautions, the burden of compliance with a new standard, either alone or as [an] addendum/amendment to the existing standard, outweighs any potential benefit;" a third SER said in his written comments that "the framework appears to induce regulatory burden without significant change to employee risk or outcome;" while a fourth SER wrote that she had "little confidence that the suggested proposed rule would confer a noticeable benefit."

One SER also disagreed with OSHA's determination that accrediting surveys only look at infection control from a patient safety standpoint, explaining that every year the surveyors come out and look at infection control from the patient perspective, but they also look at what workers are doing. One SER said that OSHA's data on hand hygiene compliance are dated, and estimated that hand hygiene compliance rates are ninety percent in hospitals. This SER told the Panel that the Joint Commission is targeting hand hygiene and that vendors have helped to boost hand hygiene compliance.

Some SERs informed the Panel that, contrary to OSHA's analysis in the background document, employees do have a mechanism for filing complaints with other federal agencies and accrediting bodies, including CMS and the Joint Commission. In his written comments, one SER reported that his hospital is monitored by CMS, the Joint Commission, the state health department and a local Quality Improvement Organization and that laboratories are subject to regular College of American Pathologist inspections. This SER said that "all of these regulatory agencies have infection control and employee health standards" and that "each have provisions for anonymous complaints by patients, families or employees, and the agencies actively follow up on such complaints." This SER's facility also has "an internal compliance hotline available for anonymous

complaints by employees." One SER stated that most complaints were filed by disgruntled former employees.

Some SERs suggested non-regulatory approaches, including education and training resources for small entities, additional funding for CMS, a focus on compliance assistance rather than enforcement, and better leadership within facilities. In a written comment, one SER suggested OSHA use an approach similar to the one used by the SHARP program where "if a facility has problems, [they are] given ... the option of working with OSHA consultants to improve and if they choose not to, then [OSHA should] impose requirements as fitting to the problems."

One SER suggested that the nomenclature be harmonized between OSHA, the World Health Organization (WHO) and CDC and recommended OSHA develop tighter definitions that line up with WHO and CDC. In her written comments, this SER stated that:

> the term infectious diseases must be specifically defined using recognized standards such as those employe[d] by the WHO or CDC. The nomenclature utilized in the document is far too broad to allow for any reasonable compliance standard. For example, the common cold by definition would be an infectious disease.

A few SERs suggested that OSHA combine rules on infection control or expand the existing Bloodborne Pathogens rule (29 CFR 1910.1030) to cover additional routes of transmission, and one SER urged OSHA to work to make the rule less duplicative with other requirements. One SER disagreed, however, saying in her written comments that this approach "would only add the burden of training to the compliance of both the new language and its effect as amendment to existing language," and that "a standard codifying contact, droplet and airborne precautions may result in unwarranted absenteeism and decreases in workplace productivity."

One SER, who agreed that medical providers are heavily regulated, went on to say that prevention was still cheaper than lawsuits and that having reasonable precautions in place was important. Similarly, a very few SERs told the Panel that, in their opinion, the risk to workers from airborne, droplet, and contact transmissible diseases was different enough from the risk from bloodborne diseases that this standard was necessary. One SER told the Panel that this rulemaking is an important effort, and that OSHA and employers need to look at worker protection, but cautioned that OSHA and employers must balance staying in business and mitigating the risk. A SER representing an anesthesiology practice told the Panel that he thinks there should be more regulations, but he recommended that OSHA tailor a standard to specific types of worksites and job duties (a recommendation that was echoed by other SERs as well). This SER also recommended that a rule be reevaluated over time.

One SER asked OSHA to do a crosswalk with other applicable regulations.

SERs representing funeral homes said that it would be helpful if a rule compelled hospitals to inform them, when they receive a body, if the cause of death was an infectious disease or to give them a material hazard warning.

Multiple SERs recommended that, if OSHA completes a rulemaking, the Agency provide a strong support program for implementation, including non-punitive compliance visits and better tools for supporting implementation. One SER requested compliance guidance and stressed the importance of OSHA providing implementation assistance for this rule. One SER recommended that OSHA coordinate this effort with state and local agencies, and another said that public health departments should also be involved.

Risk

Many SERs asked OSHA to estimate the risks that would justify an Infectious Diseases rule. Some SERs said that OSHA had not shown that there is a significant risk, and a few SERs stated that there is not enough proof that infectious diseases are an issue that needs to be regulated. One SER asked OSHA to perform a risk assessment. One SER indicated that it would be useful to see new studies and more current statistical data on why a rule is needed. A SER mentioned that the risks are not well-recognized in small medical offices and that there was more uncertainty in those settings (as opposed to hospitals, which are more studied). One SER said that there are no data to show that employees are getting sick due to occupational exposure. In written comments one SER said that "there is insufficient data that the scope of the problem justifies an additional layer of government oversight and complexity," while another SER urged OSHA to "utilize results from government agency surveys that are already being done to determine if there is a problem" and "use OSHA log-type reports to determine the true extent of the infectious diseases before imposing another standard." This SER anticipated this rule would cost billions of dollars and offer no additional protection.

Some SERs stated that they believe there is no risk of infectious diseases being transmitted to workers in their industries. Those SERs represented the following types of industries: dentists' offices, the funeral industry, waste handling, and commercial laundries.

A SER representing a laundry facility, a SER representing a podiatrist's office, a SER representing a hospital, a SER representing a waste handling facility, and a SER representing a hospice provider said that they did not know of any workers in their facilities becoming ill from workplace exposures to infectious agents. In their joint written comments, two SERs representing funeral homes said that, in the 85 and 94 years their respective facilities have been in operation, neither "funeral home has ever had an employee contract an infectious disease from patient/employee contact." A SER representing a commercial laundry stated that the laundry had safety programs and meetings and OSHA collects data on reportable illnesses, but that the data are not robust enough to allow for study-like results on the levels of risk.

One SER stated that there is no risk of infectious disease transmission (including bloodborne transmitted diseases) to dental employees. A few SERs representing dental offices said that universal precautions for bloodborne pathogens combined with common sense and not examining patients who are sick is adequate to protect workers in the dental industry. Likewise, some SERs representing funeral homes felt that bloodborne pathogens precautions were adequate to protect against the risks faced by the death care industry and reported that they do not feel that this rule would offer any additional benefit or protection to funeral industry employees.

Some SERs in healthcare facilities stated that there had been disease outbreaks among patients, and a few mentioned cases of occupational exposure among their employees. One SER said that, in his observation, some employees in clinic settings were getting sick from work, but mainly with colds and the flu. This SER stated that workers in hospitals are clearly getting sick from workplace exposure. One SER told the Panel that some types of healthcare workers are at greater risk of exposure to infectious diseases than the general public, but that other types of healthcare workers are not. This SER speculated that it would be difficult to find enough data to determine the significance of risk since the populations are small and there is only anecdotal evidence. He reported that he has yet to see a case of an infectious disease transmitted to a healthcare worker, but believes that it does happen. This SER did know of a case of meningitis being transmitted to a worker in a laboratory.

Two SERs stated that there is no risk of airborne transmission in the funeral industry and reported that their facilities do not perform any procedures that would result in materials being aerosolized. In their joint written comments, these SERs said that the risk of airborne transmission "does not exist in a funeral home, either in the transferring of the deceased from the place of death or in the preparation of the deceased" and that that the regulatory framework "does not address the actual situation in a funeral home or any potential exposure to infectious disease by funeral home employees, whether in the transfer of the decedent from the place of death or in the preparation process." These SERs said that they believe OSHA:

> is under the misconception that an autopsy suite, in a hospital, and a preparation room, in a funeral home, create the same hazard to employees working in these locations. Nothing can be further from the truth. The autopsy process is invasive, using saws and other implements that are never used in funeral service, and employs procedures that can and will result in an [aerosolization] of infectious microorganisms. A funeral preparation, in a funeral home, both in the instruments used and the procedures that are followed, is not similarly invasive and does not produce aerosolization.

However, these SERs stated that it was standard practice in many funeral homes to mask decedents during pick-up. A SER from a hospital stated that she would assume that a dead body was capable of transmitting an airborne infectious disease. Another SER representing a different funeral home reported that she perceived a clear risk of exposure

to infectious diseases to workers who pick up decedents for transport to the funeral home, and said that workers are instructed to take precautions, like putting a mask or sheet over a decedent's face, in order to protect themselves from airborne infectious agents that could be expelled from the decedent's lungs.

SERs also expressed interest in seeing a cost-benefit analysis.

Scope

Many SERS saw a fundamental difference between employers who do not routinely see persons with infectious diseases (and normally reschedule infectious patients rather than seeing them) and those who by their nature must treat persons with infectious diseases (such as hospitals, emergency medical services, and nursing homes). The former have less frequent exposures to infectious diseases and may need fewer precautions, while the latter are more likely to be regulated and inspected by other agencies.

Multiple SERs suggested that if there is to be a rule at all, the rule should not exempt very small establishments. Those SERs felt that if a rule was determined to be necessary, it should apply to all employers, even those with fewer than 20 workers. One SER, however, in her written comments recommended "at a minimum… that small entities and small employers be exempted from any … potential standard."

One SER, a long-term care provider, stated that her facility only sees a few common diseases, like influenza or *Clostridium difficile* (*C. diff*), and that residents with any other type of illness are sent to the hospital for treatment, and suggested a "carve out" for facilities that only see or treat specific diseases. This SER suggested alternative or limited standard operating procedures (SOPs) for these types of facilities. Another SER said that portions of the rule seemed over-zealous for certain settings.

A number of SERs stated that workers other than healthcare workers have occupational exposure to infectious diseases. One SER indicated that flight attendants are at as great a risk as healthcare workers, and questioned why flight attendants were excluded from the scope of the regulatory framework. Another SER said that there is a risk to flight attendants, prison guards, and chiropractors and that they should be included in the scope of the rule, while another SER said there is a risk in homeless shelters, prisons, and drug treatment centers. One SER suggested that teachers are exposed to infectious illnesses but did not think that precautions other than hand hygiene and glove use are necessary in these settings. One SER felt the regulatory framework focused too much on clinical staff and that workers such as laundry and food service workers are also exposed to infectious diseases in the workplace.

One SER felt that ambulatory surgical centers should be outside of the scope of the rule because they do not treat patients with infectious diseases. Another SER agreed that specialty providers should not be included in the scope of the rule and suggested limiting the scope to hospitals and family practice or similar providers. Two SERs representing funeral homes felt that death care services should not be included in the rule. One SER

questioned whether certain medical offices, such as offices of chiropractors, opticians, acupuncturists and physical therapists, who do not treat patients for infectious diseases, should be included in the scope.

A SER representing a podiatrist's office said that universal precautions are used in his office and airborne precautions are not necessary in his setting. Another SER told the Panel that in small offices the relative risk is different, and that in his opinion, nothing beyond the precautions used to comply with the Bloodborne Pathogens standard (29 CFR 1910.1030) is needed. This SER said that small offices are more likely to encounter diseases like MRSA or influenza than to encounter tuberculosis (TB), severe acute respiratory syndrome (SARS), and Ebola.

One SER interpreted the regulatory framework as excluding emergency medical technicians (EMTs) and other first responders. Another SER responded that he understood the rule to include EMTs.

Scope Limitation – Possibility of a simplified rule where healthcare providers are able to reschedule sick patients

One SER stated that it is already practice at her facility to reschedule patients who are sick – for the patient's comfort as well as to protect the staff. If a patient has an emergency and treatment cannot be delayed, her staff would use universal precautions, perform extra cleaning, and disinfect the office.

Another SER, representing an audiology clinic (which does not treat patients for infectious diseases), objected to any exemption that would allow for patients who are seeking care to be turned away when they have an infectious disease. She reported that in her practice, a patient would have to have his or her overall health at a certain level for an accurate evaluation to be done but said that if there was ongoing chronic pathology, it would be different and she may have to treat the patient when he or she is at less than full health in those cases.

General Impacts of a Rule[1]

One SER said that the regulatory framework was "point on" as far as the way standards are written and understood, and another SER said that the materials read easily but found it hard to get through the logic of contact, droplet, and airborne precautions.

A SER who worked as an occupational medicine doctor said that, in his opinion, OSHA will have good support from occupational medicine doctors since they see that workers are exposed to infectious diseases. This SER pointed out to the Panel that California already has an aerosol transmissible disease rule that California medical providers are already following, and felt that OSHA's regulatory framework is not much different.

[1] Comments on the costs of specific provisions of the regulatory framework will be addressed in the next section.

One SER, representing a dental office, told the Panel that, in his interpretation, the only safe way to comply with a rule as described in the regulatory framework would be to stop seeing patients.

One SER asked OSHA to clarify which infectious diseases would be covered by a rule, and another SER asked OSHA to provide a clear, concise list – possibly in bullet points – of the requirements of such a rule.

SERs were largely in agreement that a provision requiring medical removal protection (MRP) would be costly and burdensome. One SER, representing a nursing home, said that his facility would not be able to implement MRP because the facility must maintain a minimum level of staffing in order to care for patients. Another SER said that MRP is too expensive and would result in some medical offices closing down because they cannot afford to provide MRP. Another SER referred to the burden of MRP as large and "potentially business-killing." SERs were particularly concerned about the potential economic impact of MRP on very small firms.

One SER anticipated that an MRP provision would require additional training on how to do medical surveillance, on different aspects regarding a worker's own health, and on when a worker would need to see a physician or other licensed health care professional (PLHCP) for possible work-related illness.

A number of SERs did not anticipate that it would cost much to incorporate a rule based on OSHA's regulatory framework into their regular practices. A number of SERs felt that there would be some initial administrative costs, including costs to become familiar with the rule and evaluate how to comply, and to conduct review and training, but some of these SERs told the Panel that once the implementation period had passed, they anticipated few additional costs in day-to-day operations. Some SERs reported to the Panel that they were not too concerned with the regulatory framework or felt that they could implement a rule easily. However, most of these SERs thought that expenses, though small, would add little to existing protections.

A SER representing a waste handling company said that, in his opinion, most firms in his industry would have to hire a consultant or spend a significant amount of time doing research, which could be fairly expensive. This SER reported mixed feelings about the regulatory framework. He anticipated that a rule would help improve practices in the waste handling industry as a whole, but he also expressed concern that it would cost his company money to comply. A few other SERs reported using consultants to help with their infection control programs.

A few SERs were concerned that the added complexity of a new rule and potential conflicts with recommendations from other bodies would make compliance with an Infectious Diseases rule difficult, divert resources from patient care, and increase the cost of healthcare when costs are passed through to payers. One SER told the Panel that new research is constantly coming out about better ways to do things and that CDC and WHO guidelines sometimes conflict, which causes medical providers to have to look at even

more research and recommendations in an effort to determine the best way to operate. This SER was concerned that as more agencies get involved, the more likely it is that the agencies will be out of sync with one another. Another SER reported having to continually look at competing guidelines and said that an OSHA rule would make things even more complex. She advocated for a standardized process for setting recommendations and requirements.

Many SERs felt that a rule based on the regulatory framework would create additional paperwork or "paper trails" that would be burdensome without necessarily improving compliance or safety. One SER was concerned that this would be a paperwork exercise that would sit on a shelf and not result in any real, day-to-day changes.

One SER was concerned with how employers could deal with workers who don't follow the rules. Another SER echoed that concern, asserting that a number of the SARS cases in healthcare workers were the result of workers failing to follow protocols.

A SER representing funeral homes said that, in his estimate, it would cost in excess of $50,000 to $75,000 immediately in order to bring his facilities up to compliance with an infectious diseases standard. In his interpretation, the rule would require funeral homes to have ventilation systems and everything else related to clean rooms, operating room, and hospital room environments.

A number of SERs reported that the vaccination requirements in the regulatory framework would result in compliance costs for their facilities, and many told the Panel that OSHA had underestimated the costs of vaccines.

Multiple SERs reported that OSHA underestimated costs for personal protective equipment (PPE) and underestimated the amount of PPE that would need to be used to comply with an infectious diseases standard.

Some SERs asked OSHA to clarify whether this rule would change the way infectious waste or healthcare laundry are handled or the way instruments are sterilized. A SER representing a funeral home said that waste would need to be segregated for infectious decedents and that this would be difficult given the small size of the room where remains are handled.

A few SERs were concerned with the potential requirement in the regulatory framework for employers to retain medical records for thirty years. These SERs felt that thirty years was excessive and that it would be difficult and costly to retain records for that length of time. One SER said in his written comments that the requirement that "records be maintained for 30 years does not make sense medically and would place an undue burden and expense on employers."

A SER representing a home healthcare provider urged OSHA to consider the uniqueness of the home healthcare industry and the difficulties involved in working in an environment where the employer lacks control. Those working in emergency medicine

expressed similar concerns with one such SER saying, in his written comments, that "the regulatory framework would require essentially a maximum contact precaution PPE for every call" to which EMT workers responded.

Provisions of the Regulatory Framework

During the conference calls, the Panel asked the SERs a series of questions about the potential requirements in the regulatory framework. Below is a summary of their responses, both during the conference calls and in any subsequent written comments.

Written Worker Infection Control Plan (WICP) and Standard Operating Procedures (SOPs)

Many SERs reported having a WICP available online for workers to review. In some cases, the employer requires that workers review the written policies. Some SERs were concerned that they would have to rewrite plans that are already in place.

Multiple SERs felt that OSHA had underestimated the time necessary to prepare these documents. One SER reported that forty hours, which OSHA had estimated was the time a hospital would need to prepare a WICP, was reasonable, but that an additional forty hours would be necessary to prepare the written SOPs. Another SER stated that forty hours to develop the WICP is a low estimate. This SER reported that it probably takes his facility eighty hours to develop a WICP and SOPs, and thirty-two hours a year to do an annual updates. This SER told the Panel that in his facility, updates undergo a review process, which involves taking additional time to relay draft updates to the front-line staff, which also takes time. A third SER suggested that it would likely take twice as long as the Agency had estimated for employers to develop the WICP and SOPs initially, but noted that the time ultimately spent on developing and updating WICPs and SOPs would depend on the amount of OSHA compliance support offered to small entities. Multiple SERs representing long-term care facilities asserted that the development and updating of SOPs would be burdensome. For example, one such SER stated in written comments that:

> for small employers in the long term care industry, the development and ongoing updating of SOP's will be extremely burdensome. Most small employers do not have in-house resources readily available to continually track CDC or other guidance from the public health community. OSHA's use of a process safety management ("PSM") approach to this rule will place a heavy burden on small employers. Aside from the burden associated with this, small employers will have difficulty — without specific guidance from OSHA — knowing which practices need to be examined and updated.

Many SERs believed that their WICPs and SOPs already cover what a rule based on OSHA's regulatory framework would require, as well as what CDC recommends. One SER felt that OSHA's potential requirements were already covered by the provisions of

most accrediting bodies and that these provisions of OSHA's regulatory framework seemed redundant.

One SER reported that WICP templates are available from trade associations. Another SER said that templates or guidance from OSHA on preparing SOPs would be helpful to small employers.

One SER reported that its written documents are updated every three years as opposed to every year, as potentially required under the regulatory framework. In his written comments, this SER stated that the "proposal to require that the infection control plans be reviewed and updated yearly is not realistic and would add unnecessary expense in terms of time and administrative expense."

Vendors and Contractors

Some SERs asked that OSHA clarify what an employer's duty is regarding contractors and vendors that enter their facilities. One SER asked how an employer would monitor vendors and contractors given that they are not employees. Another SER said that it would be a challenge to comply with these provisions of the regulatory framework because it's very difficult to track compliance by vendors and contractors.

In written comments, multiple SERs representing long-term care facilities reported on the difficulties of monitoring vendors and contractors in the long-term care sector. One such SER stated that:

> it is a real challenge in the long term care environment to ensure that contractors are adhering to facilities' (or even their own) infectious disease procedures. In the long term care industry, often contractors are specifically selected by the residents — particularly in the case of independent healthcare practitioners. It is very difficult to establish control over these individuals.

Another SER went on to say that "it is almost impossible to monitor and ensure that all Licensed Health Practitioners have received the [influenza] vaccine as required."

A SER representing a waste handling facility asked OSHA to clarify what his establishment's duty would be for inspectors who enter the facility while the facility's operations are shut down.

Isolation Rooms or Areas

A few SERs were concerned about the provision in the regulatory framework that would require patients to be isolated. One SER said that isolating patients is doable in a large facility or a hospital, but questioned how that might work in a small office. Another SER expressed concern that it would be very costly to add a negative pressure room to an older hospital facility and noted that the only alternative for a rural hospital might be to

transfer a patient needing a negative pressure room to the nearest facility with an available negative pressure room, but that this alternative might result in a long ride for the patient.

A SER representing a small local government that included both hospitals and prisons said that jails generally don't have airborne infection isolation rooms (AIIRs) and isolation usually means putting a patient in a separate cell. She reported that the biggest issue in prisons has been TB and the need to remove TB patients to a unit with negative pressure and air filtration. She said that if a prison issues an isolation order and has someone guard the prisoner, this raises legal issues as well. This SER was also concerned about overpopulation and scarcity of community resources for the hospitals she represents: if sites that do not have available AIIRS transfer patients with suspected airborne transmissible illnesses to hospitals that have available AIIRs, this could quickly make hospitals overpopulated or make community resources scarce.

One SER felt that an Infectious Diseases rule would require all patients to be treated in an AIIR given that patients do not always disclose their symptoms. This SER also said that OSHA's estimates for setting up an AIIR were "extraordinarily low" and expressed concern that medical supply companies would not be able to meet demand if every medical office has to install an AIIR.

Personal Protective Equipment (PPE) & Respiratory Protection

Some SERs told the Panel that the Agency's cost estimates for PPE were too low and that OSHA had underestimated the number of items that would need to be used. In her written comments, one SER said that OSHA's estimate of "one surgical mask [used] per employee per shift is extremely low;" she reported that, at her facility the "nursing assistants care for [an] average of 8 residents and would not be able to use just one mask per shift." Another SER asked OSHA to clarify how much additional PPE would need to be made available to workers. One SER suggested that, rather than changing gloves once per patient, dentists typically change gloves four to six times per patient, while another SER said in her written comments that "dental personnel change gloves at least twice per patient," and that "depending on the length and extent of a procedure, a practice could go through up to four or five pairs of gloves per patient." In her written comments, one SER representing a residential care facility said that "for one patient/resident there could be up to 4-6 glove changes with morning cares, 2 glove changes with each incontinent episode, 2-3 glove changes with a routine wound dressing change and then it's time for bedtime care[] and another 4-6 changes."

One SER representing a hospital said that her facility has powered air-purifying respirators (PAPRs) and self-contained breathing apparatuses (SCBAs) available. The policy at her hospital is to defer to the highest level of protection if there is conflicting information about what type of PPE to use. Workers at her facility use N95 respirators when treating patients with TB and other airborne infections.

Some SERs told the Panel that it is up to the employee to determine the correct PPE to use. In these cases, the workers are trained on correct PPE selection and use, and in some settings, workers are working off-site (e.g., EMS and home care) and are not under the supervision of the employer while performing their job duties.

Multiple SERs reported that during flu season, patients with flu-like symptoms are given masks if they are able to wear them and that the staff also wear masks; one SER specified that workers are given N95 respirators and are told to wear them if they judge it to be appropriate. One SER representing a home care provider reported that they ask staff to wear masks during flu season since many of their patients are elderly and often cannot comfortably wear masks.

SERs, including representatives from two hospitals, one long term care provider, an EMS provider, and a funeral home, reported that they have workers who wear N95 respirators and that they are provided with fit-testing annually. A few SERs reported that they did fit testing in-house using a PortaCount machine. One SER representing a hospital said her employer prefers to use masks and that PAPRs and N95 respirators are also available as needed. A SER representing a hospital reported that about 20 percent of employees at his establishment are in the SER's respiratory protection program, and a SER representing a long term care provider said that there is at least one worker per shift who is trained and fit-tested for N95 use.

One SER representing an EMS provider told the Panel that workers at his establishment wear eye protection 100 percent of the time, use gloves, masks, and eye protection if they are performing an aerosol-generating procedure, such as giving a nebulizer, and have isolation gowns and N95s available at all times. This SER said that this basic PPE is available to workers, but speculated that it may not be sufficient to protect against every disease. In his written comments, a SER representing an EMS provider wrote that the cost for additional PPE is "a cost that cannot be borne by the current reimbursement systems for EMS enacted by CMS and the national ambulance fee schedule" and that "EMS has no way currently to recoup the increased regulatory cost."

One SER told the Panel that workers at her home care agency use PPE if they suspect a patient has a drug-resistant form of a disease.

A SER representing a waste handling firm said that, while his company provided appropriate PPE, some waste handling firms do not provide their workers with disposable gloves or other PPE.

A SER representing a funeral home told the Panel that the only PPE drivers who pick up decedents regularly wear is gloves even though she thinks they have a clear risk of exposure to infectious diseases. This SER also reported that decedents are sometimes masked or have their mouths covered to reduce the risk of air escaping the lungs, and that workers are also trained to wrap a sheet around the decedent's mouth and to stay away from bodily fluids during pick-up of bodies. Two SERs representing other funeral homes submitted joint written comments, where they reported that, in their states, transport

vehicles are required to be equipped with gloves, masks, gowns, head and shoe covering, goggles, antibacterial soap and disinfectant spray, and reported that they "are unaware of any funeral homes that do NOT practice Universal Precautions" when transporting human remains.

One SER also said that when workers come in contact with a decedent while in the funeral home that she represents, they wear full PPE including booties, gloves, a gown, a faceshield, and a mask. Additionally, the SER stated that N95 respirators are available to embalmers, but that the embalmers rarely use them. This SER was aware of some mortuaries where embalmers' PPE is limited to gloves.

Patient Screening

SERs asked for clarification on how patient screening would work. Some SERs were concerned because some infectious diseases have no visible symptoms and because patients are not always truthful or forthcoming about their symptoms.

Many SERs told the Panel that they do not have any mechanism to formally screen patients for infectious diseases before or when they arrive at the office. A few reported asking about whether a patient is sick, but that is mostly for patients going under anesthesia.

Some SERs reported that they may screen patients on the phone during reminder calls, or do cursory evaluations when patients arrive and, if a patient appears to be sick, they may be asked to reschedule. However, a few SERs said that patients may not inform the intake personnel or the doctor of a possible infectious disease either because that person does not want to reschedule their appointment or because the person is being treated for a condition unrelated to the infectious disease (e.g., EMS responding to a person with chest pain indicative of a heart ailment may not be informed that the person is also being treated for TB). Some SERs reported that if a patient appears to be sick, the staff might use additional PPE, including masks or ventilation, and may perform additional cleaning of surfaces. One SER representing an ambulatory surgical center said in her written comments that:

> [a]n extensive medical history, including a patient's infectious disease status, is performed before the patient is admitted to the facility. Our facilities do not accept patients with known infectious diseases. If a patient does arrive at the center with an infectious disease, center personnel will isolate the patient utilizing the appropriate personal protective equipment (PPE) and transfer to a higher level of care, which would cause minimal exposure to ASC personnel.

One SER representing a hospital said that patient screening is done as part of intake procedures. She reported that training is in place so workers are aware of symptoms that may require droplet or contact precautions, and, in such cases, the proper CDC precautions are implemented. However, this SER reported that the largest risk of

exposure occurs during the time it takes for a determination of what precautions to take. One SER representing a hospital said that patients who are screened as they arrive are given a mask if they appear to be sick and that information about the apparent condition of patients is relayed to the healthcare provider. Another SER representing a hospital said that if it is known that a patient with an infectious disease is coming to the hospital, staff might meet that patient outside the building and escort the patient to an isolated area.

One SER said that the hospital he represented has signs up requesting that visitors do not enter the facility if they have a cough or a fever.

Two SERs representing residential care facilities said that when a resident shows symptoms of an illness, the resident is isolated in his or her room, if appropriate (e.g. for gastrointestinal (GI) symptoms or flu-like symptoms), and that staff use universal precautions. Signage on the resident's door is used to alert staff of the need to use precautions, and once a diagnosis is made, workers use appropriate PPE based on that diagnosis. One of the two SERs noted that they do not have the ability to use airborne precautions and residents needing airborne isolation must be transferred to a hospital.

Two SERs representing home care providers said that patients are asked about symptoms (especially GI and fever) and screened for Ebola before workers enter the home. One of these SERs also echoed a previous concern that patients are not always truthful in disclosing potential symptoms.

A SER representing an EMS said that patient screening "goes out the window" in ambulance services. This SER reported that his workers use PPE that is more protective than what is recommended to protect themselves from infectious patients. This SER told the Panel that some dispatch systems have the ability to screen patients. With these systems, the dispatcher asks the caller screening questions and relays that information to the EMS responders. However, not all dispatch systems have this capability.

Some SERs stated that, because of privacy concerns, their workers are not always made aware of a patient's infectious status. A SER representing an ambulance service said that workers at his establishment are not always informed if a patient is infectious if that infection is unrelated to the reason the patient is being transported (for example, a patient who is colonized with MRSA could be transported from a nursing home for care of a hip problem and the EMT may not be informed of the MRSA colonization). In addition, all representatives from funeral homes reported to the Panel that they are rarely informed of the cause of death, including whether the person died from an infectious disease that could put the workers who handle the decedent at risk. In their joint written comments, two SERs representing funeral homes reported that a:

> death certificate, which can be written a significant time after a death and … after human remains are transferred to a funeral home and the embalming process is started … may not indicate the presence of an infectious disease that may have existed in the remains prior to death, if that disease was not the cause of death. There is, therefore, no way for a

funeral director to make an independent medical determination of the existence of an infectious disease, whether airborne or bloodborne, prior to transfer or embalming.

Vaccinations

The majority of the SERs reported providing flu vaccines and the Hepatitis B vaccine as required by OSHA's Bloodborne Pathogens standard (29 CFR 1910.1030). A few workplaces (including most hospitals, a home healthcare provider, and a funeral home) offer the full complement of vaccines recommended for healthcare workers by CDC's Advisory Committee on Immunization Practices (CDC/ACIP). A SER representing a hospital estimated that 80 to 90 percent of hospital employees are currently vaccinated and that about two percent of employees would need antibody tests. One SER wondered about how to improve employee participation in vaccination programs and how to increase the number of employees accepting vaccines. SERs were not aware of any situations where employers did not provide vaccinations when employees ask for them, and one SER said that there is a great likelihood that employers already provide any vaccine workers anticipate needing.

SERs asked whether providing health insurance that covers vaccines would be adequate to comply with the rule.

A number of SERs felt that the additional vaccines they would need to provide as a result of this provision were not necessary for their workers based on their risk. The SERs who reported feeling this way included representatives from a laundry facility, a home healthcare provider, and a long-term care facility. One SER believed that vaccines should be given as appropriate (taking contraindications into account), that care should be taken to determine if the vaccines are appropriate, and that not all vaccinations are necessary in every setting.

SERs that do not provide the full complement of CDC/ACIP recommended vaccines expressed concern about the potential costs of doing so, especially if they are required to provide those vaccines on-site. One SER was concerned with the cost of storing and potentially wasting vaccines if it would have to administer the vaccines on-site, although a different SER, representing a dentist's office, reported providing all vaccines on-site and free of charge and considered the cost negligible. This SER said that his office does not keep vaccines in stock, but is able to obtain them when needed. One SER estimated that it would cost between $125 and $200 per worker to provide the vaccines the establishment does not currently provide. In a written comment, one SER was concerned about the time it would take to complete the additional vaccinations for workers at her facility. She said that "it takes time to get the records of our employees to be able to determine where they are in the vaccine process, (i.e. have they had any of the 3 doses required, and if so, how many?)" and that there is additional time needed "once the process of actually giving the vaccine is complete, [and workers] say they want the lab."

Many SERs reported that workers are required to either accept a seasonal flu shot or to wear a mask at all times on the job during flu season. In some cases, SERs reported that this is a requirement of state or local health departments.

One SER reported that although her state makes seasonal flu shots mandatory or requires workers to wear a mask during flu season, she did not think this requirement impacted the number of flu cases she saw in the nursing home she represented. She reported that workers were not contracting the flu before the mandatory vaccine policy and that vaccines did not make a difference. Another SER, representing a hospital, disagreed with this assertion. He reported that his establishment *has* seen a drop in the number of flu cases after enacting a similar policy. He also said that his facility had seen a similar effect from the pertussis vaccine, but noted that vaccines are not one hundred percent effective.

SERs also had questions about how this requirement might interact with the MRP provision, wondering what the employer's liability would be if a worker refuses a vaccine. Some SERs questioned whether the employer would still be required to provide full MRP if a worker refuses a vaccine (as allowed under the regulatory framework) and becomes ill.

One SER said that the goal of an infection control program is to protect employees from being exposed to infectious diseases in the first place, and suggested that employers be allowed to limit the work area of a worker that declines a vaccination. The SER also stated that if declination makes it difficult for a worker to perform his or her work duties, that should be legitimate grounds for termination. Another SER was concerned about the interaction between OSHA's vaccine requirements and the Americans With Disabilities Act (ADA) requirements and wondered how things would work when workers decline vaccines for health reasons. This SER recommended specific guidance on navigating this issue, as well as on the interplay between health issues and religious beliefs.

Some SERs reported that the estimated vaccine costs provided in the SER background document were too low and others suggested that OSHA has not fully considered the costs for vaccines. A few SERs said that many workers have already received the vaccines recommended by CDC/ACIP because those vaccines are commonly given during childhood.

Medical Surveillance

SERs were concerned that employers might not be able to determine if a worker acquired an infectious disease in the workplace (i.e., whether it is "work-related"), particularly if there is an outbreak in the community. A SER representing an occupational medicine clinic responded that when the determination is not clear, both OSHA and workers' compensation insurers would defer to the PLHCP, who determines work-relatedness on a case-by-case basis. According to this SER, through questioning, analysis and sometimes testing, which can be done to determine which strain of the infectious agent caused the illness, it may be possible to differentiate a workplace from a community strain (e.g.

MRSA, *C. difficile*) and an occupational medicine doctor can make a professional judgment call.

SERs reported being concerned with determining the work-relatedness of flu, *C. difficile*, MRSA, and norovirus.

One SER said that in her facility, when workers are exposed to a patient who is later determined to require droplet or airborne precautions, a risk assessment or evaluation is completed on any workers who had unprotected exposure to that patient. Another SER representing a hospital said that his facility has procedures for tracking workers who are exposed to infectious patients.

Most SERs reported performing annual TB testing, but one SER said that TB testing is only done once, upon hire.

Medical Removal Protection (MRP)

Many of the SERs expressed concern about the MRP provision. Some SERs questioned how work-relatedness would be determined. They stated that many of the infectious illnesses that their workers contract are present in the community as well as in the workplace, and that it would be difficult to determine whether a worker became ill as a result of an exposure to a disease in the workplace or as a result of an exposure somewhere else. In his written comments, one SER elaborated:

> because an employee's exposure … can occur virtually anywhere, his or her exposure at work cannot be definitively proven. If exposure is not definitive, then the employer should not be responsible for compensation while the employee is out of work, other than honoring established paid time off policies.

One SER noted that some workers work multiple jobs, further complicating the matter of determining where an infectious disease was acquired. Another SER felt that requiring healthcare employers to provide MRP for diseases that are endemic in the community penalizes the medical profession. One SER pointed out that the risk of acquiring a bloodborne disease from the community is minimal, but, with infectious diseases transmitted by other routes, there seems to be an elevated or equal risk from the community. One SER wondered whether an OSHA rule would set up a "presumption of causation," meaning that an illness in a worker is automatically presumed to be occupationally acquired. That SER urged the Panel to assure that this was not the case. One SER suggested that it would be easier to monitor workers and prove work-relatedness if MRP was limited to diseases that are more likely to be acquired in the workplace (e.g., TB) than in the community (e.g., flu). A SER who works in occupational medicine told the Panel that work-relatedness determinations are not as difficult as they sound. This SER stated that such determinations are regularly made by occupational medicine doctors and that they must be approached on a case-by-case basis.

A SER representing an EMS establishment said that MRP-like coverage was common in EMS, and another SER, representing a funeral home, said that, while her facility provides generous medical benefits, including paid medical examinations and leave, most funeral home facilities do not.

Some SERs were concerned that MRP would create perverse incentives. They were concerned that workers that could get paid time off by claiming they are ill with a workplace-acquired infectious disease might take advantage of such a system and claim to be infected with a workplace-acquired infectious disease when they were not sick. OSHA clarified that, according to the draft regulatory framework, an employer must do an evaluation and consult with a PLHCP before MRP is provided. The PLHCP would make the determination regarding MRP, and workers would not be able to arbitrarily invoke it. In response to this, one SER said that this process would be very disruptive to a small employer. In written comments, one SER expressed concern "that some employees could take advantage of MRP, leaving [the] facility either short-handed or forced to carry more employees than [the facility] had budgeted for." Another SER said that an MRP provision "will result in increased cost for health evaluations and compensation and makes for an adversarial employer-employee relationship where there does not need to be one" and expressed concern that "every time an employee falls ill, the employee may try to take advantage of the employer for wages and benefits and the employer will feel obligated to try to prove the illness is not work-related."

Similarly, some SERs were concerned that employers would be reluctant to provide benefits if workers could get MRP for illnesses. A SER told the Panel that adding another program on top of workers' compensation was a bad idea. This SER said that workers' compensation is set up to avoid a legal fight over whether or not an illness or injury occurred in the workplace, and an MRP provision could introduce lawsuits. This SER felt that MRP would be extraordinarily difficult to implement and would set up legal battles. One SER wondered what an employer's liability would be when a worker becomes ill as a result of not following the employer's procedures. Another SER wondered what an employer's liability would be when a worker refuses a vaccine and then became ill.

The SERs also questioned how MRP would interact with other forms of compensation available to sick workers, such as employer-provided sick leave or other paid time off, workers' compensation, and unpaid leave allowed under the Family Medical Leave Act (FMLA). In written comments, one SER said:

> the interplay between the [Consolidated Omnibus Budget Reconciliation Act (COBRA)] health benefit extension, medical leave of absence rules under [the Family Medical Leave Act (FMLA), [Affordable Care Act (ACA)] open enrollment rules for changing benefits, and [Employee Retirement Income Security Act (ERISA)] exempt plans all impact whether an employer would even be able to comply with the proposed framework as it relates to continuing health benefits without violating existing federal statute and rules.

Many SERs suggested that OSHA consider whether an employer-provided combination of medical insurance and paid leave is an adequate substitute for MRP, with one SER suggesting that employers only be required to provide MRP if they do not provide health insurance or paid time off. One SER interpreted the regulatory framework to say that paid time off would not be able to be used because that would be taking away compensation and the regulatory framework does not allow that. One SER recommended that the employer only be responsible for what workers' compensation does not cover (i.e., the difference between what workers' compensation pays and a worker's normal earnings). One SER from Missouri told the Panel that Missouri's Workers' Compensation program does not allow an employer to pay the gap between what workers' compensation pays and the worker's total normal earnings. Therefore, in order to fulfill OSHA requirements, this SER's establishment would not be able to use workers' compensation and would bear the full burden of paying a worker's full wages. A SER from Arkansas informed the Panel that Arkansas workers' compensation does not cover infectious diseases except HIV and hepatitis, and another SER concurred that workers' compensation does not always cover illnesses and definitely would not cover workers who need to be excluded from the workplace for precautionary reasons following an exposure event. Multiple SERs representing long-term care facilities were concerned about the costs of MRP when worker's compensation did not apply. One such SER stated that "from informal conversations with certain workers compensation insurers, [it was found] that many OSHA-covered infectious diseases will not be supported by workers compensation, causing the full costs to be borne by the employers." Another SER was concerned that workers would file more workers' compensation claims as a result of this provision, which would cause the employer's workers' compensation insurance rate to increase. Some SERs said that, in most cases, workers' compensation does not kick in for a number of days (usually seven to ten) and many illnesses would be resolved before the end of that period. One SER felt that it might make sense to have MRP coverage only until workers' compensation coverage commenced, and another suggested that an employer only be responsible for providing MRP when the employer is shown to be negligent. Multiple SERs reported that part-time workers in their establishments do not have access to paid sick leave, and a few SERs wondered whether other OSHA rules include MRP provisions.

The SERs felt that the cost to pay a worker who is unable to work would be very burdensome to small and very small employers. A few SERs told the Panel that having to provide MRP on top of other benefits and hiring replacement staff (possibly for up to eighteen months) would bankrupt them or put them out of business. Multiple SERs mentioned that in addition to paying a worker who was unable to work, they would need to pay a worker to cover the shifts that the sick worker would miss (sometimes because of an operational requirement from the state). This would represent an additional burden on top of the cost of paying the salary and benefits of the out-of-work worker. Conversely, one SER mentioned that she did not think providing MRP for an illness with a short duration would be difficult, but that if a worker is out for six months to a year, the establishment would need to hire another employee and that would be a problem for small entities. One SER pointed out that the burden of providing MRP would not be

equal across all providers, and the SERs encouraged OSHA to look at different types of providers with respect to their employees' risk of exposure and to consider the size of affected employers when evaluating the impact of this provision. Other SERs mentioned that, in the case of a worker in a highly-compensated occupation, the worker's normal total earnings would far exceed the limit on workers' compensation payments. One SER wrote in his written comments that the MRP "requirement is both cost-prohibitive and punitive to healthcare employers."

One SER was concerned about the potential for a significant amount of testing that would be needed to identify the cause or source of an illness because a lot of symptoms are non-specific to particular diseases. This SER stressed that the regulated community would need very good guidance on how to conduct these investigations and to identify the sources of illnesses. Another SER was concerned that this provision might force workers to visit a doctor more often to determine if an illness is work-related, and if the worker is diagnosed with influenza (which is not covered by MRP for most workplaces), the cost of the doctor's visit would need to be paid by the worker since the employer would not be required to cover the costs in this case. One SER stated that there might be some benefit to having workers who have a fever be seen by a PLHCP in order to rule out serious conditions. This SER felt that the MRP provision would provide workers incentive and compensation for being screened by a PLHCP, where no incentive or compensation currently exists, and felt that there might be some benefit to that. Another SER wondered if OSHA had considered the case where a worker's preexisting health conditions result in a slower than expected recovery from an infectious disease and asked about the cost implications in such a case.

One SER told the Panel that it was important to encourage workers to stay home when they are sick so that they do not expose other workers or patients to infectious diseases. This SER suggested that OSHA not look at a worker with an infectious disease as only either able to work or totally disabled, and that the Agency should consider the worker's ability to work remotely. This SER believes it is important to encourage people to stay active and that even if a worker is not able to be at the physical location of his or her employer, the worker should be allowed to work remotely or be reassigned to other duties if feasible. Another SER informed the Panel that his establishment had been able to reassign workers who had been exposed to pertussis in the workplace to non-patient care duties.

Medical Removal Protection - Quarantine

The Panel asked some SERs what issues they would anticipate if the MRP provision included a quarantine requirement when quarantine is determined to be medically necessary (as in the case of Ebola).

One SER pointed out that the connection to the workplace would need to be clear. For example, would an employer need to pay a quarantined doctor who travelled to Africa as a volunteer on his or her own time and contracted the disease there?

SERs reiterated concerns about determining work-relatedness and how a MRP for quarantine requirement would interact with paid leave, workers' compensation, and health insurance. One SER reiterated a call to allow workers who are able to work remotely to do so and others restated their concerns about the cost burden for smaller establishments.

Some SERs wondered about the scope of a potential requirement. For example, would a convenience store owner be required to provide paid quarantine to a worker at that store who was exposed to Ebola in the workplace? In addition, SERs wondered whether janitors or other cleaners would be eligible for paid quarantine.

One SER pointed out that the costs would vary based on where a worker is quarantined. He reminded the Panel that scenarios involving the worker staying in a facility, scenarios involving the worker staying home, and scenarios involving the removal of a person from all public contact would have different issues and encouraged OSHA to address the costs of these different scenarios.

Training

SERs were concerned about the provision in the regulatory framework requiring that workers be able to ask questions and have those questions answered as part of the required training. One SER reported using computer-based training and said that an instructor is not present while workers complete the training and that the program her establishment uses does not have the capacity for workers to submit questions through the program. Other SERs reported that the training they provide is done with a live instructor or facilitator (sometimes an infection control specialist, a human resources representative, or an education coordinator) and that the training may make use of videos, online modules, and competency testing. One SER urged OSHA to not allow computer-based training, stating that it is too generic and that the training needs to be job-specific in order to be effective.

Most SERs reported providing training upon hire and annually. Frequently, the training on infection prevention was combined with other topics such as bloodborne pathogens, hazard communication, compliance with the Health Insurance Portability and Accountability Act (HIPAA), or respiratory protection. The training programs described by SERS vary in duration (one hour to a full (eight-hour) day). In his written comments, one SER reported that all employees at his facility "undergo thorough training in infection control at the time of initial hire with yearly updates also required." He said that the "training covers all of the elements listed in the proposed regulatory framework," that additional training is provided "as needed, as required by new infectious threats such as Ebola," and that training records are tracked electronically.

One SER was concerned about what it would cost to provide a copy of the WICP. She reported that the document is long and that workers frequently just throw it out. Another SER said that his facility makes the plan available to workers online but does not provide a paper copy.

SERs stated that they believe that the costs that OSHA has estimated for training are too low. One SER asked in her written comments whether OSHA had considered "the cost to pay the employees to attend these mandatory in-service (training) sessions, as well as pay extra staff to cover the units while the other staff is attending their training."

4. Panel Findings and Recommendations

Based on the input from the SERs and its own consideration of the issues, the Panel offers the following findings and recommendations to OSHA.

Need for a Rule and Alternatives, Risk, and Scope

Risk

SERs were generally concerned that significant risk or significant occupational exposures may not be present in all of the industries a standard might cover. Most SERs reported that they had never had a case of an occupationally-acquired infectious disease in their workplace. However, some mentioned workers' compensation claims, others said it was impossible to determine if an illness was workplace acquired, and some SERs mentioned outbreaks that occurred in their facilities.

The panel recommends that OSHA not proceed with issuing a proposed rule until it assesses available data on risk to address the need for the rule for each potentially covered task and work setting.

Scope

In general, SERs representing specialized ambulatory care facilities that do not treat patients for infectious diseases, commercial laundries, medical waste handlers, and funeral homes, felt that the precautions required under OSHA's Bloodborne Pathogens (BBP) standard (29 CFR 1910.1030) sufficiently protect workers in their industries.

The Panel recommends that OSHA consider excluding from the scope of an Infectious Disease rule certain work settings and job tasks where it has determined that the BBP standard is adequate to provide protection for workers in those work settings and performing those job tasks.

If OSHA determines that in certain work settings and for certain job tasks, there would be relatively few additional procedures needed to adequately protect workers beyond what is required by the BBP standard, the Panel recommends that OSHA modify the BBP standard rather than issuing a new rule for those work settings and job tasks.

The Panel recommends that OSHA also consider tailoring requirements by setting and task. For example, OSHA should consider differentiating between facilities where healthcare workers routinely provide direct patient care to persons with infectious diseases and facilities where healthcare workers do not routinely provide direct patient care to persons with infectious diseases (e.g., ambulatory care facilities that do not routinely treat patients with infectious diseases). As another example, the Panel recommends that OSHA consider differentiating between facilities where healthcare workers routinely provide direct patient care to persons with infectious diseases and facilities that perform other covered tasks only (such as laundry facilities, medical waste handlers, and funeral homes).

Need for a Rule and Alternatives to the Regulatory Framework

This section covers alternative approaches to rulemaking as a whole. Alternatives addressing potential modifications to the scope and dropping or modifying specific provisions of OSHA's preferred alternative (i.e., the regulatory framework) are covered in separate sections of the Panel Findings and Recommendations.

Most SERs questioned the need for a rule, especially given current regulations, guidelines, and oversight related to accreditations and certifications. Most SERs reported having some form of accreditation or certification, although in many cases this does not include an on-site inspection of infection control practices. Some SERs also told the Panel that their accrediting bodies have a mechanism for filing and investigating worker complaints. SERs regulated by CMS pointed out that they are already inspected and already have performance targets for preventing infections in their patient populations. Some SERs representing hospitals also mentioned that they are subject to monetary penalties if the targets are not met. Many SERs expressed a concern that additional regulation would not improve compliance and that adding an additional regulation to the healthcare sector would increase the complexity of infection control plans and potentially lead to negative patient outcomes. Most SERs believed that coming into compliance with a new OSHA rule would not be a good use of the limited resources they have available for infection control.

Almost all SERs said they are in compliance with CDC or other applicable guidelines. They therefore anticipated that compliance with a new OSHA rule would result in few or minimal substantive risk-reducing changes in behavior. They did, however, anticipate that they would incur significant costs under a new OSHA rule because they would need to familiarize themselves with, and review their infection control programs to ensure compliance with, the OSHA standard. They believe that following CDC or other applicable guidelines is sufficient.

Many SERS saw a fundamental difference between employers who do not see infectious persons routinely (and normally reschedule infectious patients) and those who by the nature of their settings and job tasks must treat persons with infectious diseases (such as hospitals, emergency medical services, and nursing homes). According to these SERs the

former have less frequent exposures and may need fewer precautions, while the latter are more likely to be regulated and inspected by other agencies.

The Panel recommends that OSHA carefully review existing regulations and guidance on infection control in determining the need for a rule (e.g., CDC guidance and conditions of participation for Medicare and Medicaid), and consider whether a new OSHA rule is necessary to improve worker health and safety in light of existing regulations and guidance.

The Panel recommends that, if OSHA finds a rule is needed, OSHA consider including in the rule a statement that OSHA will deem employers following applicable guidelines, such as those issued by the CDC, to be in compliance with the OSHA rule.

The Panel recommends that OSHA review the evidence concerning risk in settings that do not routinely provide care to infectious patients (in other words, settings where exposures are less frequent) and that OSHA consider excluding these settings from a rule.

The Panel recommends that if OSHA finds such settings in need of some form of regulation, OSHA consider requiring such settings to develop and implement only procedures for intake screening of infectious patients (i.e., under this alternative, these settings would not be required to adhere to any other provisions contained in OSHA's preferred alternative (the regulatory framework)).

Several SERs pointed out that, in some circumstances, OSHA could use its enforcement powers under the general duty clause even in the absence of a regulation. Most SERs requested that OSHA consider non-regulatory or less burdensome approaches to addressing the risk of workers being exposed to infectious diseases in the workplace. The suggested approaches included, among other ideas, additional education, training, and compliance assistance including non-punitive inspections.

The Panel recommends that OSHA consider a rule that would be focused solely on training. Such a rule would be designed to assure that all employees remain up-to-date on the most current and relevant CDC or other applicable guidelines for infection control.

To address the concern by SERs that coming into compliance with a new OSHA rule on infectious diseases would not be a good use of the limited resources SERs have available for infection control, the Panel recommends that OSHA carefully consider whether a non-regulatory approach could be devised that would both a) be a reasonable alternative to a rule and b) meet OSHA's requirement to protect workers. Such a non-regulatory approach might include guidance materials (e.g., Safety and Health Topics web pages, pamphlets, fact sheets, quick cards, checklists) and compliance assistance aimed at helping employers follow CDC and other applicable guidelines.

The Panel recommends that, should a rule be proposed, OSHA develop education/outreach materials throughout the rulemaking process. The Panel also recommends that OSHA include task- or setting-specific guidance within the preamble of the proposed rule.

The Panel also recommends that OSHA consider developing task- or setting-specific education/outreach materials as part of compliance assistance for employers implementing the rule.

General Impacts of a Rule

Cost estimates

A number of SERs told the Panel that OSHA's unit cost estimates for PPE use and vaccines were too low. They also said that OSHA had underestimated the amount of PPE that would be used. Most SERs anticipated that they would incur costs related to MRP, vaccinations, initial program review, familiarization with the rule, and training if a rule is promulgated as described in the regulatory framework. With the exception of MRP, most SERs did not anticipate significant costs for most small entities. A few SERs thought that some of the requirements would result in significant costs.

The Panel recommends that OSHA review unit cost estimates and estimated use frequencies. For example, some SERs reported that they routinely replaced PPE much more quickly than OSHA estimated.

The Panel recommends that, in determining whether the regulatory framework requirements with which most employers already comply are justified, OSHA carefully examine the additional costs associated with administrative activities, such as the costs associated with an employer familiarizing itself with a new OSHA standard and reviewing its programs to assess compliance.

Baseline Compliance

Most SERs told the Panel that they are already following CDC guidelines and most described infection control programs that largely match what CDC requires. This means that, with the exception of MRP, most SERs believe they are largely complying with OSHA's regulatory framework.

The Panel recommends that OSHA reassess its estimates of baseline compliance in light of SER comments.

The Panel recommends that OSHA fully assess baseline compliance rates and apply its estimates of baseline compliance when estimating the illnesses that would be prevented by a new OSHA standard and the expected benefits of such a standard.

The Panel recommends that the provisions of any proposed rule match the CDC or other applicable guidelines for infection control as closely as feasible.

Provisions of the regulatory framework

Medical Removal Protection

Most SERs were concerned about the medical removal protection provision included in the regulatory framework. The SERs were in agreement that this provision could severely impact smaller establishments and were unclear about how this provision would interact with other forms of compensation like employer-provided health insurance, paid sick leave or time off, the employee's own insurance, and workers' compensation. SERs also agreed that it would be difficult to determine whether a worker's illness was due to a workplace exposure or to exposure in the community. SERs also felt it would be unfair to require an employer to pay for MRP in cases where a worker declines a vaccination and later becomes ill with a vaccine-preventable illness or in cases where a worker becomes ill as a result of failing to follow the employer's procedures. SERs questioned why OSHA would want to change the existing system.

Many SERs suggested that OSHA consider whether a combination of employer-provided health insurance, paid sick leave, workers' compensation, the employee's own insurance and/or disability coverage could be substituted for MRP. SERs told the Panel that, while most workers have access to benefits, some do not, including part-time employees. Some SERs also expressed concern about the extent of workers' compensation coverage. The SERs told the Panel that workers' compensation in some states does not cover all types of infectious diseases and that employers may not be legally allowed to pay the difference between what workers' compensation pays and a worker's total normal earnings. The SERs also reported that, even when workers' compensation is available, there are issues such as waiting periods, caps on the amount that can be paid to a worker, and other considerations that limit the coverage of workers' compensation.

The Panel recommends that OSHA carefully analyze whether a rule that does not include medical removal protection could meet OSHA's goal of protecting workers from exposure to infectious diseases and that OSHA consider dropping the provision if possible.

The Panel recommends that OSHA further analyze the impacts of the medical removal protection provision on small and very small firms. The Panel also recommends that OSHA analyze the impacts such a provision would have on firms of all sizes in the event of a large-scale outbreak or pandemic.

The Panel recommends that OSHA limit any requirement for employers to provide MRP to situations where workers do not have access to other forms of coverage such as sick leave, health insurance, disability insurance, or workers' compensation.

The Panel recommends that OSHA explicitly define how the Agency would expect employers to determine whether a worker's illness was acquired through a workplace exposure. If the rule includes any presumptions regarding the source of exposure in situations where it is unclear, that is, if the source is presumed to be work-related in unclear cases, the Panel recommends that OSHA clearly justify the basis for such a presumption.

If there is an MRP requirement, the Panel recommends that OSHA more carefully outline how that requirement would interact with other sources of compensation for illnesses.

Coverage of Quarantine

SERs raised the same objections to MRP for quarantine as they did to MRP in general. Some SERs also brought up the issue that MRP for quarantine might have additional costs depending on exactly where and how quarantine has to be conducted.

The Panel recommends that OSHA consider all of the recommendations with respect to MRP for illnesses in deciding whether and how to extend MRP to cover quarantines.

The Panel recommends that OSHA analyze the costs associated with the conditions of specific quarantine scenarios in deciding whether and how to extend MRP to cover quarantines.

Vaccinations

Most SERs whose facilities are covered by CMS reported to the Panel that their facilities provide all of the ACIP/CDC recommended vaccinations. Most SERs who represented settings that were not covered by CMS almost never provide all of the ACIP/CDC recommended vaccinations, but instead limit the provided vaccinations to the seasonal flu vaccine and those vaccinations required by OSHA's Bloodborne Pathogens standard (29 CFR 1910.1030). Many SERs who reported to the Panel that their facility currently follows the CDC guidelines on infection control do not provide all of the ACIP/CDC recommended vaccinations. Some SERs do not offer all of the ACIP/CDC recommended vaccinations because they claim that workers in their industries are not exposed to the diseases the ACIP/CDC vaccines prevent.

The Panel recommends that OSHA examine the basis for the ACIP/CDC recommendations and whether those recommendations are applicable to all settings within the scope of the regulatory framework.

SERs voiced concerns about interactions between the regulatory framework provision that would require employers to offer, but allow workers to decline, vaccines and employer- or state-mandated requirements that workers be vaccinated or that workers wear facemasks if they decline vaccinations. SERs also wondered whether MRP and

payment for medical treatment should be mandated where a worker becomes ill with a vaccine-preventable disease after declining an employer-provided vaccine.

The Panel recommends that OSHA carefully analyze whether, and how, the regulatory framework provisions that would require employers to offer, but allow workers to decline, vaccines would interact with employer- or state-mandated requirements that workers be vaccinated or that workers wear facemasks if they decline vaccinations.

The Panel also recommends that OSHA consider adding appropriate exemptions to the requirements for MRP and payment for medical treatment, for example, for situations in which a worker becomes ill with a vaccine preventable disease after declining an employer-provided vaccine.

Some SERs felt it was unclear whether employers would need to provide vaccinations to their workers on-site and have all vaccines available on-demand, or whether employer-provided health insurance that covers the full cost of the vaccinations would be adequate to comply with this provision.

The Panel recommends that OSHA consider allowing any mechanism of payment for vaccines so long as the recommended vaccinations are provided at no out of pocket cost to the worker.

Airborne Infection Isolation Rooms (AIIR) and Engineering Controls

Some SERs interpreted the regulatory framework to say that facilities that do not currently have engineering controls, such as AIIRs or autopsy suites, would need to install such controls in order to be in compliance with the regulatory framework's goal of protecting workers. Other SERs were concerned that, in rural areas, where the availability of AIIRs is limited, they would need to install AIIRs to avoid having to send patients on long trips to hospitals or other more fully-equipped facilities.

The Panel recommends that OSHA clarify when engineering controls are needed. The Panel further recommends that OSHA examine whether additional AIIRs are needed in hospitals or other settings.

Medical Surveillance and Exposure Incidents

SERs questioned how medical surveillance is to be done and what constitutes an exposure incident. SERs also wondered whether this could be paid for through employer-provided health insurance.

The Panel recommends that OSHA clarify the definition of an exposure incident. The Panel further recommends that OSHA allow employer-provided health insurance to pay for medical surveillance.

Definitions
One SER suggested that OSHA develop tighter definitions so that the language used is consistent with language used by WHO and CDC.

The Panel recommends that OSHA evaluate the terminology and definitions used in relevant CDC and WHO publications and incorporate the terminology and definitions from those publications wherever possible.

Medical records
Some SERs questioned the need for employers to maintain exposure incident and other records for thirty years and felt that doing so would be difficult and burdensome.

The Panel recommends that OSHA reconsider the need for employers to retain records for thirty years and examine whether it could adopt much shorter retention periods, such as three years. OSHA should further evaluate the potential costs associated with maintaining records for different periods of time.

Appendix A

Small Business Advocacy Review Panel Members and Staff Representatives for the Potential OSHA Standard on Occupational Exposure to Infectious Diseases in Healthcare and Other Related Settings

Robert E. Burt	Occupational Safety and Health Administration (OSHA)
Andrew Levinson	OSHA
Valentine Schaeffer	OSHA
Jessica Stone	OSHA
Thomas Nerad	OSHA
Margy Lambert	OSHA
Sharon Carr	OSHA
Charles McCormick	OSHA
Bryan Lincoln	OSHA
LaJuane Paige	OSHA
Ian Moar	Department of Labor Solicitor (DoL SOL)
Lauren Goodman	DoL SOL
Lee Grabel	DoL SOL
Anne Ryder	DoL SOL
Cortney Higgins	Office of Information and Regulatory Affairs, OMB
Charles Maresca	Office of Advocacy, Small Business Administration
Bruce Lundegren	Office of Advocacy, Small Business Administration
Jonathan Porat	Office of Advocacy, Small Business Administration

Appendix B: SBREFA Infectious Disease Teleconference SER Participants

Wednesday, November 12, 2014 (1:00pm – 4:00pm)

Kayvon Haghigi, DDS, MD, FACS	(*Dentist*)
Becky Keller	(*Pathways Hospice*)
Rick Kislia	(*Crescent Laundry*)
Dr. Philip Obiedzinski	(*Office of Podiatrists*)
Todd Opp	(*Glendive Medical Center*)
Lyn Pethtel	(*Salem Community Hospital*)
Douglas Rodriguez	(*Fishers Pediatric Dentistry*)
Georgine Snyder	(*Diakon Lutheran Social Ministries*)
Rich Norcross	*(Medical Waste Services)*
Michael Bomberger	*(Community Hospital Onaga, Holton Family Health Clinic, St. Mary's Clinic)*
Mindy Thompson	*(Helen R. Walton Children's Enrichment Center)*
Francis Califano	*(North Shore-LIJ Physician and Ambulatory Services)*

Appendix B: SBREFA Infectious Disease Teleconference SER Participants

Wednesday, November 12, 2014 (1:00pm – 4:00pm)

John Bing	*(JBing & Assoc. Anesthesia Services)*
Robert Blink	*(Worksite Partners Medical Group)*

Appendix B: SBREFA Infectious Disease Teleconference SER Participants

Thursday, November 13, 2014 (9:00am – 12:00pm)

Janet Snipes	(*Holly Heights Nursing Home)*
Carole Yeung, RN	(*Baptist Home Health Network)*
Scott George	*(Mid-America Dental & Hearing)*
Dr. Douglas Smith	*(Intermountain Healthcare)*
John Russell	*(Cape County Private Ambulance Service, Inc.)*
Jim Sakell	(*Cypress Glen Retirement Community)*
Hal Miller	*(Larson-Miller Medical Waste Disposal Service)*
Saul Wasserman	*(Shiel Medical Laboratory)*
Dr. Mary Yarbrough	*(Vanderbilt University)*

Appendix B: SBREFA Infectious Disease Teleconference SER Participants

Friday, November 14, 2014 (1:00pm – 4:00pm)

Barbara Ball, RN	(*Good Shepherd Nursing Home)*
Rita Bowen	*(Sutter Surgery Center)*
Barbara Campbell	(*Community Health Center)*
Daniel Fenton, RN	(*Cibola General Hospital)*
Leslie Marsh	(*Lexington Regional Health Center)*
Carol Moehrle	(*Idaho North Central District)*
Dr. Trevor Neal	*(Office of Podiatrists)*
Dr. Janice Pliszczak	*(Office of Dentists)*
John D. Slack	*(Slack Funeral Home, P.A.)*
David Weber	*(David J. Weber Funeral Homes, P.A.)*
Andrew Byrd	*(Keswick Multi-Care Center)*
Jim Parks	*(Accu Medical Waste)*

Appendix B: SBREFA Infectious Disease Teleconference SER Participants

Judy Dahl *(Johnson Memorial Health Services)*

Friday, November 14, 2014 (1:00pm – 4:00pm)

Dr. Barbara Aung *(Aung Foot Health)*

Dr. Melissa Heche *(Doctor of Audiology)*

Elizabeth Blakenship *(Southridge Village Assisted Living)*

Dr. Joseph D'Amico *(Professional Anesthesia Services of Eastern Pennsylvania)*

Sue Luster *(Home Health Options Group)*

Patti Tatlock *(St. Mary's Hospital)*

Appendix B: SBREFA Infectious Disease Teleconference SER Participants

Thursday, November 20, 2014 (5:00pm)

Cindy Diedrich	*(Rona-Fitchburg Ambulance)*
Jenna Moerk	*(Hillside Memorial Park)*
Vicki Erickson	*(Home Health Visiting Nurses)*

December 5, 2014

TO: Mr. Robert Burt, Chair
SBAR Panel on Infectious Diseases
Occupational Safety and Health Administration
U.S. Department of Labor
200 Constitution Avenue, NW
Washington, DC 20210

From: Barbara Ball, RN, MSN
Inservice Educator
Good Shepherd Nursing Home
159 Edgington Lane
Wheeling, WV 26003

RE: Written Comments on the proposed OSHA Infectious Diseases Regulations

Dear Mr. Burt,

I am writing today as the representative from Good Shepherd Nursing Home, a 192-bed skilled and intermediate care facility. We have dual Medicare/Medicaid Certification, undergoing rigorous annual surveys by our regulating bodies, Centers for Medicare and Medicaid Services and the Office of Health Facilities Licensure and Certification of the State of West Virginia.

We have been designated as a Five-Star facility since the inception of CMS's Five Star Quality Rating System. In addition, we qualified for OSHA's SHARP Award beginning in 1999 and have had that award renewed every two years since that time. I was very involved in implementing the Safety Program for our Employees that resulted in this designation. This past year, I also assisted our Assisted Living facility to achieve SHARP status. This is why our Administrator, Donald Kirsch, asked me to be involved in this current process of reviewing the proposed Infectious Disease regulation.

As a facility that employs approximately 240 persons, I echo the concerns of many of the other participants in the teleconference regarding the costs that these regulations would cause.

- Medical Removal Protection: The cost and burden of administering this requirement is a major concern. I agree with the concerns brought up in the teleconference and am sure many others have addressed this area of concern at length, so I will only bring up the following concerns.
    - The major question that I see as an issue is how can it be shown that the illness was work-related vs. community acquired.
    - As a care facility for the elderly, we have a legal and ethical obligation to provide care for our residents. I am concerned that some employees could take advantage of MRP, leaving our facility either short-handed or forced to carry more employees than we had budgeted for.
- PPE Requirements: These seem to be underestimated, considering the several times per day a resident requires care from the staff. And the statement that one surgical mask per employee

per shift is extremely low...our nursing assistants care for average of 8 residents and would not be able to use just one mask per shift.

- Administrative Controls: The increased vaccination expectation would be a major burden to employers.
    - We currently provide the Hepatitis B Vaccine and follow-up labwork (titer) at no cost to our employees, as per the Bloodborne Pathogen Standard. As one of the nurses who has been involved in this process, I can tell you it takes time to get the records of our employees to be able to determine where they are in the vaccine process, i.e. have they had any of the 3 doses required, and if so, how many, and then once the process of actually giving the vaccine is complete, there is the follow-up issue when they say they want the lab but then never actually go to have the blood drawn, which requires more time.
    - We also provide, at no cost to the employees, the annual influenza vaccine. (And in 2009, when the H1N1 flu was prevalent, we also provided our employees with that vaccine at no charge.)The administration of this is not as difficult to complete, but it does still take staff time to administer.
    - To think that we would be required to provide MMR, Tdap, Varicella, and any other vaccines that could be specified is, frankly, overwhelming in terms of recordkeeping and administration. (As part of our Infection Control Inservice Education last year, we did have the nurse from our local Health Department speak to our employees and she included information to them about what immunizations are recommended for adults. So you can see, we do see the value in educating our employees about their own health as well as resident care related issues.)
- Training: As part of my current duties, I provide Orientation and Annual training to our staff. We always include Infection Control as part of our topics. I address not only the required bloodborne pathogen and tuberculosis training, but also training on topics such as Cdiff, norovirus, multi-drug resistant organisms such as MRSA and VRE, influenza, and this year we included ebola and the enterovirius D68. Review of our Inservice Training is covered as part of our annual survey and I am sure if we had problems with infections, that we would do extra training in those areas.
    - It is a challenge to include all the required topics each year to all employees and if we are required to include all the points outlined about each and every type of infection each year, it would certainly take 2-3 hours to prepare annually (remember, we are teaching the same topic every year to the same people so I try to come up with a different way to teach the required topics).
    - I am not sure if I saw estimates for the cost to pay the employees to attend these mandatory inservice sessions, as well as pay extra staff to cover the units while the other staff is attending their training.

In summary, I would recommend OSHA take a hard look at the real life implications of this rule and the burden it would place on small businesses. I would recommend an approach similar to the one that we were involved in several years ago that led us to obtain SHARP status...that if a facility has problems,

give them the option of working with OSHA consultants to improve and if they choose not to, then impose requirements as fitting to the problems. Utilize results from government agency surveys that are already being done to determine if there is a problem. Use OSHA log-type reports to determine the true extent of the infectious diseases before imposing another standard.

Thank you for this opportunity to be involved in this process,

Barbara Ball, RN, MSN

Colorado Health Care Association
and Center for Assisted Living

11-25-14

Mr. Robert Burt, Chair
SBAR Panel on Infectious Diseases
Occupational Safety and Health Administration
U.S. Department of Labor
200 Constitution Avenue, NW
Washington, DC 20210

Re: Written Comments on OSHA's Infectious Disease SBAR Panel

Dear Mr. Burt:

Thank you for convening and serving as Chair of OSHA's SBAR Panel on Infectious Diseases. We appreciate OSHA's consideration of the comments received and the concerns expressed by the Small Entity Representatives ("SERs") throughout the process.

I am writing on behalf of Colorado Health Care Association and Center for Assisted Living (CHCA/CCAL). CHCA/CCAL represents the majority of Colorado's Nursing Homes and many assisted living residences. We serve as a support group for providers and vendors that care for the country's most vulnerable population, the frail and the elderly.

At the outset, we would like to emphasize the unique nature of the nursing home and assisted living environment (the "long term care industry"). The long term care industry must navigate multiple regulatory schemes designed to protect the safety and health of employees *and* the safety and health of residents. In the long term care industry, residents are guaranteed certain rights, which can impact how a facility is able to implement workplace safety and health rules. For residents, their rooms are their "homes" and facilities can be prohibited from taking certain actions which infringe upon how a resident is allowed to "live" in their homes. As OSHA continues to examine this rule, it is important for the Agency to specifically review how the requirements will be implemented in the long term care industry given the unique residents-rights issues involved.

As with many of the other Small Entity Representatives ("SERs") involved in the SBAR Panel review, we have experience with OSHA's bloodborne pathogens standard and recognize that OSHA has borrowed some of the principles from that standard in this regulatory initiative. We have concerns however, as to whether OSHA has justified the need for this action in the first instance. Furthermore, several of the provisions we fear will be difficult and burdensome to implement. We ask that OSHA review the need for the rule and many of its provisions before proceeding with a proposal.

Worker Infection Control Plan

The lynchpin of OSHA's approach in this rulemaking is the requirement that employers develop a Worker Infection Control Plan ("WICP"). The WICP seems similar in design to a

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An Affiliate of American Health Care Association/National Center for Assisted Living

bloodborne pathogen exposure control plan. According to the draft proposal, developing a WICP will involve identifying the potential sources of infection at a facility and the employees potentially exposed. It would need to be updated annually.

In addition to the WICP, there is a requirement for employers to implement a number of Standard Operating Procedures ("SOPs") that are consistent with recognized and generally accepted good infection control practices. These SOPS would need to be updated as the Centers for Disease Control ("CDC") or other organizations implement or change guidance in the area of infectious disease. OSHA has identified the need for numerous SOPs.

For small employers in the long term care industry, the development and ongoing updating of SOPs will be extremely burdensome. Most small employers do not have in-house resources readily available to continually track CDC or other guidance from the public health community. OSHA's use of a process safety management ("PSM") approach to this rule will place a heavy burden on small employers. Aside from the burden associated with this, small employers will have difficulty – without specific guidance from OSHA – knowing which practices need to be examined and updated.

Host-Contractor Provisions

We are also concerned about the proposed requirements for contractor safety. As set forth in the SBREFA materials, OSHA is requiring host employers to ensure that contractors, vendors, or independent healthcare practitioners, adhere to infectious control procedures at least as effective as the host employer's.

While we understand OSHA's overall concern with ensuring all employers at a facility are following good hygiene practices and implementing appropriate protective measures, it is a real challenge in the long term care environment to ensure that contractors are adhering to facilities' (or even their own) infectious disease procedures. In the long term care industry, often contractors are specifically selected by the residents – particularly in the case of independent healthcare practitioners. It is very difficult to establish control over these individuals.

In addition, in the long term care industry, many families will hire "sitters" to come into the facility to spend time with resident family members. These sitters are often not "employees" under the Occupational Safety and Health Act of 1970 and it will be extremely difficult for small employers to take action to ensure that these contractors are in full compliance with OSHA's proposed requirements.

Medical Screening and Medical Removal Protection

OSHA's proposed framework would require employers to provide certain vaccinations to employees as provided by recognized and generally accepted good infection control practices. In addition, medical screening and surveillance services would need to be provided to employees post exposure. In addition, if it is determined that employees must remain outside of work due to a medical condition related to workplace exposure to an infectious disease, employers must ensure that these employees maintain full pay and benefits during this time.

We have concerns regarding how these costs will be handled by small employers in the long term care industry and would encourage OSHA to examine very closely whether workers compensation will cover certain infectious diseases. From informal conversations with certain workers compensation insurers, we understand that many OSHA-covered infectious diseases will not be supported by workers compensation, causing the full costs to be borne by employers.

When examining the costs of these provisions, we encourage OSHA to also consider the practical impact of medical removal protection ("MRP") on small employers. Many small employers do not have large staffs to draw from to cover for work absences, particularly extended work absences. In these situations, employers may need to hire from temporary staffing agencies or make other arrangements. When determining the appropriateness of MRP, we encourage the Agency to consider the full financial burden associated with hiring a second employee, while maintaining full pay and benefits of the employee out of work on medical removal (without any offset from workers compensation).

We also request that OSHA examine the purpose of MRP in this rule *vis-à-vis* prior OSHA health standards that have required MRP. In those other standards, the Agency has required MRP based on evidence that employees may be reluctant to report illnesses or participate in medical surveillance for fear of losing pay and benefits. We ask OSHA to examine specifically if there is such evidence in the area of infectious disease in the affected industries to justify this burden before proceeding to include MRP in any proposed rule.

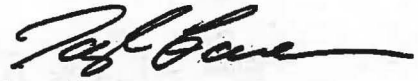
Cost Estimates

We appreciate OSHA's efforts to estimate the costs of the proposal. However, our initial review of the costs suggests that they are understated, particularly with respect to the provision and use of personal protective equipment ("PPE").

As a general matter, OSHA has estimated that much of the PPE can be used multiple times throughout a shift (e.g., a facemask can be used until visibly soiled). We respectfully suggest that OSHA – for cost estimate purposes – substantially increase the number of times per shift that PPE must be changed. As a best practice, many employers have implemented single-use practices and particularly with employees with direct patient care responsibilities. We also anticipate that for certain disease outbreaks recognized and generally accepted infection control practices could mandate single use for PPE. We respectfully request that OSHA consider this when issuing any proposed rule.

Again, we appreciate OSHA conducting the SBAR Panel review and considering the concerns of affected SERs. Should the Agency have any further questions related to the proposal or its impacts on the long term care industry, we would be happy to assist.

Sincerely,



Doug Farmer
President & CEO, CHCA/CCAL

Intermountain Healthcare
36 South State Street
Salt Lake City, Utah 84111-1486
801.442.2000

November 26, 2014

Mr. Robert Burt, Chair
SBAR Panel on Infectious Diseases
Occupational Safety and Health Administration
U.S. Department of Labor
200 Constitution Avenue, NW
Washington, DC 20210

Dear Mr. Burt:

Thank you for the opportunity to participate on your conference call on November 13, 2014 and to provide written comments on the proposed OSHA Infectious Diseases Rule. As the Associate Chief Medical Officer for Intermountain Healthcare I have oversight responsibilities for Infection Control and Employee Health, and I have also served as Medical Director for our Rural Region hospitals. Based in Utah, Intermountain Healthcare is a vertically integrated health care system with 22 hospitals, 35,000 employees, 159 clinics and our own insurance product. Nine of our hospitals are small, rural facilities and five of them are designated as Critical Access Hospitals.

The importance of strong infection control practices to protect patients, families and health care workers cannot be overstated. Spurred by the IOM reports on patient harm, our hospitals have worked tirelessly over the last 15 years to reduce patient harms of all varieties, including nosocomial infections. We are also committed to protecting our employees from harms and injuries of all sorts, including infections. Our motivation for providing strong infection control is consistent with our mission of helping people live the healthiest lives possible. Most of our employees are insured by our internal health plan giving us additional motivation to prevent infections for our employees. As will be discussed in further detail below, there are also reputational and financial incentives to protect our patients and employees from infectious complications.

From both the perspective of small hospitals and of a larger healthcare system, Intermountain has serious reservations about the proposed Infectious Diseases Rule. We already comply with most of the proposed measures (the ones consistent with Center for Disease Control (CDC) guidelines) and for OSHA to add another layer of regulatory oversight would be overlapping, duplicative, and would add extra expense at a time when hospitals are under great pressure to provide high quality health care in a more cost effective manner.

Intermountain hospitals, and I suspect all hospitals, already follow CDC and Healthcare Infection Control Practices Advisory Committee (HICPAC) guidelines on infection control. All of our hospitals have written infection control plans. We perform a thorough review and update of each plan every three years, but often update them more frequently, as during our current Ebola preparedness work. Our plans include the elements outlined in your Regulatory Framework proposal and are available online to all employees. Vendors, contractors and Licensed Independent Practitioners are required to comply with the infection control practices outlined in the plans. The OSHA proposal to require that the infection control plans be

reviewed and updated yearly is not realistic and would add unnecessary expense in terms of time and administrative expense.

All of our hospitals have written procedures and policies which guide our approach to infectious agent hazard evaluations, hand hygiene (with > 90% compliance), PPE use and availability, decontamination, handling of potentially infectious materials, medical surge procedures, etc. To rework these policies and procedures into whatever Standard Operating Procedure (SOP) format is required by OSHA would be an additional and unnecessary burden of time and administrative expense.

Intermountain Healthcare employees are well cared for in terms of medical screening, surveillance and vaccinations. We provide at no cost or require proof of immunity for Influenza, Measles, Mumps, Rubella, Tetanus, Diphtheria, Pertussis, Varicella and Hepatitis B. Vaccinations are a mandatory condition of employment, though health care workers can receive a medical or religious exemption. Our annual influenza vaccination rate is above 99%. To allow an employee to decline recommended vaccinations on the basis of personal preference is unwise and puts patients and employees at risk of preventable infections.

When one of our employees at Intermountain is exposed to infection at work (e.g. needle stick injury), we provide prompt evaluation and follow up at no cost to the employee. If treatment and/or medication is required we provide that to the employee at no cost. As per our HR policies, if an employee is required to miss work because of an infection or an exposure, we pay that employee their usual wages and benefits. We keep records of all infection exposure incidents. Your proposed requirement that such records be maintained for 30 years does not make sense medically and would place an undue burden and expense on employers.

All new employees at Intermountain undergo thorough training in infection control at the time of initial hire with yearly updates also required. The training covers all of the elements listed in the proposed regulatory framework. We provide additional training as needed, as required by new infectious threats such as Ebola. Training records are tracked electronically.

Although Intermountain complies with most of the elements outlined in the proposed regulatory framework, we still believe that adding this layer of regulatory oversight is unnecessary and duplicative. Our hospitals are already closely monitored by a variety of regulatory bodies including the Centers for Medicare & Medicaid Services (CMS), the Joint Commission, the state health department and our local Quality Improvement Organization (QIO). Our labs are subject to regular CAP inspections. It is very important for all hospitals to receive and maintain CMS certification. Compliance with CMS Conditions of Participation, and with Joint Commission standards is a major focus for us. All of these regulatory agencies have infection control and employee health standards with which we must comply. Each have provisions for anonymous complaints by patients, families or employees, and the agencies actively follow up on such complaints. We also have an internal compliance hotline available for anonymous complaints by employees.

CMS and other payors have instituted various financial incentives to motivate hospitals to improve care and avoid infectious complications. The CMS Value Based Purchasing initiative tracks hospitals' performance on CAUTIs, CLABSIs, Mortality, Core Measures, etc. Hospitals can lose up to 2% of their total CMS reimbursement for failure to improve and/or perform at very high compliance levels. The CMS Hospital Acquired Condition Program monitors NHSN data on CAUTI, CLABSI and Surgical Site Infections (SSIs) for colon surgeries and hysterectomies. Next year they will add Methicillin-resistant

staphylococcus aureus (MRSA) and Clostridium difficile colitis (C. diff) infections. Hospitals performing in the lowest quartile on these measures can lose an additional 1% of total CMS payments. A number of private insurers are refusing to pay for "never events" such as central line infections or surgical site infections.

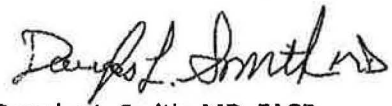
The above initiatives are weighted towards preventing infectious complications and have substantial financial implications for both large and small hospitals. This is particularly true for small not for profit facilities which operate on very narrow margins. Just as important as the financial incentives, however, are the associated reputational implications of these programs. CMS and other payors are increasingly insisting on transparency of quality data, including data relating to infectious complications. Consumers are increasingly able to access such data and use it to decide where they will go to receive their health care. This is true in even small rural markets where individuals may choose to drive long distances to receive health care if they perceive a lack of quality or safety at their local hospital.

The various financial and reputational factors discussed above have led to considerable improvement in health care associated infections over the last few years and will continue to drive improvement in the foreseeable future. These are what may be termed market forces and tend to have much more influence on institutional behavior than mere regulatory or rule-based approaches. In our experience, excessive regulation adds expense to industry and actually impedes real progress towards quality improvement as organizations devote time and effort towards regulatory compliance rather than focusing on improving quality.

Let me emphasize that the same measures taken to improve patient safety and prevent hospital associated infections have a direct influence on employee safety. Vaccinations, isolation procedures, hand hygiene, appropriate use of PPE, safe handling of infectious waste and multiple other interventions serve to protect both patients AND employees. Simply put, you cannot do one without the other.
In summary, Intermountain Healthcare believes there is insufficient data that the scope of the problem justifies an additional layer of government oversight and complexity. Much of the data cited in the representative materials is badly out of date (e.g. hand hygiene data from 2008). Estimates provided by OSHA for the time needed to prepare and update required documents are probably half of what would actually be required. Current regulatory oversight by CMS and accrediting bodies along with market forces and reputational considerations are sufficient to influence ongoing improvement by hospitals to prevent infectious complications in our patients and employees.

Thank you once again for the opportunity to participate on the SBREFA panel and to provide written comments. Please feel free to contact me with any questions or concerns.

Respectfully submitted,



Douglas L. Smith, MD, FACP
Associate Chief Medical Officer
Intermountain Healthcare

Paige, Lajuane M. - OSHA CTR

From: Georgine Snyder <SnyderG@diakon.org>
Sent: Tuesday, November 25, 2014 9:17 AM
To: Paige, Lajuane M. - OSHA CTR
Subject: OSHA's small business Advocacy Review Panel on Occupational Exposure to Infections Disease

Good Afternoon,
Mr. Robert Burt, Chair
SBAR Panel on Infectious Diseases
Occupational Safety and Health Administration
U.S. Department of Labor
200 Constitution Avenue, NW
Washington, DC 20210

I participated in the conference call on this topic on November 12, 2014 and would summarize my comments as follows:

Significant concern over the medical removal program including wages and benefit accrual etc.

After decades of business in longterm care no employee cases have surfaced from exposure to ill residents.

All vaccinations mentioned would not necessarily help our employee population who are not exposed to children with diseases such as Measles, mumps and rubella while adding cost for titers and immunizations. Td is provided as needed when an injury is sustained. Influenza and Hep B are already offerred. Tb testing is already being done.

More specific explanation is needed as to how the medical removal program would interface with Family Medical Leave.

Somehow it seems that Workers Compensation providers would have to cover the employee who became ill in and out of the course of their work. In our case , we are self insured so we pay from the first dollar anyway.

Longterm Care is already required to have Infection Control Policies so I believe this component is redundant.

Thank You for the opportunity to participate in the meaningful discussion.

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CARE CENTER
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November 28, 2014

Mr. Robert Burt, Chair
SBAR Panel on Infectious Diseases
Occupational Safety and Health Administration
U. S. Department of Labor
200 Constitution Avenue, NW
Washington, DC 20210

Re: Written Comments on OSHA's Infectious Disease SBAR Panel

Dear Mr. Burt:

Thank you for convening and serving as Chair of OSHA's SBAR Panel on Infectious Diseases. We appreciate OSHA's consideration of the comments received and the concerns expressed by the Small Entity Representatives ("SERs") throughout the process.

I am writing on behalf of Holly Heights Nursing Home, a 133 bed long term care facility in Denver, CO.

At the outset, we would like to emphasize the unique nature of the nursing home and assisted living environment (the "long term care industry"). The long term care industry must navigate multiple regulatory schemes designed to protect the safety and health of employees and the safety and health of residents. In the long term care industry, residents are guaranteed certain rights which can impact how a facility is able to implement workplace safety and health rules. For residents, their rooms are their "homes" and facilities can be prohibited from taking certain actions which infringe upon how a resident is allowed to "live" in their homes. As OSHA continues to examine this rule, it is important for the Agency to specifically review how the requirements will be implemented in the long term care industry given the unique residents-rights issues involved.

As with many of the other small Entity Representatives ("SERs") involved in the SBAR Panel review, we have experience with OSHA's bloodborne pathogens standard and recognize that OSHA has borrowed some of the principles from that standard in this regulatory initiative. We have concerns however, as to whether OSHA has justified the need for this action in the first instance. Furthermore, several of the provisions we fear will be difficult and burdensome to implement. We ask that OSHA review the need for the rule and many of its provisions before proceeding with a proposal.

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www.hollyheightsncc.com

Worker Infection Control Plan

The lynchpin of OSHA's approach in this rulemaking is the requirement that employers develop a Worker Infection Control Plan ("WICP"). The WICP seems similar in design to a bloodborne pathogen exposure control plan. According to the draft proposal, developing a WICP will involve identifying the potential sources of infection at a facility and the employees potentially exposed. It would need to be updated annually.

In addition to the WICP, there is a requirement for employers to implement a number of Standard Operating Procedures ("SOPS") that are consistent with recognized and generally accepted good infection control practices. These SOPS would need to be updated as the Centers for Disease Control ("CDC") or other organizations implement or change guidance in the area of infectious diseases. OSHA has identifies the need for numerous SOP's.

For small employers in the long term care industry, the development and ongoing updating of SOP's will be extremely burdensome. Most small employers do not have in-house resources readily available to continually track CDC or other guidance from the public health community. OSHA's use of a process safety management ("PSM") approach to this rule will place a heavy burden on small employers. Aside from the burden associated with this, small employers will have difficulty – without specific guidance from OSHA – knowing which practices need to be examined and updated.

Host-Contractor Provisions

We are also concerned about the proposed requirements for contractor safety. As set forth in the SBREFA materials, OSHA requiring host employers to ensure that contractors, vendors, or independent healthcare practitioners, adhere to infections control procedures at least as effective as the host employer's.

While we understand OSHA's overall concern with ensuring all employers at a facility are following good hygiene practices and implementing appropriate protective measures, it is a real challenge in the long term care environment to ensure that contractors are adhering to facilities" (or even their own) infectious disease procedures. In the long term care industry, often contractors are specifically selected by the residents – particularly in the case of independent healthcare practitioners. It is very difficult to establish control over these individuals. As I stated in the conference call meeting, in Colorado it is almost impossible to monitor and ensure that all Licensed Health Practitioners have received the influence vaccine as required.

In addition, in the long term care industry, many families will hire "sitters" to come into the facility to spend time with resident family members. These sitters are often not "employees" Under the Occupational Safety and Health Act of 1970 and it will be extremely difficult for small employers to take action to ensure that these contractors are in full compliance with OSHA's proposed requirement.

Medical Screening and Medical Removal Protection

OSHA's proposed framework would require employers to provide certain vaccinations to employees as provided by recognized and generally accepted good infection control practices. In addition, medical screening and surveillance services would need to be provided to employees post exposure. In addition, it is determined that employees must remain outside of work due to a medical condition related to workplace exposure to an infectious disease, employers must ensure that these employees maintain full pay and benefits during this time.

We have concerns regarding how these cost will be handled by small employers in the long term care industry and would encourage OSHA to examine very closely whether workers compensation will cover certain infectious diseases. From informal conversations with certain workers compensation insurers, we understand that many OSHA-covered infectious diseases will not be supported by workers compensation, causing the full costs to be borne by the employers. We also ask that you evaluate the increased cost to the employers through increased Worker's Compensation insurance programs, as well as employer cost not covered by the insurance.

When examining the cost of these provisions, we encourage OSHA to also consider the practical impact of medical removal protection ("MRP") on small employers. Many small employers do not have large staffs to draw from to cover for work absences, particularly extended work absences. In these situations, employers may need to hire from temporary staffing agencies or make other arrangements. When determining the appropriateness of MRP, we encourage the Agency to consider the full financial burden associated with hiring a second employee, while maintaining full pay and benefits of the employee out of work on medical removal (without any offset from workers compensation).

We also request that OSHA examine the purpose of MRP in this rule vis-à-vis prior OSHA health standards that have required MRP. In those other standards, the Agency has required MRP based on evidence that employees may be reluctant to report illnesses or participate in medical surveillance for fear of losing pay and benefits. We ask OSHA to examine specifically if there is such evidence in the area of infectious disease in the affected industries to justify this burden before proceeding to include MRP in any proposed rule.

Cost Estimates

We appreciate OSHA's efforts to estimate the costs of the proposal. However, our initial review of the costs suggests that they are understated, particularly with respect to the provision and use of personal protective equipment ("PPE")

As a general matter, OSHA has estimated that much of the PPE can be used multiple times throughout a shift (e.g., a facemask can be used until visibly soiled). We respectfully suggest that OSHA – cost estimate purposes – substantially increase the number of times per shift that PPE must be changed. As a best practice, many employers have implemented single-use practices and particularly with employees with doing direct patient care responsibilities. We also anticipate that for certain disease outbreaks recognized and generally accepted infection control practices could mandate single use for PPE. We respectfully request that OSHA consider this when issuing any proposed rule.

Again, we appreciate OSHA conducting the SBAR Panel review and considering the concerns of affected SER's. Should the Agency have any further questions related to the proposal or its impacts on the long term care industry, we would be happy to assist.

Sincerely,

Janet Snipes

Janet Snipes
Administrator

December 3, 2014

TO: Mr. Robert Burt, Chair
SBAR Panel on Infectious Diseases
Occupational Safety and Health Administration
U.S. Department of Labor
200 Constitution Avenue, NW
Washington, DC 20210

From: Janice K. Pliszczak, DDS, MS, MBA, MAGD
4525 West Seneca Turnpike
Syracuse, NY 13215-9785
(315) 469-3229 (O)
janicep@twcny.rr.com

RE: Written Comments on the proposed OSHA Infectious Diseases Regulations

Dear Mr. Burt,

I recommend strongly that the Occupational Safety and Health Administration (OSHA) refrain from development of a new standard to address the protection of healthcare workers from infectious diseases not already covered by the Bloodborne Pathogens (BPP) standard.

OSHA has not demonstrated that there is "a significant risk of material impairment of employee health"

Unlike tracking of HIV by the Centers for Disease Control (CDC), and tracking of bloodborne pathogens that find significant risk, OSHA has not yet provided sufficient data to provide significant risk of material impairment to employee health. While I believe strongly in being proactive in efforts to contain the spread of disease before it begins, I would also caution against rushing to a quantitative response to recent news stories, for example, about Ebola. That is, rather than develop more standards that might cause a lengthier educational curve for compliance, it is more timely and critical to enforce compliance with current standards and response protocols.

A new standard may decrease common sense precautions

Establishment of any standard carries with it the risk that the parties required to comply will do just enough to comply, and nothing more. Based upon the *Infectious Diseases SBAR Panel Issues Document* ("Issues Document"), some of the requirements in consideration as part of the potential new standard set the bar lower than what is currently practiced.

For example, page 15 of the Issues Document suggests wearing a facemask until visibly soiled. In my experience, most dentists change masks after each patient since there are aerosols flying onto the mask.

The Issues Document also estimates a requirement of on pair of gloves per patient. In practice, dental personnel change gloves at least twice per patient. Depending on the length and extent of a procedure, a practice could go through up to four or five pairs of gloves per patient: one pair of gloves to anesthetize the patient before giving them time to numb; changing gloves if one has to leave the room to do a hygiene exam; for the assistant, changing gloves if he or she has to retrieve an additional instrument or material; etc.

These practices are dictated by common sense. Practicing to the minimal requirement of a new standard would forego common sense for a compliance mindset, which has the risk of resulting in *lesser* precautions and greater disease risk.

Given the adequacy of current precautions, the burden of compliance with a new standard, either alone or as addendum/amendment to the existing standard, outweighs any potential benefit

I work in an office of four people including myself. My office is typical of the vast majority of dental practices. The proposed rule would be unduly burdensome for the small dental practice in terms of time and expense; as an example of expense, OSHA estimates a flu shot at $11, when I in fact pay $35-40 for the same. Maintaining my strong recommendation that the standard not be developed, I would at a minimum recommend that small entities and small employers be exempted from any such potential standard (Alternative 3 and 5 on page 30 of the Issues Document).

OSHA also noted that the guidelines could be incorporated into existing guidelines; this would only add the burden of training to the compliance of both the new language and its effect as amendment to existing language. Moreover, a standard codifying contact, droplet and airborne precautions may result in unwarranted absenteeism and decreases in workplace productivity.

Nonetheless, I believe a standard would be worth development if it truly conveys an unduplicated benefit that fills a void. Unfortunately, the new standard in consideration for development would not provide such a benefit. As OSHA noted, much of what is in consideration for addressing contact, droplet, and airborne pathogens is already covered in the BPP. The remainder is covered by common sense.

As a simple example from my practice, I had a patient's mother call to say that she was just diagnosed with strep throat, and I simply rescheduled the appointment. If an infectious patient has a toothache, I might prescribe an antibiotic and see them in a few days.

Broadly, to echo another task force member who voiced opposition on a task force call, OSHA has not completed a sufficient cost-benefit analysis to pursue development of a new standard at this time.

Sincerely,

Janice K. Pliszczak, DDS, MS, MBA, MAGD

Cypress Glen
RETIREMENT COMMUNITY
100 Hickory Street • Greenville, NC 27858
(252) 830-0036 • Fax (252) 830-0411
www.CypressGlen.org

Written response to the SBAR Panel review of infectious diseases regulatory framework

We appreciated the opportunity to participate in the panel discussion of the infectious diseases regulatory framework review. As our SHARP recognition and low incident rates indicate, Cypress Glen promotes a culture of safety and takes the well-being of our employees seriously.

As a non-profit continuing care retirement community providing long term care, assisted living and memory care services, the proposed regulation would apply to several departments, from nursing staff to housekeeping to food service; covering approximately 200 employees.

Our chief concern regarding this standard is the application of medical removal protection. We believe that the requirement is both cost-prohibitive and punitive to healthcare employers. The most common infectious disease that we foresee affecting our workplace is norovirus. Due to its virulence, norovirus outbreaks are typically widespread through the city; occurring in the local hospital, the local university and the school system. Because an employee's exposure during outbreaks can occur virtually anywhere, his or her exposure at work cannot be definitively proven. If exposure is not definitive, then the employer should not be responsible for compensation while the employee is out of work, other than honoring established paid time off policies. These additional labor costs cannot be easily absorbed by a non-profit business, nor is it just to require only healthcare employers to shoulder this burden when other workplaces (schools, universities) pose the same exposure risks.

Thank you for taking our concerns into consideration when completing your review.

Jim Sakell
Director of Facility Services

Paige, Lajuane M. - OSHA CTR

From: John J Russell MD <jrussell@clas.net>
Sent: Wednesday, December 03, 2014 3:10 PM
To: Paige, Lajuane M. - OSHA CTR
Cc: Lundegren, Bruce E.; North, Tristan; Maria Bianchi
Subject: Re: Written Comments on the proposed OSHA Infectious Diseases Regulations
Attachments: SER Written Comments on OSHA ID Framework.docx

Ms Paige;

Please see the attached document to be forwarded to Mr Burt. Thank-you for allowing me to participate in this process, it has been a learning experience.

John J. Russell MD
Cape County Private Ambulance Service, Inc.
1458 N. Kingshighway
Cape Girardeau MO 63701
573-335-2191

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From: Paige, Lajuane M. - OSHA CTR [mailto:Paige.Lajuane@dol.gov]
Sent: Monday, December 01, 2014 3:02 PM
To: Paige, Lajuane M. - OSHA CTR
Cc: Burt, Robert - OSHA; bruce.lundegren@sba.gov; McCormick, Charles - OSHA
Subject: Thank You!

Dear Small Entity Representative,

Thank you for your participation and help over the last several months. Your comments have been extremely helpful in guiding OSHA's work on an Infectious Diseases Rule. OSHA, along with the Small Business Administration's Office of Advocacy and the Office of Management and Budget appreciate your hard work.

We would still like to receive written comments from you, up until the close of business on Wednesday, December 3. Please submit comments as your comments, and please do not represent them as comments of a trade association or as representing a trade association. However, if your trade association has provide you with comments that you endorse, you can send them to us as a separate attachment, and the Panel will consider them.

Thank you again.

Yours,
LaJuane Paige
SBREFA Coordinator

John D. Slack, CFSP and David J. Weber, CFSP, CCO, have been asked by the SBA to serve as SER's on this panel for the proposed Infectious Disease Standard. We own and operate small privately owned funeral homes in Maryland. Mr. Slack's funeral home services approximately 175 families annually and is located in Ellicott City, MD. David J. Weber has two small privately owned and operated funeral homes in Baltimore. One is located near Catonsville, MD and the other is in the Fells Point area of Baltimore. Combined, these two facilities service about 75 families per year.

Both of us recognize the need for such a standard in a hospital setting, as evidenced by the testimony taken from a number of the presenters during the November 14, 2014 panel hearing. We do not dispute that, in those health settings, there is a real possibility of exposure to airborne infectious disease. This condition, however, does not exist in a funeral home, either in the transferring of the deceased from the place of death or in the preparation of the deceased. Any actual or potential exposure to infectious disease is met by the Bloodborne Pathogen Standard, which is scrupulously followed by the funeral profession.

From some of the questions asked and the materials previously provided by OSHA, it is clear that OSHA is under the misconception that an autopsy suite, in a hospital, and a preparation room, in a funeral home, create the same hazard to employees working in these locations. Nothing can be further from the truth. The autopsy process is invasive, using saws and other implements that are never used in funeral service, and employs procedures that can and will result in an aerosolation of infectious microorganisms. A funeral preparation, in a funeral home, both in the instruments used and the procedures that are followed, is not similarly invasive and does not produce aerosolization. The only constant between a hospital autopsy suite and a funeral home preparation room, is the presence of dead human remains and nothing else.

In a funeral preparation there is no significant risk of material impairment to employees, providing direct patient care or performing their covered tasks, from aerosolized infectious disease. Any potential hazard that does exist is contained by the OSHA Bloodborne Pathogen Standard. The effect of the OSHA Bloodborne Pathogen Standard, and its ability, through Universal Precautions, to address the type of infection that may occur in funeral service, as well as its effectiveness in maintaining the safety and health of funeral service employees, is clearly evidenced by OSHA's own designation of funeral service as a low hazard industry.

Funeral service, unlike an acute care facility such as a hospital, also is not and will never be privy to forehand knowledge regarding cause of death, conditions of death, or the presence of significant airborne infectious disease that may have existed when the deceased patient was still alive. A death certificate, which can be written a significant time after a death and, often by necessity, after human remains are transferred to a funeral home and the embalming process is started, also may not indicate the presence of an infectious disease that may have existed in the remains prior to death, if that disease was not the cause of death. There is, therefore, no way for a funeral director to make an independent medical determination of the existence of an infectious disease, whether airborne or bloodborne, prior to transfer or embalming. For this reason, Universal Precautions, under the Bloodborne Pathogen Standard, are followed in every case.

Funeral Service, while not subject to third party accreditation, is subject to existing

federal and state OSHA standards, as well as random inspections by state health departments, regarding minimal levels of sanitation and procedures designed to effectively protect the general public and funeral home employees.

The OSHA materials provided have not demonstrated that there is a significant risk of material impairment of employee health to employees providing direct patient care or performing their covered tasks in the practice of funeral service. The proposed Infectious Disease Standard does not address the actual situation in a funeral home or any potential exposure to infectious disease by funeral home employees, whether in the transfer of the decedent from the place of death or in the preparation process. The proposed regulation will not further reduce the risk of infection to funeral service employees. The inclusion of funeral service in the proposed Infectious Disease Standard is unnecessary, duplicative and onerous.

It is our position that funeral service should be exempted from the proposed Infectious Disease Standard, given the fact that any actual hazard is fully covered by employers' compliance with the existing OSHA Bloodborne Pathogen Standard, including Universal Precautions, and funeral service's classification by OSHA as a low hazard industry which evidences the effectiveness of the OSHA Bloodborne Pathogen Standard to control work related infectious disease.

Furthermore, it has come to our attention that a concern has been raised regarding the potential exposure when moving a deceased remains and the possible lack of utilization of Personal Protective Equipment by funeral home staff for these tasks.

We are unaware of any funeral homes that do NOT practice Universal Precautions for this task. At the very least, funeral home staff are wearing gloves and masks during the transfer of the deceased. Many funeral homes take the added precaution of placing a mask on the deceased. In Maryland, it is also required that our transport vehicles be equipped with gloves, masks, gowns, head and shoe covering, goggles, antibacterial soap and disinfectant spray.

The Slack Funeral Home, P.A. and David J. Weber Funeral Homes, P.A., have been providing funeral services for 85 years and 94 years respectfully. Six employees are employed at the Slack Funeral Home and eight employees are currently employed at the David J. Weber Funeral Homes. Neither funeral home has ever had an employee contract an infectious disease from patient/employee contact.

We thank you for granting us the opportunity to comment on the proposed Infectious Disease Standard.

Very truly yours,

David J. Weber, CFSP, CCO
David J. Weber Funeral Homes, P.A.

John D. Slack, CFSP
Slack Funeral Home, P.A.

November 25, 2014

Mr. Robert Burt, Chair
SBAR Panel on Infectious Diseases
Occupational Safety and Health Administration
U.S. Department of Labor
200 Constitution Avenue, NW
Washington, DC 20210

Re: Written Comments on OSHA's
Infectious Disease SBAR Panel

Dear Mr. Burt:

Thank you for convening and serving as Chair of OSHA's SBAR Panel on Infectious Diseases. We appreciate OSHA's consideration of the comments received and the concerns expressed by the Small Entity Representatives ("SERs") throughout the process.

I am writing on behalf of Louisiana Nursing Home Association and its 260 member nursing facilities and assisted living facilities, and the 30,000 Louisianans employed by them.

At the outset, we would like to emphasize the unique nature of the nursing facility and assisted living environment (the "long term care profession"). The long term care profession must navigate multiple regulatory schemes designed to protect safety and health of employees and the safety and health of residents. In the long term care profession, residents are guaranteed certain rights, which can impact how a facility is able to implement workplace safety and health rules. For residents, their rooms are their "homes" and facilities can be prohibited from taking certain actions which infringe upon how a resident is allowed to "live" in their homes. As OSHA continues to examine this rule, it is important for the Agency to specifically review how the requirements will be implemented in the long term care profession given the unique residents' rights issues involved.

As with many of the other Small Entity Representatives ("SERs") involved in the SBAR Panel review, we have experience with OSHA's bloodborne pathogens standard and recognize that OSHA has borrowed some of the principles from that standard in this regulatory initiative. We have concerns, however, as to whether OSHA has justified the need for this action in the first instance. Furthermore, several of the provisions, we fear, will be difficult and burdensome to

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implement. We ask that OSHA review the need for the rule and many of its provisions before proceeding with a proposal.

Worker Infection Control Plan

The lynchpin of OSHA's approach in this rulemaking is the requirement that employers develop a Worker Infection Control Plan ("WICP"). The WICP seems similar in design to a bloodborne pathogen exposure control plan. According to the draft proposal, developing a WICP will involve identifying the potential sources of infection at a facility and the employees potentially exposed. It would need to be updated annually.

In addition to the WICP, there is a requirement for employers to implement a number of Standards Operating Procedures ("SOPs") that are consistent with recognized and generally accepted good infection control practices. These SOPs would need to be updated as the Centers for Disease Control ("CDC") or other organizations implement or change guidance in the area of infectious disease. OSHA has identified the need for numerous SOPs.

For small employers in the long term care profession, the development and ongoing updating on SOPs will be extremely burdensome. Most small employers do not have in-house resources readily available to continually track CDC or other guidance from the public health community. OSHA's use of a process safety management ("PSM") approach to this rule will place a heavy burden on small employers. Aside from the burden associated with this, small employers will have difficulty – without specific guidance from OSHA – knowing which practices need to be examined and updated.

Host-Contractor Provisions

We are also concerned about the proposed requirements for contractor safety. As set forth in the SBREFA materials, OSHA is requiring host employers to ensure that contractors, vendors, or independent healthcare practitioners, adhere to infectious control procedures as effective as the host employer's procedures.

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In addition, in the long term care profession, many families will hire "sitters" to come into the facility to spend time with resident family members. These sitters are not "employees" under the Occupational Safety and Health Act of 1970 and it will be extremely difficult for small employers to take action to ensure that these contractors are in full compliance with OSHA's proposed requirements.

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OSHA's proposed framework would require employers to provide certain vaccinations to employees as provided by recognized and generally accepted good infection control practices. In addition, medical screening and surveillance services would need to be provided to employees post exposure. In addition, if it is determined that employees must remain outside of work because of a medical condition related to workplace exposure to an infectious disease, employers must ensure that these employees maintain full pay and benefits during this time.

We have concerns regarding how these costs will be handled by small employers in the long term care profession and would encourage OSHA to examine very closely whether workers compensation will cover certain infectious diseases. From informal conversations with certain workers compensation insurers, we understand that many OSHA-covered infectious diseases will not be supported by workers compensation, causing the full costs to be borne by employers.

When examining the costs of these provisions, we encourage OSHA to also consider the practical impact of medical removal protection ("MRP") on small employers. Many small employers do not have large staffs to draw from cover to cover for work absences, particularly extended work absences. In these situations, employers may need to hire from temporary staffing agencies or make other arrangements. When determining the appropriateness of MRP, we encourage the Agency to consider the full financial burden associated with hiring a second employee, while maintaining full pay and benefits of the employee out of work on medical removal (without any offset from workers compensation).

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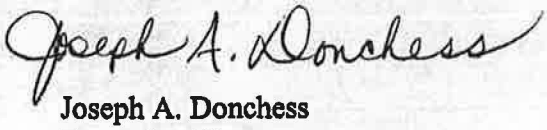
We appreciate OSHA's efforts to estimate the costs of the proposal. However, our initial review of the costs suggests that they are understated, particularly with respect to the provision and use of personal protective equipment ("PPE").

As a general matter, OSHA has estimated that much of the PPE can be used multiple times throughout a shift (e.g., a facemask can be used until visibly soiled). We respectfully suggest that OSHA – for cost estimate purposes – substantially increase the number of times per shift that PPE must be changed. As a best practice, many employers have implemented single-use practices and particularly with employees with direct patient care responsibilities. We, also, anticipate that for certain disease outbreaks, recognized and generally accepted infection control practices could mandate single use for PPE. We respectfully request that OSHA consider this when issuing any proposed rule.

Again, we appreciate OSHA conducting the SBAR Panel review and considering the concerns of affected SERs. Should the Agency have any further questions related to the proposal or its impacts on the long term care profession, we would be happy to assist.

Sincerely yours,



Joseph A. Donchess
Executive Director

JAD:jb

Paige, Lajuane M. - OSHA CTR

From: Judy Dahl <jdahl@jmhsmn.org>
Sent: Tuesday, December 02, 2014 10:06 AM
To: Paige, Lajuane M. - OSHA CTR
Cc: Lundegren, Bruce E.
Subject: infectious disease panel

Thank you for allowing me to participate in this panel. It has been an interesting experience. My comments are as follows.
(1).I believe, we in health care, are doing most of what you are proposing by following the Blood Borne Pathogen guideline and that further rules/regulations would be redundant. We are also held to the CDC standard, MPCA, DOT and of course the MN Dept. of Health which covers a most of the proposed rules.
(2). I'm concerned with how it would be decided if an illness is work related or is community acquired. This would include such illnesses as influenza and Norwalk virus. These illnesses are usually brought into the facility from the outside by employees and visitors.
(3). We already have a very pro-employee workman's comp. program in MN. Workman's comp is a huge expense already, so you need to define this much better.
(4). Your estimate of glove use is WAY below what is the current practice in healthcare. For one patient/resident there could be up to 4-6 glove changes with morning cares, 2 glove changes with each incontinent episode, 2-3 glove changes with a routine wound dressing change and then it's time for bedtime cares and another 4-6 changes.
(5). Our care center is an old building. If we had to put in an airborne isolation room it would be very expensive. Also, how many rooms would we need because airborne infections usually effects more than one person how would we decide who goes where? The care center is also the resident's home and it is important it be treated as such.
(6). What if we have done all the required training and the employee does not follow the training and guidelines, and because of their own choice, gets sick, is the employer still responsible?
(7). I believe Alternative 2, which is to rely on enforcement under the general duty clause, is the best approach.
Again, thank you for the opportunity to participate, Judy Dahl RNBC, ADON

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LEXINGTON REGIONAL HEALTH CENTER

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December 3, 2014

TO: Mr. Robert Burt, Chair
SBAR Panel on Infectious Diseases
Occupational Safety and Health Administration
U.S. Department of Labor
200 Constitution Avenue, NW
Washington, DC 20210

From: Leslie Marsh, CEO
Lexington Regional Health Center
P.O. Box 980
Lexington, NE 68850

RE: Written Comments on the proposed OSHA Infectious Diseases Regulations

Dear Mr. Burt,

I'd like to offer the following comments as a follow up to the telephone conversation held on November 14, 2014. My comments are based upon my experiences at Lexington Regional Health Center (LRHC) where I served as the Chief Nursing Officer from 1998 to 2010 and as the CEO since May of 2010. Prior to moving to LRHC I was the Employee Health Nurse at Good Samaritan Hospital in Kearney, Nebraska. LRHC is a 25 bed Critical Access Hospital serving approximately 25,000 people in south central Nebraska. Good Samaritan Hospital is a 270-bed PPS hospital that is the major referral center for south central Nebraska.

One common element at my small Critical Access Hospital and at the much larger regional referral hospital is that both are operating in an environment that is heavily regulated. In fact, all hospitals that receive federal funding, such as through the Medicare program, are heavily regulated. Best practices require that we follow all applicable CDC guidelines. While the CDC guidelines are not literally regulations they function as such in the healthcare workplace environment. Conditions of participation reference CDC guidelines are strictly adhered to. Additional oversight agencies such as The Joint Commission and DNV require adoption and implementation of CDC and other nationally recognized health agency guidelines.

The emergence of HIV/AIDS created an extreme awareness of the workplace dangers inherent in health care settings. Facilities were required to create extensive Exposure Control Plans and adopt Standard or Universal Precautions. The adoption of these new practices changed the mindset of healthcare workers because the new default position was an assumption that the patient was infectious. Over time, this precautionary paradigm led to respiratory hygiene programs where masks are now required in many specified situations. Many organizations, although not mandated, require all employees that choose not to receive a flu shot are required to wear a mask when there is any possible risk of exposure. This protects both patients and healthcare workers.

Through professional conferences, formal and informal networking, accreditation, and various levels of external oversight our hospitals are continually involved in creating policies designed to reduce the likelihood of transmission of infections. With this existing environment the central question is what is the benefit of the proposed OSHA regulatory framework relative to its cost.

According to recent reports generated by OSHA (i.e. Facts About Hospital Worker Safety), musculoskeletal injuries, stemming from falls and lifts, comprise the vast majority of injury or illness occurring in the health care. Illness only accounted for 7 percent of events, which resulted in days away from work. Reviewing LRHC records relating to employee illnesses over a five year period shows that we had zero occurrences.

Rural hospitals are under increasing financial stress, with 43 hospitals closing since 2010. As a responsible executive then, I have to be very efficient in how I use scarce resources. Implementing the OSHA proposal would inflict a new set of costs on my hospital. If I had confidence that these new costs would have substantial benefits, I would find a way to make the resources available for implementation with or without formal regulations. Under the current circumstances though, I have little confidence that the suggested proposed rule would confer a noticeable benefit. It's been several years since I had an economics course, but I well remember the notion of opportunity cost. Any money I spend on the proposed rule takes money from other endeavors. There is a considerable laundry list of costs that would stem from this new regulation: record keeping and storage (for 30 years beyond employment); training that is fundamentally redundant relative to our existing training; the initial implementation costs (writing, managing, signage, monitoring and evaluating) and supply costs. The costs as defined in the current proposed rule are not representative of our actual experience. Operating in an increasingly cost conscious environment, my hospital cannot magically generate free resources to address a largely redundant exercise.

As a healthcare manager I understand that my skilled workforce is critical to the success of our community hospital. Whether it is a response to emerging challenges like Ebola, MERs or SARs or continual refinement of protocols for influenza, meningitis and tuberculosis, I am already committed to providing the safest possible work environment. Agencies like the CDC and professional organizations like the AHA and AMA are continually providing up-to-date guidance relating to infection control. Given the recognized expertise of the existing resources I see minimal benefit from the proposed regulation. I understand the national cost-benefit analysis has not been completed. I have confidence that at my facility the costs of the proposed regulations far outweigh the benefits.

I appreciate the work that OSHA has done to create safer environments for workers. I also appreciate OSHA's willingness to hear the concerns of small businesses. While the proposed rule was drafted to further protect workers, the costs imposed on small businesses would be onerous. Thank you for considering these comments.

Sincerely,

Leslie Marsh

lmarsh@lexrhc.org

308-324-8303

AHCA. NCAL.
AMERICAN HEALTH CARE ASSOCIATION NATIONAL CENTER FOR ASSISTED LIVING

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December 2, 2014

Mr. Robert Burt, Chair
SBAR Panel on Infectious Diseases
Occupational Safety and Health Administration
U.S. Department of Labor
200 Constitution Avenue, NW
Washington, DC 20210

Re: Written Comments on OSHA's Infectious Disease SBAR Panel

Dear Mr. Burt:

Thank you for convening and serving as Chair of OSHA's SBAR Panel on Infectious Diseases. We appreciate OSHA's consideration of the comments received and the concerns expressed by the Small Entity Representatives ("SERs") throughout the process.

I am writing on behalf of the American Health Care Association and the National Center for Assisted Living. The American Health Care Association and National Center for Assisted Living (AHCA/NCAL) represent more than 12,000 non-profit and proprietary skilled nursing centers, assisted living communities, sub-acute centers and homes for individuals with intellectual and developmental disabilities. By delivering solutions for quality care, AHCA/NCAL aims to improve the lives of the millions of frail, elderly and individuals with disabilities who receive long term or post-acute care in our member facilities each day.

At the outset, we would like to emphasize the unique nature of the nursing home and assisted living environment (the "long term care industry"). The long term care industry must navigate multiple regulatory schemes designed to protect the safety and health of employees *and* the safety and health of residents. In the long term care industry, residents are guaranteed certain rights, which can impact how a facility is able to implement workplace safety and health rules. For residents, their rooms are their "homes" and facilities can be prohibited from taking certain actions which infringe upon how a resident is allowed to "live" in their homes. As OSHA continues to examine this rule, it is important for the Agency to specifically review how the requirements will be implemented in the long term care industry given the unique residents-rights issues involved.

As with many of the other Small Entity Representatives ("SERs") involved in the SBAR Panel review, we have experience with OSHA's bloodborne pathogens standard and recognize that OSHA has borrowed some of the principles from that standard in this regulatory initiative. We have concerns however, as to whether OSHA has justified the need for this action in the first instance. Furthermore, several of the provisions we fear will be difficult and burdensome to implement. We ask that OSHA review the need for the rule and many of its provisions before proceeding with a proposal.

Worker Infection Control Plan

The lynchpin of OSHA's approach in this rulemaking is the requirement that employers develop a Worker Infection Control Plan ("WICP"). The WICP seems similar in design to a bloodborne pathogen exposure control plan. According to the draft proposal, developing a WICP will involve identifying the potential sources of infection at a facility and the employees potentially exposed. It would need to be updated annually.

In addition to the WICP, there is a requirement for employers to implement a number of Standard Operating Procedures ("SOPs") that are consistent with recognized and generally accepted good infection control practices. These SOPS would need to be updated as the Centers for Disease Control ("CDC") or other organizations implement or change guidance in the area of infectious disease. OSHA has identified the need for numerous SOPs.

For small employers in the long term care industry, the development and ongoing updating of SOPs will be extremely burdensome. Most small employers do not have in-house resources readily available to continually track CDC or other guidance from the public health community. OSHA's use of a process safety management ("PSM") approach to this rule will place a heavy burden on small employers. Aside from the burden associated with this, small employers will have difficulty – without specific guidance from OSHA – knowing which practices need to be examined and updated.

Host-Contractor Provisions

We are also concerned about the proposed requirements for contractor safety. As set forth in the SBREFA materials, OSHA is requiring host employers to ensure that contractors, vendors, or independent healthcare practitioners, adhere to infectious control procedures at least as effective as the host employer's.

While we understand OSHA's overall concern with ensuring all employers at a facility are following good hygiene practices and implementing appropriate protective measures, it is a real challenge in the long term care environment to ensure that contractors are adhering to facilities' (or even their own) infectious disease procedures. In the long term care industry, often contractors are specifically selected by the residents – particularly in the case of independent healthcare practitioners. It is very difficult to establish control over these individuals.

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Again, we appreciate OSHA conducting the SBAR Panel review and considering the concerns of affected SERs. Should the Agency have any further questions related to the proposal or its impacts on the long term care industry, we would be happy to assist.

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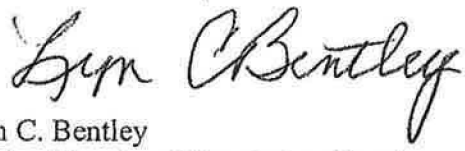

Lyn C. Bentley
Senior Director of Regulatory Services

Care Providers
Of Minnesota

November 26, 2014

Mr. Robert Burt, Chair
SBAR Panel on Infectious Diseases
Occupational Safety and Health Administration
U.S. Department of Labor
200 Constitution Avenue, NW
Washington, DC 20210

Re: Written Comments on OSHA's Infectious Disease SBAR Panel

Dear Mr. Burt:

Thank you for convening and serving as Chair of OSHA's SBAR Panel on Infectious Diseases. We appreciate OSHA's consideration of the comments received and the concerns expressed by the Small Entity Representatives ("SERs") throughout the process.

I am writing on behalf of Care Providers of Minnesota. Care Providers of Minnesota is a non-profit membership association with the mission to Empower Members to Performance Excellence. Our 850+ members across Minnesota represent non-profit and for-profit organizations providing services along the full spectrum of care. We are the state affiliate for the American Health Care Association/National Center for Assisted Living.

At the outset, we would like to emphasize the unique nature of the nursing home and assisted living environment (the "long term care industry"). The long term care industry must navigate multiple regulatory schemes designed to protect the safety and health of employees *and* the safety and health of residents. In the long term care industry, residents are guaranteed certain rights, which can impact how a facility is able to implement workplace safety and health rules. For residents, their rooms are their "homes" and facilities can be prohibited from taking certain actions which infringe upon how a resident is allowed to "live" in their homes. As OSHA continues to examine this rule, it is important for the Agency to specifically review how the requirements will be implemented in the long term care industry given the unique residents-rights issues involved.

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Again, we appreciate OSHA conducting the SBAR Panel review and considering the concerns of affected SERs. Should the Agency have any further questions related to the proposal or its impacts on the long term care industry, we would be happy to assist.

Sincerely,

Patti Cullen, CAE
President/CEO
Care Providers of Minnesota

Cc: Tom Pollock, Chair, Board of Directors
Doug Beardsley, Vice President of Member Services

AHCA
ARKANSAS HEALTH CARE ASSOCIATION

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Little Rock, Arkansas 72201
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arhealthcare.com

AALA
ARKANSAS ASSISTED LIVING ASSOCIATION

December 3, 2014

Mr. Robert Burt, Chair
SBAR Panel on Infectious Diseases
Occupational Safety and Health Administration
U.S. Department of Labor
200 Constitution Avenue, NW
Washington, DC 20210

Re: Written Comments on OSHA's Infectious Disease SBAR Panel

Dear Mr. Burt:

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I am writing on behalf of Arkansas Health Care Association and Arkansas Assisted Living Association. Established in 1951, Arkansas Health Care Association (AHCA) is the state's largest organization of long term care providers, representing 93% of the licensed long term care facilities in Arkansas. Its responsibilities are to educate, inform and represent members and member facilities before government agencies, other trade associations and related industries. The organization provides training, education and assistance to care facilities across the state, promoting high-quality care for patients and strict professional standards for staff. AHCA also strives to cooperate with the state legislature and state Office of Long Term Care to improve the quality of life in licensed long term care facilities in Arkansas.

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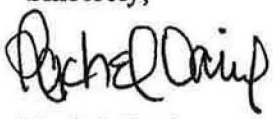

Rachel Davis
Executive Director

Paige, Lajuane M. - OSHA CTR

From: Rick Kislia <rkislia@crescentlaundry.com>
Sent: Wednesday, December 03, 2014 2:04 PM
To: Paige, Lajuane M. - OSHA CTR
Subject: RE: Thank You!

Lajuane,

Here are my comments in the form of answers to the questions that were asked early in the process. Please let me know if you need more information.

Thanks,
Rick Kislia

- Do you currently follow the CDC guidelines on infectious disease control?

We follow the CDC guidelines as they apply to hospital laundry operations. This includes universal precautions, PPE, HBV vaccinations, initial hire training and recurrent training.

- Are you subject to third-party accreditation and how rigorous is that process?

We are certified as a Hygienically Clean Healthcare Laundry by TRSA and have accreditation by the Healthcare Laundry Accreditation Council. Both organizations have standards that must be followed to achieve the certification/accreditation. Both have plant inspections as part of the process. The TRSA Hygienically Clean certification includes biological laboratory testing of textiles produced by the laundry.

- Have you had employees contract infectious disease at work?

We have not had any issues with our employees contracting infectious diseases.

- Has OSHA demonstrated (through the materials provided) that there is "a significant risk of material impairment of employee health"?

I do not see a demonstration of "a significant risk of material impairment of employee health" in a laundry that is currently following industry best practices as described by the certification/accreditation bodies.

- Have the OSHA materials allowed you to adequately assess the level of risk or to know how many employees are contracting infectious diseases at work (besides antidotal evidence)?

I do not see any data that would support the ability to determine our level of risk.

- Is a federal OSHA mandate necessary or are current practices adequate?

Current practices are adequate.

- Would an OSHA rule be overlapping, duplicative, or redundant?

Some of the OSHA rule would be overlapping, duplicative and redundant to current requirements for Bloodborne Pathogens compliance as well as Workers Compensation remedies for employees who have workplace caused illness or injury.

- Are there non-regulatory alternatives OSHA should consider, such as providing information, establishing a national emphasis programs, using the General Duty Clause, or other approaches that OSHA should consider?

I do not believe the laundry industry needs anything more than the current requirements.

- Should OSHA include more or less employers under the standard than it currently envisions (i.e., should some types of employers be exempted and other added)?

OSHA should limit the number of employers under the standard to those that have direct contact with patients.

From: Paige, Lajuane M. - OSHA CTR [mailto:Paige.Lajuane@dol.gov]
Sent: Monday, December 01, 2014 3:02 PM
To: Paige, Lajuane M. - OSHA CTR
Cc: Burt, Robert - OSHA; bruce.lundegren@sba.gov; McCormick, Charles - OSHA
Subject: Thank You!

American Hospital Association

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August 4, 2010

David Michaels, Ph.D., MPH
Assistant Secretary of Labor for Occupational Safety and Health
OSHA Dockets Office
Docket No. OSHA-2010-0003
U.S. Department of Labor
Room N-2625
200 Constitution Avenue, N.W.
Washington, DC 20210

RE: Department of Labor; Occupational Safety and Health Administration; Docket No. OSHA-2010-0003; Infectious Diseases, Request for Information; (Vol. 75, No. 87), May 6, 2010.

Dear Dr. Michaels:

On behalf of our more than 5,000 member hospitals, health systems and other health care organizations, and our 40,000 individual members, the American Hospital Association (AHA) appreciates the opportunity to comment on the Occupational Safety and Health Administration's (OSHA) Request for Information (RFI) on Infectious Diseases. We hope that our comments, and those of our members, will assist OSHA in making an informed and balanced decision as to whether further action is warranted.

America's hospitals are dedicated to the health and safety of patients and health care personnel. Protecting against and preventing the transmission of infectious diseases that result from occupational exposures are top priorities. The AHA encouraged hospitals to respond to the RFI and to share the steps they take to protect employees and patients against infectious diseases. While many of OSHA's questions require a hospital-specific response, we provide below responses to those questions for which there is a general practice common among most hospitals or where the question is more broadly directed to health care stakeholders.

The AHA believes that hospitals and health care systems have effective and comprehensive programs in place that integrate the need to protect patients and health care personnel, and that there is no need for an additional standard. The existing infection prevention and control standards, including their assessment and enforcement by regulatory, accrediting and certifying bodies, have proven to be functional and appropriate, and substantial resources are dedicated to their regular maintenance and improvement.

OVERARCHING COMMENTS

Health and safety of hospital personnel. The health and safety of patients and health care professionals are equally important and inter-related. Infection prevention measures to control transmission from infected patients to others are only successful if health care personnel also are protected; one directly impacts the other. Hospitals realize that protecting patients and personnel from exposures to infected individuals cannot wait for a diagnosis. Therefore, the cornerstone of hospitals' infection prevention and control (IPC) and employee health (EH) programs is education and training of new employees, as well as periodic refresher training, on the routine use of Standard Precautions.

Employee health programs. The EH program develops and implements systems for diagnosis, treatment and prevention of infectious diseases in health care personnel. The IPC and the EH programs typically work collaboratively to develop policies and procedures for health care personnel, such as placement evaluations, health and safety education, evaluation of potentially harmful infectious exposures and implementation of appropriate preventive measures, coordination of plans for managing outbreaks among personnel, provision of care to personnel for work-related illnesses or exposures, education on infection risks related to employment or special conditions, development of guidelines for work restrictions when an employee has an infectious disease, and maintenance of health records on all personnel.

EH programs also manage the OSHA occupational injury and illness reporting programs, including maintaining OSHA logs, and other relevant agencies' reportable disease processes. Another critical component of the EH programs is immunization. Many of the communicable diseases common to health care personnel are vaccine-preventable, and appropriate vaccine use protects both health care workers and patients. Immunization programs also are highly cost-effective.

Enforcement and accountability. We believe that OSHA has mischaracterized IPC and EH programs as "voluntary." These programs are essential for patient and personnel safety, and are mandated by the Centers for Medicare & Medicaid Services (CMS) and all accrediting agencies with deemed status from CMS, such as The Joint Commission and Det Norske Veritas. That is, in order to be considered participating providers and to receive reimbursement for services furnished to Medicare beneficiaries, hospitals must comply with IPC conditions of participation that are required and enforced by CMS, the accreditation organizations and state agencies involved in the survey and certification of hospitals. In addition, hospitals that are participating providers in Medicare and Medicaid but which do not comply with CMS standards, risk loss of their certification, or even their license, if CMS determines the facility has unsafe conditions related to infection control standards or life safety codes. CMS and other agencies' enforcement actions affect both patients and health care personnel. For example, CMS' infection control standards and interpretative guidelines explicitly address health care personnel health and safety.

We have attached a copy of CMS' comprehensive infection control interpretive guidelines for further examination. OSHA will see that the basis for CMS' standards is evidence-based guidelines from the Centers for Disease Control and Prevention (CDC), such as the *Guideline for Infection Control in Health Care Personnel* and *Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings.* Other specific guidelines utilized by CMS, accrediting organizations and state agencies address *M. tuberculosis*, hand hygiene, environmental infection control and many other guidelines critical for the health and safety of health care personnel, such as the CDC's

Advisory Council on Immunization Practices recommendations for immunizations. Most of these CDC documents can be found at http://www.cdc.gov/hicpac/pubs.html.

Safety culture and the reduction of healthcare-acquired infections (HAI). The AHA strongly agrees with the importance that OSHA ascribes to developing a safety culture within health care facilities. Hospitals have expressed their commitment to a safety culture through many successful voluntary programs that demonstrate sustained HAI reductions. One excellent example is a program from the Keystone Center for Patient Safety and Quality of the Michigan Health & Hospital Association that has proven to reduce central-line associated bloodstream infections to nearly zero in intensive care units. As part of the Department of Health and Human Services' *Action Plan to Prevent Healthcare Associated Infections*, and with the AHA's leadership and involvement, the Agency for Healthcare Research and Quality is funding efforts to emulate Michigan's Keystone success story across the nation. More than 30 states participate in "On the CUSP: Stop HAI."

Dramatic reductions in HAIs seen in these types of initiatives are the result of health care personnel working together to minimize, and even eliminate, infections in patients. But again, these programs also reduce the risk of health care personnel exposure through high rates of compliance with hand hygiene and proper use of protective barriers. The Keystone initiative is based on regular input and measurement of the safety culture among the staff in care units throughout the hospital, using checklists to raise awareness of "doing the right thing all of the time." Such efforts translate into a greater overall focus on safety within health care facilities, whether through the use of barriers or through the safe use of devices. We have encouraged our members to share their individual successes with OSHA in their responses to the RFI.

Hospital safety management programs also foster a safety culture by focusing on health care personnel's interaction with the hospital environment, including preventing the transmission of infection. Hospitals devote much time and effort to facility-wide performance measurement and improvement. These programs include reduction of safety risks, addressing occupational illness and actions that will prevent all types of safety risks, including sharps injuries.

In conclusion, we are confident that, after reviewing the responses from the AHA and our members, OSHA will find that hospitals and health care systems have effective and comprehensive programs that integrate the need to protect patients and health care personnel, and that there is no need for an additional standard. In order to justify a new standard, OSHA must demonstrate that these comprehensive and stringently enforced programs are insufficient, and that gaps in the existing programs have led to measurable increases in occupationally acquired infections.

If you have any questions regarding our comments and attached responses, please contact me or Roslyne Schulman, director for policy development, at (202) 626-2273 or rschulman@aha.org.

Sincerely,

Rick Pollack
Executive Vice President

Enclosure

ATTACHMENT

AHA RESPONSES TO CERTAIN OSHA QUESTIONS

A. General

Question 3. One of the most important steps in determining how to effectively protect workers from infectious diseases is identifying who is at risk of exposure. What recommendations do you have for how to determine which employees are potentially exposed to contact, droplet, and airborne transmissible diseases in the type of workplace about which you are responding? How many of your total workers have a risk of exposure to such diseases during the performance of their job duties? What proportion of your workforce does this represent? What are the job titles or classification(s) of these workers? What are the job duties of these workers? To which diseases are they exposed?

AHA Response. Infection prevention and control (IPC) programs in acute-care hospitals take several key factors into consideration in determining who is at risk:

- Hospitals are concerned about the health and safety of all occupants of the facility, including patients, health care personnel and visitors. Therefore, the IPC programs must assess the risk of airborne, droplet and contact exposures for all occupants, and, as a result, a major focus is on environmental/engineering controls for the overall environment.

- A hospital's risk assessment must consider the population it serves in order to evaluate the types of communicable disease likely to be seen in the facility. Hospitals use the reportable communicable disease entries published weekly from local and state public health agencies, as well as the Centers for Disease Control and Prevention's (CDC) *Morbidity and Mortality Weekly Report* (MMWR). Therefore, specific risks may vary by locale. For example, for *Mycobacterium tuberculosis* (MTB), CDC guidelines state that because some communities have minimal risk, hospitals in those communities need neither carry out TB testing nor develop respiratory protection programs.

- General risks. All hospital personnel, whether they perform direct care or support services, are considered to be at some level of risk due to the basic principle of "universal precautions," meaning that all patients are considered to be potentially infectious. Therefore, standard precautions apply to all health care personnel and all receive basic education and training.

- Specific risks. The disease exposure risk for direct care personnel does not depend on whether they treat a primarily adult versus a pediatric/neonatal patient population. Instead, the risk assessment considers factors such as: whether the patient is suspected or known to have a communicable disease; type, frequency and duration/intensity of procedures which the direct care personnel will be performing; and degree of contact with the patient. For example, risks are generally considered to be higher for personnel working in the hospital's emergency department because they would be evaluating patients with potentially communicable diseases (e.g., tuberculosis) and the emergency department staff often is responsible for furnishing higher-risk pulmonary procedures such as bronchoscopies. As noted in our overarching comments, IPC programs place major emphasis on prevention and routine use of Standard Precautions. The IPC

programs address potential risks by department/procedures and indicate if specific additional personal protective equipment (PPE) should be used in addition to Standard Precautions.

With regard to OSHA's question about the job duties of workers and the diseases to which they are exposed, the AHA believes that exposure control plans typically reflect similar specific job titles or classifications developed for the OSHA bloodborne pathogen standard as well as for the CDC's influenza vaccination recommendations, which reference direct care personnel, personnel with frequent contact and support services personnel managing contaminated equipment. With regard to specific disease exposures, as noted above, hospitals' risk assessments will reflect the diseases prevalent in the community, whether airborne (e.g., MTB), large droplet (e.g., influenza, norovirus) or contact transmissible diseases (e.g., scabies and various bacterial infections). IPC programs place major emphasis on prevention and routine use of Standard Precautions.

Question 4. Workplaces vary in the types of infectious diseases and the number of infected individuals encountered. OSHA is interested in the types of diseases that your workplace encounters and how often they are encountered. Please describe your workplace's experience with infectious diseases over the past 10 years (e.g., which diseases, how often).

AHA Response. This question of "experience" is ambiguous and may be interpreted differently by some as meaning employees or patient admissions. For example, some may sum up the past 10 years of infectious disease classifications coded in medical records. Others may use hospitals' copies of state-required forms for each type of recorded reportable disease sent to their local health department. Yet others may use reportable disease logs for employees only (e.g., OSHA Form 300A) as reported to the local health department. Finally, some may only report exposures to infectious diseases, not actual diseases. We encourage OSHA to consider this ambiguity when reviewing responses to this question.

Question 5. OSHA is interested in data and information that will further assist in characterizing workers' occupational exposure to contact, droplet, and airborne transmissible infectious diseases.

a) OSHA encourages the submission of your workplace or your industry's experience with these diseases and the impact of infectious diseases on your workers (e.g., type and number of exposure incidents, occupationally-acquired infectious diseases, days of work missed, and fatalities).

AHA Response. Due to the ambiguity around the term "experience," we urge OSHA to take into consideration the various sources of information that hospitals could provide. The implication, though not stated explicitly, is that the data requested are from the OSHA Form 300A, used to collect and report occupationally-acquired disease. However, some data submitted by hospitals may be limited to exposures and not include disease outcomes.

b) Please provide information about any database that collects and aggregates data on occupationally-acquired infectious diseases (e.g., Federal, State, provider network, or academic).

AHA Response. It is not clear whether OSHA is interested primarily in databases that collect data electronically or databases that collect data manually would also be of interest to OSHA. Beyond the data generated by OSHA Form 300A, that may be collected either way, other electronic systems

include the CDC's National Healthcare Safety Network (NHSN) module for health care personnel exposures and a number of commercial stand-alone databases for tracking sharps-related incidents and immunization status/vaccination rates.

c) *Please provide any additional information, including peer-reviewed studies, which addresses occupational exposure to infectious agents that you think OSHA should consider.*

AHA Response. We recommend that OSHA review the CDC's "*Guidelines for Infection Control in Healthcare Personnel, 1998.*" The CDC's Healthcare Infection Control Practices Advisory Committee (HICPAC) is in the process of updating this guideline. However, the current guidelines contain multiple citations of studies involving infectious agents for which prevention/treatment strategies were put into place and tested.

Question 6. Infection control (IC) programs are currently the primary means of controlling occupational exposure to infectious agents. However, these programs are largely voluntary. OSHA is particularly interested in case studies that highlight experience in the implementation and effectiveness of IC programs in protecting workers against infectious diseases (e.g., the extent to which employers are fully implementing and consistently following their written IC programs).

AHA Response. We believe that OSHA has mischaracterized IPC programs as "voluntary" since hospitals, ambulatory care centers, other care-delivery sites and related entities understand that such programs are not only essential for safety, but mandated by CMS and by all accrediting agencies with deemed status from CMS, such as The Joint Commission and Det Norske Veritas. That is, in order to be considered participating providers and receive reimbursement for services furnished to Medicare beneficiaries, hospitals are required to comply with IPC conditions of participation mandated and enforced by CMS, the accreditation organizations and state agencies involved in the survey and certification of hospitals. In addition, hospitals that are Medicare and Medicaid participating providers but do not comply with CMS standards, risk losing their certification or even their license, if CMS determines the facility has unsafe conditions related to infection control standards or life safety codes. CMS and other agencies' enforcement actions affect both patients and health care personnel. Therefore, CMS infection control standards and interpretative guidelines explicitly address health care personnel health and safety. We have attached a copy of CMS' comprehensive infection control interpretative guidelines, which address all aspects of an IPC program including the issue of protecting health care personnel.

a) *For example, has your workplace had instances where a significant increase in infections (among either patients or workers) required more rigorous implementation of your IC program? If so, please describe any factors that contributed to the increase and what steps your workplace took to address the situation.*

AHA Response. The CDC guidelines anticipate occasional clusters of infections or outbreaks. In addressing such clusters, hospitals start with the CDC Guidelines' "transmission-based" section recommendations that are outlined in Tier I. That is, they determine whether the basic Standard Precautions have been implemented properly, such as through the measurement of adherence to hand hygiene protocols and the use of barriers, thereby ensuring basic practices are at high rates of compliance. Then hospitals make a determination about the need to move to Tier II, which involves additional steps to bring the outbreak under control, even as the cause of the cluster or outbreak is investigated.

b) Please provide any studies that demonstrate the difference in infection rates between situations where the IC program had lapsed and situations where rigorous implementation of control measures was instituted.

AHA Response. The cause of the cluster or outbreak may not necessarily be a "lapse" in the IC program, but sometimes results from a single unexpected source from the environment, identified during the investigation. The hospital's initial response will always be to take steps to protect patients and health care personnel in order to stop further transmission until the cause is known. Hospital personnel follow recommendations contained in the CDC's isolation guidelines and in its multi-drug resistant organism (MDRO) guidelines in these situations.

Question 7. While OSHA has a Bloodborne Pathogens standard (Sec. 1910.1030), the Agency does not have a comprehensive standard that addresses occupational exposure to contact, droplet, and airborne transmissible diseases. The Agency has other standards [(e.g., Respiratory Protection (Sec. 1910.134) and General Personal Protective Equipment (Sec. 1910.132)] that may apply and, in some situations, Section 5(a)(1) of the OSH Act (the General Duty Clause) would apply. OSHA is interested in commenter's insights regarding the adequacy of existing OSHA requirements to protect workers against occupational exposure to infectious agents.

AHA Response. Although hospitals comply with the OSHA Bloodborne Pathogen standard, the General Industry Respiratory Protection standard and other applicable standards as required, the impact of these requirements in terms of worker protection is difficult to determine in isolation from the impact of other practices that hospitals engage in as a result of compliance with the evidence-based CDC guidelines and CMS requirements. For instance, while hospitals are aware of and compliant with the OSHA Bloodborne Pathogen standard, the substantial reduction in hepatitis B infections among health care personnel is primarily a result of the high level of efficacy of the hepatitis B vaccine (HBV) and hospital attention to the CDC guideline recommendations related to "universal precautions" and safe use of sharps devices. Another example relates to the OSHA General Industry Respiratory Protection Standard. While hospitals that utilize particulate respirators, primarily N-95 respirators, are compliant with the OSHA standard, it is important to note that the CDC Tuberculosis guidelines also address respiratory protection as part of the facility's overall risk assessment. This CDC guideline continues to be the key resource for hospitals. In addition, the OSHA standard is actually referenced in the CMS Infection Control Interpretive Guideline attached at the end of our comment letter. Further, hospitals view the OSHA General Duty clause as comparable to CMS' general requirement for a "safe and sanitary" environment. This requirement is enforced when CMS surveyors determine that a serious violation to a Life Safety code requirement has occurred in a hospital.

Question 8. California OSHA recently issued a standard for occupational exposure to "Aerosol" Transmissible Diseases (ATD) that covers infectious diseases transmitted through the airborne and droplet routes. IC programs that are established in most healthcare settings address exposure to contact, droplet, and airborne transmissible diseases. Please explain whether the Agency's deliberations on occupational exposure to infectious diseases should focus on only droplet and airborne transmission or if contact transmissible diseases should also be included.

AHA Response. The AHA did not understand the need or justification for California's ATD standard given that the studies examined by OSHA and stakeholders failed to demonstrate that the

rate of TB in health care personnel was any higher than the TB rate in the general population. CDC droplet precautions (as described in the CDC's isolation guidelines) are implemented to prevent all exposures, including in health care personnel, and are enforced by other agencies. Contact transmission, the most common mode of transmission, is equally important. A great deal of education and training time is spent on prevention, and CDC guidelines are already enforced by various agencies. We believe that current CDC guidelines, enforced by other agencies, are adequate and another standard would be duplicative and burdensome for health care facilities.

Question 9. If the Agency pursues rulemaking and promulgates a standard, jurisdictions with OSHA-approved State plans will be required to cover workers who OSHA determines are at occupational risk for exposure to infectious agents, including public employees. State and local governments are defined very broadly, and would typically include such entities as a university hospital associated with a State university as well as public hospitals and health clinics. What public sector healthcare or healthcare-related workers are at increased risk for occupational exposure to infectious agents? Please describe conditions unique to any of these occupations that are not seen in the private sector. Please describe any other issues specific to OSHA-approved State plans that the Agency should consider.

AHA Response. University contracts that involve the rotations of students through hospital training already include the same requirements for health assessment that apply to other settings, such as requiring proof of HBV vaccination, as well as training to reduce occupational exposure.

B. Infection Prevention and Control Plan

Question 10. CDC/HICPAC's 2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings recommends an IC program for addressing the transmission of airborne and other infectious diseases. In certain settings, CMS and The Joint Commission require that health care facilities have such programs. If you are subject to the CMS or Joint Commission requirements or otherwise have an IC program, please provide information on the elements of this program (e.g., early identification of infectious patients, implementation of transmission-based control measures, HCW training) and how the program works.

AHA Response. Hospital infection prevention and control programs are comprehensive and each key element, including occupational health elements, must meet the detailed requirement of the CMS infection control interpretive guidelines. These interpretive guidelines require hospital infection prevention and control programs to be based on CDC's evidence-based guidelines.

Question 11. In most cases, an IC program is managed by an infection control preventionist or other designated person. For example, the CDC/HICPAC guidelines recommend that the IC program be managed by individuals with training in infection control. Who manages your program? What percentage of this individual's time is spent managing the IC program?

AHA Response. The management of IC programs varies based on facility size and resources. For example, in small or rural hospitals and critical access hospitals (CAHs), the same person may direct both the IPC and EH program.

Question 12. For the IC program(s) established in your workplace, please describe, in detail, the resource requirements and associated costs, if available, expended to initiate the program(s) and conduct the program(s) annually. Please estimate, in percentage terms where possible, the extent to which the components or elements in your program(s) are typical of those practiced throughout your industry.

AHA Response. The personnel and non-personnel resources and associated costs for IC programs vary widely and are generally proportional to the size, sophistication, case mix, and estimated risk of the populations served by the hospital. Personnel and non-personnel resources would likely include:

- Personnel resources:
  - Infection preventionist/infection control manager;
  - Hospital epidemiologist (or access to a clinician);
  - Surveillance technicians (in larger institutions);
  - Employee health program support (varies by size of facility);
  - Administrative support; and
  - Computer support personnel.
- Non-personnel resources:
  - Office space, computer equipment and supplies and other related equipment;
  - Microbiology laboratory support, including reference laboratory and pathology support; (In small or rural hospitals, such as CAHs, such laboratory support is often obtained under arrangement from another laboratory); and
  - Education and training support necessary to achieve and maintain competency, including tuition and related travel costs, as necessary.

Question 13. In your industry, for the IC programs established in your workplace or for IC programs in other workplaces of which you are aware, are there any components or features that may present economic difficulties to small businesses? Please describe and characterize in detail these components and why they might present difficulties for small businesses.

AHA Response. Small rural hospitals and CAHs are financially vulnerable organizations that have difficulty absorbing additional costs. Our particular concern involves CAHs and other small hospitals that already comply with the CDC guidelines and associated CMS/accreditation standards, but which would be required, under a new OSHA infectious disease standard, to bear the additional cost and burden of putting into place and maintaining an OSHA compliance program for what is likely to be a redundant standard.

Question 14. Periodic evaluation of IC program effectiveness is recommended by CDC/HICPAC and required by The Joint Commission and CMS for most types of facilities under their jurisdiction. Please describe how your workplace or industry evaluates the effectiveness of its IC program, including the methods and criteria used. How often does your workplace evaluate its program? Please describe the results your program has achieved (e.g., if there has been a decrease in patient and/or worker infections). Please describe any specific problems and/or successes that have been encountered in the implementation and operation of the program.

AHA Response. CMS conditions of participation and accrediting agency standards call for a minimum of annual and/or periodic evaluations that involve risk re-assessments and making

necessary changes when new or revised hospital programs affect IC surveillance goals and strategies. Many hospital IC programs also undertake quarterly reviews of trends and issues for the organization's Board of Trustees, utilizing the hospital's quality, safety or infection control committees, and reporting on measurable performance improvement outcomes, including explicit employee health measures. It is important to reiterate that the successes in reducing HAIs also lower exposure risks to employees.

C. Methods of Control

Question 17. CDC/HICPAC, CMS, and The Joint Commission provide a variety of approaches that employers can implement to reduce or eliminate workers' exposure to infectious agents. For example, a well-structured IC program can include: immunizations for vaccine-preventable diseases, isolation precautions to prevent exposures to infectious agents, training, personal protective equipment, management of workers' risk of exposure to infected persons, including post exposure prophylaxis, and work restrictions for exposed or infected personnel. Please describe the types of problems/obstacles your workplace or industry encountered with implementing specific control measures. Please include a discussion of each control measure, the problem/obstacle encountered, the affected worker group, and any particularly effective solutions your workplace or industry has implemented to address the obstacle/problem.

AHA Response. Supply chain limitations have been a major obstacle for hospitals with regard to implementing control measures. For example, in recent years, supplies of seasonal influenza vaccine have been either short or delayed due to manufacturing problems and regulatory actions by federal agencies. In the 2009 H1N1 pandemic, the delay in availability of vaccine for immunizing health care workers was a result of the emergence of a novel H1N1 virus strain in the Spring of 2009 and the competing demand on manufacturing capacity from the parallel production of seasonal influenza vaccine. However, the obstacles are not limited to vaccines. This past year hospitals experienced supply chain shortages of many other supplies linked to the response to the pandemic, including N-95 particulate respirators, surgical and procedure masks, hand sanitizer, and injection supplies and equipment.

Limited U.S. manufacturing capacity of essential items, unreliable raw material supply chains and economic conditions and market incentives that lead to "just in time" inventory strategies for health care facilities are at the heart of these obstacles. Solutions to these supply chain issues would likely involve increasing U.S. manufacturing capacity for essential supplies and equipment, using more efficient and effective manufacturing processes, and locating alternate sources for raw materials needed to manufacture essential items.

Another obstacle to putting into place effective control measures, particularly for seasonal and pandemic influenza vaccination campaigns, relates to conflicting messages sent by leaders within the health care system. The AHA believes that in order to improve influenza vaccination rates among health care personnel, hospitals need strong internal leadership that supports annual vaccinations and provides clear, fact-based and timely education and communication initiatives. But strong hospital leadership is only part of the equation for improving vaccination rates among health care workers. Hospitals frequently have found that certain unions representing health care workers have sought to delay or block the implementation of employee vaccination programs. Vaccination rates of health care workers could be improved with union support of hospitals' vaccination policies and programs.

Question 18. When developing and implementing infection control measures in your workplace, are there any recommended controls that you have found to be ineffective or unnecessary in controlling infectious diseases? If so, please explain how you arrived at this conclusion.

AHA Response. The AHA believes the use of the CDC guidelines provide sufficient flexibility to identify and use the most effective controls for any given situation. The guidelines are evidence-based and supported by clinical experience.

Question 20. CDC/HICPAC's 2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings addresses the need for a safety culture and its role in improving a workplace's IC program (e.g., worker adherence to safe work practices). Please describe the policies and actions undertaken in your workplace or industry to develop and maintain a culture of worker safety. Please describe any means that have been particularly effective in fostering a safety culture and any problems or obstacles that have been encountered in developing and/or maintaining the safety culture.

AHA Response. The nation's hospitals recognize the importance of developing a safety culture involving teams working together toward reducing HAIs in patients and reduced exposures and transmission to patients and health care personnel alike. Hospitals have expressed their commitment to a safety culture through many successful voluntary programs that demonstrate sustained HAI reductions. One excellent example is the program from the Keystone Center for Patient Safety and Quality of the Michigan Health & Hospital Association that has proven to reduce central-line associated bloodstream infections to nearly zero in intensive care units. As part of the Department of Health and Human Services' *Action Plan to Prevent Healthcare Associated Infections* and with the AHA's leadership and involvement, the Agency for Healthcare Research and Quality (AHRQ) is funding efforts to emulate Michigan's Keystone success story across the nation. More than 30 states are participating in "On the CUSP: Stop HAI."

Dramatic reductions in HAIs seen in these types of initiatives are the result of health care personnel working together to minimize, and even eliminate, infections in patients. But again, these programs also reduce the risk of health care personnel exposure through high rates of compliance with hand hygiene and proper use of protective barriers. The Keystone initiative is based on regular input and measurement of the safety culture among the staff in care units throughout the hospital, using checklists to raise awareness of "doing the right thing all of the time." Such efforts translate into a greater overall focus on safety within health care facilities, whether through the use of barriers or through the safe use of devices.

Hospital safety management programs also foster a safety culture by focusing on the health care personnel's interaction with the hospital environment, including preventing the transmission of infection. Hospitals devote significant time and effort on facility-wide performance measurement and improvement. These programs include reduction of safety risks, addressing occupational illness and actions that will prevent all types of safety risks, including sharps injuries. The Joint Commission focuses heavily on hospitals' safety programs that engage employees in a culture of safety.

Question 21. Poor adherence to infection control measures (e.g., failure to use necessary PPE or to follow recommended hand hygiene practices) can be one indicator of the breakdown of an IC

program. Please describe what actions have been undertaken in your workplace or industry to assess and enforce adherence to infection control measures. What obstacles has your workplace encountered in maintaining adherence and are there any particularly successful ways you have found to maintain adherence (e.g., training initiatives, worker incentives)? Please discuss any underlying factors that you feel may affect non-compliance with current infection control guidelines and standards in your facility.

AHA Response. Hand hygiene is generally included in all "checklists" used to reduce HAIs and also is closely monitored as a major quality measure in organizations. Hospitals use the CDC's hand hygiene guidelines. Also, CMS and the hospital accrediting organizations place great focus on hand hygiene as well and closely observe actual practice on scheduled and non-scheduled surveys. Hospitals are creative in their methods to aim for 100 percent adherence for both patient and worker protection. For example, "Speak Up" campaigns encourage patients and families to inquire whether a health caregiver has washed his/her hands, and the increased availability of alcohol-based hand rubs and well-placed sinks also are major tools in adherence.

Question 22. The use of proper PPE is an essential component of an effective IC program. For example, CDC/HICPAC recommends that facemasks (e.g., surgical masks) be worn by workers when droplet precautions are implemented and respirators be worn under certain circumstances when airborne precautions are in place. Please describe how your workplace determines when a facemask (e.g., surgical mask) is used for worker protection and when a respirator is used for worker protection. How does your workplace determine which employees use a facemask and which use a respirator? If your workplace uses different types of respirators, please describe what types and when they are used.

AHA Response. The AHA has encouraged hospitals to comply with OSHA's respiratory protection standard when airborne precautions are in use and as recommended in the CDC guidelines. In recent years, the two main situations requiring respirator use involve TB and the 2009 H1N1 pandemic and both were addressed through CDC guidelines.

The CDC TB guidelines recommend a risk assessment be conducted and, if the criteria are met, the hospitals must implement worker TB evaluation as well as institute a full respiratory protection program. This includes education, fit-testing of respirators, and training on how to do a fit-check after donning of a respirator. The interim CDC *Guideline for Infection Control in Healthcare Settings*, issued at the outset of the 2009 H1N1 pandemic, led to a far greater number of health care personnel requiring education, training and fit-testing. Due to widespread respirator shortages as the pandemic progressed, staff performing procedures generating short range aerosols were given priority for N95 respirators. However, those hospitals which had sufficient supplies of respirators used them in accordance with the CDC guidelines. Once the revised guidance for prevention of influenza is finalized by the CDC, the AHA expects that hospitals will comply with recommendations for the use of facemasks for routine care and N95 respirators only for the listed procedures generating short-range aerosols.

Question 23. NIOSH regulates the testing and certification of respiratory protective equipment, has established minimum performance standards, and conducts independent testing and verification of all respirators prior to certification. The Food and Drug Administration (FDA) approval process for facemasks does not have established minimum performance standards and allows manufacturer submitted data. As noted in a 2009 IOM report, a 2008 study that examined the filter performance

of nine different types of facemasks using the sodium chloride NIOSH challenge test, found wide variation in penetration (4 percent to 90 percent) of smaller aerosol particles. Therefore, the protective properties of different manufacturers' facemasks may vary. Is there a need for a more rigorous certification/approval process for facemasks and additional independent verification of personal protective properties of devices?

AHA Response. A single standard for facemask performance would be of value. However, while we are aware of the cited IOM report, we also are aware of related information on testing facemasks and respirators shared at subsequent IOM meetings and NIOSH workshops that raised questions about whether aerosolized saline is an appropriate particle surrogate for aerosolized human mucous. The AHA recommends that OSHA work with FDA for further input on this issue.

Question 24. Some HCWs have medical conditions or are receiving treatments that impair their ability to resist infection. These HCWs may be unable to develop protective immune responses after vaccination. What is your workplace or industry doing to educate its workers about these conditions? What approaches are being used/should be used to address the special needs of HCWs with these conditions?

AHA Response. There are many employee privacy and confidentiality issues that must be considered in this situation. Hospitals assess a prospective employee's laboratory results during pre-employment reviews, and would provide, in this situation, additional one-on-one counseling sessions on the importance of understanding and adhering to Standard Precautions. The hospital's employee health program will accommodate these workers as much as possible but there is no known "safe" unit in hospitals for assignment. As a basic premise, all patients in the hospital are considered to be potentially infectious. Any asymptomatic patients may be incubating infections and exposing others with an infectious disease agent such as influenza or varicella. In addition to Standard Precautions, such employees are urged to always report potential exposures so that they can be assessed, tested and receive appropriate prophylaxis.

D. Vaccination and Post-Exposure Prophylaxis

Question 25. In the Bloodborne Pathogens standard (Sec. 1910.1030), OSHA requires that hepatitis B vaccinations be made available to employees occupationally exposed to blood or other body fluids. It should be noted that while employers are required to offer the vaccine, employees are permitted to decline it. CDC/Advisory Committee for Immunization Practices (ACIP) recommends a number of other vaccines for various groups of HCWs including: influenza (both seasonal and the 2009 H1N1); measles, mumps, rubella (MMR); varicella; tetanus, diphtheria, pertussis; (Td/Tdap); and meningococcal vaccines. What vaccinations, other than hepatitis B, do you consider to be necessary to protect workers from occupational exposure to infectious agents? Who should receive these vaccinations, and why? Does your workplace offer vaccines other than the hepatitis B vaccine to workers and how do you determine who is offered these vaccines?

AHA Response. The CDC guidelines emphasize the importance of these vaccines, many of which are childhood vaccines required by school systems; others are boosters such as Tdap. The CMS infection control interpretive guidelines also require that the state surveyors review this information. A recent publication [Wei SC, et al. Clin Infectious Dis Aug 1: 2010; 51(3):315-321] demonstrates the effectiveness of Tdap in protecting against pertussis in a school, even in an outbreak setting.

Most employee health programs have policies requiring a thorough immunization history for employees. Employee health policies also require testing for antibodies to HBV and other diseases, such as varicella (if the employee does not have proof of immunity). This would apply to all personnel. If the individual is lacking immunity, some hospitals may administer the vaccines in-house or refer the employee to local public health for vaccinations. The AHA encourages hospitals to follow ACIP guidelines for health care personnel vaccination. These guidelines are currently being updated.

Question 26. The Bloodborne Pathogens standard (Sec. 1910.1030) requires that employers follow certain administrative and recordkeeping procedures (e.g., signing a declination statement; placing an employee's vaccination status in his/her medical record). Does your workplace or industry use similar administrative and recordkeeping procedures for vaccines other than hepatitis B? If not, please describe what administrative and recordkeeping procedures are or should be used.

AHA Response. As a matter of policy, hospitals maintain a record of prior and/or current immunization.

Question 27. Post-exposure prophylaxis (PEP) and evaluation for bloodborne pathogen exposures, such as hepatitis B and HIV, are addressed in the Bloodborne Pathogens standard [Sec. 1910.1030(f)]. OSHA is interested in post-exposure evaluation and PEP for other infectious diseases. Please describe the current PEP and evaluation practices in your workplace. For what infectious agent exposures should workers be provided with PEP and/or evaluation? Please describe the disease, its associated PEP, and the PEP efficacy.

AHA Response. Hospitals focus on ensuring that health care personnel are immunized against infections that are vaccine-preventable, including influenza. Beyond that, hospitals follow CDC guidelines for the proper treatment or PEP, depending on the type of infectious agent exposure.

Question 28. In some instances, a vaccine may be available for a disease but a worker may decline vaccination. Please describe procedures in your workplace that ensure workers who have declined vaccination have access to necessary PEP.

AHA Response. As noted earlier, hospitals offer appropriate PEP to all exposed employees, regardless of vaccine status.

Question 29. In order to appropriately evaluate the health status of a worker, some basic health information is needed. CDC/HICPAC recommends a personnel health service program for infection control that includes a number of components including: pre-placement evaluations, evaluation and treatment of exposure-related illnesses, and work restriction or work-exclusion policies for exposed HCWs. OSHA is interested in the prevalence, content and efficacy of such personnel health service programs.

a) *What should be included in a pre-placement medical evaluation for a worker who will be exposed to infectious agents? Please describe the possible components of the medical history and physical exam and specific tests (e.g., TB skin test, spirometry, blood tests). How are pre-placement medical evaluations of workers addressed in your workplace? What do these evaluations include? If pre-placement medical evaluations are used in your workplace, have*

they been effective, and what metrics are used to evaluate effectiveness? Give the rationale, including references if available.

AHA Response. Hospitals follow CDC's *Guidelines for Infection Control for Healthcare Personnel* and a medical history and a physical exam are included in their pre-placement programs. Elements include, for example, past infectious disease history, exposures, vaccines and tests for TB (if appropriate per CDC TB guidelines), vaccine titers, and overall health and fitness for the job being sought.

b) *What type of ongoing medical surveillance or periodic medical evaluations should be provided for exposed workers? Please describe the possible components of such surveillance or evaluations. How often should periodic medical evaluations be conducted? In what situations should medical evaluations or surveillance be performed (e.g., return-to-work, fitness for duty)? How are periodic medical evaluations addressed in your workplace?*

AHA Response. Comprehensive IPC programs involve surveillance by infection preventionists and/or the employee health program to ensure the provision of recommended follow-up treatment or testing following an exposure assessments. The "return to work" policies and procedures also are closely followed to ensure it is safe for employees to return.

E. Communication of Hazards

Question 31. Both initial and periodic worker training are recognized as important components of an effective IC program. Initial training provides information that workers need to protect themselves against exposures to hazards while periodic training refreshes worker knowledge, reinforces the importance of the IC program and provides a means of introducing new information and procedures.

a) *What information should be included in initial training for workers who may be exposed to infectious agents? What is the best format for providing initial training to these workers (e.g., specifying a minimum number of hours of training, specifying training content based on job tasks, specifying that training be adequate to demonstrate specified competencies, by a combination of these methods or by some other method)?*
b) *How frequently does your workplace provide workers with refresher training on its IC program? What information should be included in periodic refresher training for workers who may be exposed to infectious agents?*
c) *What is the best format for providing periodic training to these workers (e.g., specifying a minimum number of hours of training, specifying training content based on job tasks, specifying that training be adequate to demonstrate specified competencies, by a combination of these methods or by some other method)?*
d) *Should refresher training be provided based on lack of competency, or be provided at regular time intervals regardless of demonstrated competency?*

AHA Response. Hospitals follow the CDC guidelines and routinely offer initial and at least annual training on infectious disease beyond MTB and bloodborne infections. They also routinely offer training utilizing the most recent evidence-based information to ensure that the information provided to health care personnel is timely and relevant.

F. Recordkeeping

Question 32. Please describe the worker health surveillance system used in your workplace. Does the system include tracking of occupational exposures to infectious agents and/or occupationally-acquired infectious diseases? Please describe the procedures used by your workplace to determine whether an infectious disease is considered to have been occupationally-acquired. How is the worker health surveillance information collected under the system used in your IC program? Please describe the factors that affect the success implementation of such surveillance systems.

AHA Response. Hospitals follow the CDC guidelines and investigate each reported exposure using the latest information and updates from CDC to determine, for each specific disease, whether the exposure was an occupational- or community-based exposure. As recommended in CDC guidelines, employees are tracked for appropriate follow-up, using testing as needed.

Question 33. The OSHA requirements for recording and reporting occupational injuries and illnesses contain an exemption for the common cold and flu (Sec. 1904.5(b)(2)(viii)). However, the Agency has determined that, if certain criteria are met, occupationally-acquired 2009 H1N1 pandemic influenza is recordable (OSHA Directive CPL-02-02-075). As OSHA more broadly considers the issue of occupational exposure to infectious agents, what are the implications, if any, for the Agency's existing recording and reporting requirements under Sec. 1904?

AHA Response. OSHA's criteria appear to refer to initial reporting of individual cases of infection during the beginning of a pandemic. Now that the H1N1 virus is incorporated into the seasonal influenza vaccine, we believe that H1N1 should now fall under the common cold and flu exemption, especially since the CDC has in place its sentinel surveillance systems for measuring seasonal influenza cases in offices and emergency departments. However, the incorporation of H1N1 into the seasonal influenza vaccine does put a new emphasis on the importance of health care personnel and others receiving seasonal vaccination.

Further, the AHA is concerned about the increased burden that would fall on hospitals for reporting additional infectious agents, for example MRSA, when it is very difficult to determine colonization and to distinguish occupationally-acquired infection versus community-acquired infection. We are also concerned about conflicting reporting requirements that would arise if OSHA begins to require additional reporting of infections not typically required by state reporting systems, not supported by evidence, or for which PEP is effective.

G. Economic Impacts and Benefits

Question 34. As the Agency considers possible actions to address the prevention and control of infectious diseases (e.g., prospective standards or guidelines), what are the potential economic impacts associated with the promulgation of a standard specific to the hazards of infectious diseases? Describe these impacts in terms of benefits from the reduction of incidents and illnesses; effects on revenue and profit; and any other relevant impact measure. If you have any estimates of the costs of controlling infectious disease hazards, please provide them.

AHA Response. As discussed throughout our comments and responses, the AHA does not see any additional benefit from the imposition of a highly redundant set of requirements by OSHA. We believe that there would be a considerable financial burden involved in documenting compliance for a standard with such an unproven benefit.

Question 36. What are the potential benefits of more widespread compliance with infection control guidelines? How can OSHA best assure such compliance takes place?

AHA Response. The AHA does not believe that it is necessary for OSHA to develop an additional standard that will only serve to duplicate much of what is already in place. Existing infection prevention and control standards, including their assessment and enforcement by regulatory, accrediting and certifying bodies, have proven to be functional and appropriate, with substantial resources dedicated to their regular maintenance and improvement. In order to justify a new standard, the burden remains on OSHA to demonstrate that these comprehensive and stringently enforced programs are insufficient, and that gaps in the existing programs have led to measurable increases in occupationally acquired infections.

H. Impacts on Small Entities

Question 38. How, and to what extent, would small entities in your industry be affected by a potential comprehensive OSHA infectious diseases standard regulating occupational exposure to infectious agents? Do special circumstances exist that make controlling infectious diseases more difficult or more costly for small entities than for large entities? Describe these circumstances.

AHA Response. Small rural hospitals and CAHs are financially vulnerable organizations that have difficulty absorbing additional costs. Our particular concern involves CAHs and other small hospitals that already comply with the CDC guidelines and associated CMS/accreditation standards, but which would be required, under a new OSHA infectious disease standard, to bear the additional cost and burden of putting into place and maintaining an OSHA compliance program for what is likely to be a redundant standard that would provide no additional benefit.

Paige, Lajuane M. - OSHA CTR

From: Bowen, Rita <BowenR2@sutterhealth.org>
Sent: Tuesday, December 02, 2014 8:56 PM
To: Paige, Lajuane M. - OSHA CTR
Subject: SERs Comments
Attachments: OSHA Letter.pdf

Good Afternoon

I am submitting these comments on behalf of Sutter Health Surgery Center Division, representing 35 Medicare-certified ambulatory surgery centers in California. Thank you for the opportunity to comment on the behalf of the Ambulatory US Occupational Safety and Health Administration's (OSHA) proposal for a new occupational safety and health rule on occupational exposure to infectious diseases. Since most surgery centers are small, lean businesses, the proposed rule would add cost and staffing requirements for ASC. The goal for our surgery centers is to provide high quality, cost effective patient care, thereby reducing Medicare money spent for surgical services. Therefore, we oppose the additional burdens outlined in the proposed rule for the following reasons:

- There is no clear evidence that there is a problem. OSHA concedes that it does not have data on the exact number of occupationally-acquired infectious diseases in the United States and other developed countries because there are no centralized surveillance systems that specifically document all occupationally-acquired infectious diseases.
- ASCs already comply with infection control standards and regulations from federal agencies, state licensing boards, and accreditation organizations. In Medicare's (CMS) Conditions for Coverage (CfCs) for ASCs, Section 416.51(b) requires facilities. ASCs provide training and education in infection control and occupational exposure upon hire, prior to exposure, and annually. This training is presently overseen by an Infection Preventionist at the ASC.
  Adding another set of guidelines that are similar to the guidelines already being enforced by OSHA and other agencies will cause more confusion as well as added financial and staffing burdens.
- ASCs do not admit patients with known infectious diseases. However, in the proposed rule, ASCs are being included as "ambulatory care settings" which encompasses many different entities, including primary care physicians, urgent care centers, and oncology clinics. This category is used to refer to healthcare workers in settings with a heightened risk of exposure to infectious diseases, which does not apply to the ASC setting
- Concerns regarding medical removal protection (MRP) requirements and how it will be determined whether the employee acquired the infectious disease at the ASC, since many infectious disease can be contracted in any public environment.

In addition, I have attached the comments from the Ambulatory Surgery Center Association (ASCA), who represents the interests and concerns of 5,300 surgery center nationwide.

Again, thank you for the opportunity to participate as a small entity representative-it has been a very instructional process.

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December 2, 2014

Mr. Robert Burt, Chair
SBAR Panel on Infectious Diseases
Occupational Safety and Health Administration
U.S. Department of Labor
200 Constitution Avenue NW
Washington, DC 20210

Re: Written Comments on OSHA's Infectious Disease SBAR Panel

Dear Mr. Burt:

Thank you for convening and serving as Chair of OSHA's SBAR Panel on Infectious Diseases. We appreciate OSHA's consideration of the comments received and the concerns expressed by the Small Entity Representatives ("SERs") throughout the process.

I am writing on behalf of the Washington Health Care Association, a statewide non-profit organization representing nearly 500 assisted living and skilled nursing facilities.

At the outset, we would like to emphasize the unique nature of the nursing home and assisted living environment (the "long term care industry"). The long term care industry must navigate multiple regulatory schemes designed to protect the safety and health of employees *and* the safety and health of residents. In the long term care industry, residents are guaranteed certain rights, which can impact how a facility is able to implement workplace safety and health rules. For residents, their rooms are their "homes" and facilities can be prohibited from taking certain actions which infringe upon how residents are allowed to "live" in their homes. As OSHA continues to examine this rule, it is important for the Agency to specifically review how the requirements will be implemented in the long term care industry given the unique residents-rights issues involved.

As with many of the other Small Entity Representatives ("SERs") involved in the SBAR Panel review, we have experience with OSHA's bloodborne pathogens standard and recognize that OSHA has borrowed some of the principles from that standard in this regulatory initiative. We have concerns, however, as to whether OSHA has justified the need for this action in the first instance. Furthermore, we fear several of the provisions will be difficult and burdensome to implement. We ask that OSHA review the need for the rule and many of its provisions before proceeding with a proposal.

Worker Infection Control Plan

The lynchpin of OSHA's approach in this rulemaking is the requirement that employers develop a Worker Infection Control Plan ("WICP"). The WICP seems similar in design to a bloodborne

pathogen exposure control plan. According to the draft proposal, developing a WICP will involve identifying the potential sources of infection at a facility and the employees potentially exposed. It would need to be updated annually.

In addition to the WICP, there is a requirement for employers to implement a number of Standard Operating Procedures ("SOPs") that are consistent with recognized and generally accepted good infection control practices. These SOPS would need to be updated as the Centers for Disease Control ("CDC") or other organizations implement or change guidance in the area of infectious disease. OSHA has identified the need for numerous SOPs.

For small employers in the long term care industry, the development and ongoing updating of SOPs will be extremely burdensome. Most small employers do not have in-house resources readily available to continually track CDC or other guidance from the public health community. OSHA's use of a process safety management ("PSM") approach to this rule will place a heavy burden on small employers. Aside from the burden associated with this, small employers will have difficulty—without specific guidance from OSHA—knowing which practices need to be examined and updated.

Host-Contractor Provisions

We are also concerned about the proposed requirements for contractor safety. As set forth in the SBREFA materials, OSHA is requiring host employers to ensure that contractors, vendors, or independent healthcare practitioners, adhere to infectious control procedures at least as effective as those of the host employer.

While we understand OSHA's overall concern with ensuring all employers at a facility are following good hygiene practices and implementing appropriate protective measures, it is a real challenge in the long term care environment to ensure that contractors are adhering to facilities' (or even their own) infectious disease procedures. In the long term care industry, often contractors are specifically selected by the residents, particularly in the case of independent healthcare practitioners. It is very difficult to establish control over these individuals.

In addition, in the long term care industry, many families will hire "sitters" to come into the facility to spend time with resident family members. These sitters are often not "employees" under the Occupational Safety and Health Act of 1970 and it will be extremely difficult for small employers to take action to ensure that these contractors are in full compliance with OSHA's proposed requirements.

Medical Screening and Medical Removal Protection

OSHA's proposed framework would require employers to provide certain vaccinations to employees as provided by recognized and generally accepted good infection control practices. In addition, medical screening and surveillance services would need to be provided to employees post-exposure. In addition, if it is determined that employees must remain outside of work due to a medical

condition related to workplace exposure to an infectious disease, employers must ensure that these employees maintain full pay and benefits during this time.

We have concerns regarding how these costs will be handled by small employers in the long term care industry and would encourage OSHA to examine very closely whether workers compensation will cover certain infectious diseases. From informal conversations with certain workers compensation insurers, we understand that many OSHA-covered infectious diseases will not be supported by workers compensation, causing the full costs to be borne by employers.

When examining the costs of these provisions, we encourage OSHA to also consider the practical impact of medical removal protection ("MRP") on small employers. Many small employers do not have sufficient staff to draw from to cover for work absences, particularly extended work absences. In these situations, employers may need to hire from temporary staffing agencies or make other arrangements. When determining the appropriateness of MRP, we encourage the Agency to consider the full financial burden associated with hiring a second employee, while maintaining full pay and benefits of the employee out of work on medical removal (without any offset from workers compensation).

We also request that OSHA examine the purpose of MRP in this rule *vis-à-vis* prior OSHA health standards that have required MRP. In those other standards, the Agency has required MRP based on evidence that employees may be reluctant to report illnesses or participate in medical surveillance for fear of losing pay and benefits. We ask OSHA to examine specifically if there is such evidence in the area of infectious disease in the affected industries to justify this burden before proceeding to include MRP in any proposed rule.

Cost Estimates

We appreciate OSHA's efforts to estimate the costs of the proposal. However, our initial review of the costs suggests that they are understated, particularly with respect to the provision and use of personal protective equipment ("PPE").

As a general matter, OSHA has estimated that much of the PPE can be used multiple times throughout a shift (e.g., a facemask can be used until visibly soiled). We respectfully suggest that OSHA – for cost estimate purposes – substantially increase the number of times per shift that PPE must be changed. As a best practice, many employers have implemented single-use practices and particularly with employees with direct patient care responsibilities. We also anticipate that for certain disease outbreaks, recognized and generally accepted infection control practices could mandate single use for PPE. We respectfully request that OSHA consider this when issuing any proposed rule.

Again, we appreciate OSHA conducting the SBAR Panel review and considering the concerns of affected SERs. Should the Agency have any further questions related to the proposal or its impacts on the long term care industry, we would be happy to assist.

Sincerely,

WASHINGTON HEALTH CARE ASSOCIATION

Robin Dale, CEO

December 2, 2014

TO: Mr. Robert Burt, Chair
SBAR Panel on Infectious Diseases
Occupational Safety and Health Administration
U.S. Department of Labor
200 Constitution Avenue, NW
Washington, DC 20210

From: Scott George, CEO
Mid-America Dental & Hearing Center
1050 W. Hayward Dr.
Mt. Vernon, MO 65712

RE: Written Comments on the proposed OSHA Infectious Diseases Regulations

Dear Mr. Burt,

I am writing you today to recommend that you withdraw the proposed OSHA Infectious Diseases regulations as they will be extremely harmful to small health care businesses, drive up the cost of health care in America, and have little discernable effect on the spread of these diseases. This letter is my comments regarding that recommendation.

First a little background. My primary duties are as a Business Practice Manager for a company that handles the nonprofessional side of business for a multi-office dental practice, a multi-office hearing care practice, and to a lesser extent, a single physician family practice.

I have been involved in small business regulatory issues since the 90's. First, as a delegate to the 1995 White House Conference on Small Business; then, testifying in front of the U.S. Senate on the 1996 Small Business Regulatory Fairness Act (SBREFA). I am pleased that OSHA is complying with that legislation by convening this small business panel to seek the input of affected small businesses and to consider ways to minimize the impact of proposed regulations on small businesses.

"One small business speaks for many" has been one of guiding principles of SBREFA. Many small businesses are too busy, or too intimidated, to speak up on how regulations impact their businesses and the employees lives. While some on this panel may fall in the too busy category, we recognize that the few small businesses on this panel must speak for the hundreds of thousands who cannot. I ask that you heed our comments in that light.

Also relevant, is that I live in Mt. Vernon, Missouri where the TB Sanatorium for Missouri was built in 1907. For decades, every Missouri resident with TB was required to come here until they were no longer active. The health care workers in our families treated them. Their families moved here. They all lived among us. I made many visits to the TB Sanatorium during my teen years.

Additionally, I served four years on the initial federal Small Business Regulatory Fairness Board (for Region VII), have worked for state level regulatory fairness legislation, and am serving my second term on the Missouri State Small Business Regulatory Fairness Board. Throughout those years of service, it has been very gratifying that many state and federal agencies have taken Reg Fair to heart seeking the

input of affected small businesses, minimizing the impact of regulations, reducing and eliminating fines for first time offences, and recognizing that helping small businesses comply with regulations is much more effective than coercing compliance through onerous fines publicly levied.

In that spirit, I welcome the opportunity to be part of the OSHA Infectious Diseases SBAR Panel. Just as during my years on the Reg Fair board, small businesses expect to be able to ask tough, but fair, comments and questions; and, OSHA expects to heard when they respond with competent and capable answers.

Finally, OSHA sent out follow-up questions related to Ebola protections. Answers to those questions are also included near the end.

My Written Questions and Comments follow:

- Where is the data that health care workers are becoming infected on the job? The CDC tracks every health care worker that got HIV on the job. When I called the CDC on the infectious diseases, they stated they do not track these diseases.
    - Our facilities have been in business for 35 years with no known infection of any of these diseases. We have diligently followed the blood borne pathogens standard. A recent OSHA inspector noted that this was the best dental facility he had ever been in. Then, handed us a list. To his credit, he was helping us comply; rather than, coercing us.
    - OSHA's handouts alluded to a TB study done 17 years ago for a never published TB regulation. If that data was so compelling, why wasn't the regulation done then?
    - Other handout references talked about other studies as if it was a given that workers were getting these diseases on the job. Yet, no one on my conference call indicated that this was a problem in their work place.
    - The OSHA handout stated that since the OSHA Blood Born Pathogen standard was so effective. Yet, after the early 90's sensational media stories about dental patients becoming infected with HIV, OSHA burdened the dental business with the Blood Borne Pathogen standard. When I testified in front of Congress in 1996, of the 43 employees who ever had gotten HIV on the job, not one was a dental health care worker.
    - Following the most recent sensational stories about the Tulsa surgeon who never properly cleaned or sterilized his instruments, free tests were given to everyone who asked. Not one patient or employee had contracted any infectious blood borne disease attributable back to his offices.
    - Most health care workers, who contract HIV, do so because of life style choices. Back in 1996, the CDC identified thousands of such workers. Yet, only 43 were verified to have gotten it on the job.
    - Note that in response to one follow-up question, OSHA stated that if an employee contracted one of these infectious diseases, they were presumed to have gotten it on the job. In follow up questions, they backtracked and said only if it was demonstrated to have been on the job.
    - Since all of these diseases are prevalent in society, how would one ever determine that the infection came from the work place. Sounds like a great opportunity for trial attorneys showing the poor, sick employee being picked on by the big, rich employer.
    - So, where are the current data studies showing that employees are contracting these infections diseases on the job in sufficient numbers to warrant the proposed regulation?

- Without data to demonstrate there is a problem with employees getting these diseases in the workplace, OSHA should withdraw the proposed rules. Or, at the very least, limit them to only those work places with a demonstrated risk.

- Why does this proposed regulation come up now?
  - As noted earlier, the TB regulation was drafted in 1997 and never implemented. What has changed?
  - It is telling that OSHA only mentioned Ebola in several of their responses. Ebola certainly has been sensationalized in the media for the past several months. It certainly appears that Ebola is on OSHA's mind. Thankfully, it appears that the Ebola situation is coming under control. There has been no major outbreak.
  - I pray Ebola does not become a national issue. If it did, how would this standard have protected our co-workers and the general public?
  - Certainly, OSHA would not want to appear to be part of the "let no crisis go to waste" crowd. Therefore, Ebola should not be used as a reason to implement; unless, these regulations would inhibit an outbreak. Because they do not, the proposed regulations should be withdrawn.

- Where is the true cost benefit analysis?
  - The dental profession, really their patients through the increased cost of dental care, spends billions every year on the OSHA Blood Born Pathogen standard. Remember? In the mid-90's, the CDC could not identify a single dental health care worker who got HIV on the job. Recently, the CDC stated there was one single dental worker case. One single dental health care worker compared to billions of dollars lost every year.
  - The startup and operating cost estimates are very low. OSHA's estimates back in the early 90'sfor blood borne pathogens were very low. Their startup estimates were about $7,500 per practice with about $1,700 in annual operating costs. Our one practice incurred over $25,000 in capital expenses, uncounted hundreds of hours in setting up the programs and training doctors and staff, and an estimated nearly $200,000 annual operating costs.
  - The medical removal operating costs were not even included in the estimates. Of course, they are so significant, they would bankrupt the analysis. And, they will bankrupt affected small health care practices leaving no choice but to close. The costs of paying for key employees to be off weeks, months, or even years, until they are fit to return to duty, are simply huge. Many of these health care businesses, including hospitals, are in rural areas. Thus, forcing many poor and elderly citizens to drive long distances to seek health care. The medical removal costs must be included in a true cost benefit analysis.
  - Based on our prior experiences, the startup costs could be off by a factor of 10. Even without the medical removal costs, operating costs for training, equipment, and supplies are easily off by a factor of 10.
  - Add in medical removal costs, and the costs of these regulations far exceed any possible benefits. Therefore, the proposed regulations should be withdrawn.

- Unintended consequences should be considered.
  - When Blood borne Pathogens standard was applied to the dental profession, we lost staff. They could not accept the risk of taking HIV home to their families. Skilled dental professionals and technicians left the dental field forever. Several Doctors stated they

were just going to retire. Thankfully, none did immediately. One doctor retired a year later citing the hassle and lost productivity related to the blood borne standard. How many health care professionals will quit or retire?
  - How will we identify patients with these diseases? Most small businesses will not have the wherewithal to immediately diagnose while the patient is in the waiting room. So, the patient must self-identify. Some smalls are likely to refuse service as they cannot handle the restrictions. Just like what happened with HIV patients, infected patients quickly learn to not self-identify; thus, putting everyone at risk.

- Universal Precautions will require treating every patient as if they are infected with these diseases.
  - As indicated above, patients quickly learn not to self-identify when they have blood borne diseases.
  - Some active TB carriers demonstrate no symptoms and may not even know they have the disease.
  - Treating infected patients differently runs the risk of HIPAA violations and discrimination charges.
  - We now follow universal precautions treating every patient as if they have blood borne diseases. We would have little choice; but, to treat every patient as if they have an infectious disease.
  - IS every patient to be treated to the extra steps required in these regulations? Every operatory and every bed in every hospital a safe room? Few large or small businesses can afford that. It will push many out of business.

- The medical removal requirement will impose huge costs on small businesses. And, it completely bypasses the state Worker's Compensation programs that now protect both employees and small businesses.
  - Anyone hurt or injured on the job falls under workers comp. Why treat infectious diseases any different? If small businesses must pay full salary and benefits, with no loss of job status, until an employee is fit to return to duty, most such small businesses will be bankrupted and forced to close down.

- The medical removal requirement sets up an unnecessary point of contention between employees and employers.
  - Proving whether or not an employee contracted an infectious disease on the job is a boon to trial attorneys and a huge drain on small businesses.
  - In their response to questions, OSHA took the position that if there is any likelihood the employee got the disease on the job, the company was at fault and the employee was eligible for medical removal. Remember the 43 number from the mid-90's above. Only 43 health care workers got HIV on the job. Most HIV infections were from life style.
  - Later, OSHA restated their position to only when it was proved that the employee got it on the job. Here come the lawyers leaving the company to prove they did NOT get it on the job.
  - Workers Comp programs take the legal hassle out of the determination.
  - Based on the last two points, the medical removal requirement should be removed from the regulations allowing the state Workers Compensation programs to cover the issue.

- For contact transmissible infectious diseases, it appears that the current blood borne standard universal precautions are sufficient to protect health care workers.
  - Our direct health care workers use Personal Protective Equipment, such as gloves, when treating patients. Hand washing is acknowledged to be the best protection.
  - Front desk personnel use protective equipment, such as plastic bags, to avoid direct contact with dental prosthetics and hearing aids.
  - However, contact transmissible agents, like MRSA, can be on anything the patient touches. Think cash money, credit cards, and patient history paper work.
  - Is OSHA suggesting that everyone glove up to handle money, credit cards, or paper records? Is this a real risk? Then, it exists in every retail establishment nation-wide.
  - Where's the data that shows how many health care workers have gotten these infections on the job. Or, the data that current blood borne pathogens standards are not working.
  - Without any demonstrated additional risk, contact transmissible diseases should be dropped from the proposed regulations.

- For droplet transmissible infectious diseases, it appears that the current blood borne standard universal precautions are sufficient to protect health care workers.
  - Direct health care workers use Personal Protective Equipment, such as masks, when treating patients.
  - Front desk personnel have some degree of separation with the front counters.
  - However, droplet transmissible agents, like influenza, can be in every breath exhaled. Is OSHA suggesting that everyone mask up to check-in patients, take payments, walk down hallways, or talk with patients?
  - Is this a real risk? If so, it exists in every retail, government, and other establishment nation-wide.
  - Where is the data that shows how many health care workers have gotten these infections on the job. Or, the data that current blood borne pathogens standards are not working.
  - Without any demonstrated additional risk, droplet transmissible diseases should be dropped from the proposed regulations.

- For airborne transmissible agents, like TB, it appears that the current blood borne standard universal precautions are sufficient to protect health care workers.
  - Direct health care workers use Personal Protective Equipment, such as masks, when treating patients.
  - Front desk personnel have some degree of separation with the front counters.
  - Yet, these viruses, like TB, are quite robust. If a TB-active person walks down a hallway, everyone else walking down that hallway is breathing in the TB virus. TB active people walk thru stores, churches, malls, and everywhere people gather.
  - Remember that I live where the Missouri TB Sanatorium operated for decades. They obviously had no safe rooms. Fresh air and exercise were the only known treatments. Why didn't we all get TB?
  - Is OSHA suggesting that everyone mask up to check-in patients, take payments, walk down hallways, or talk with patients? Is this a real risk? If so, it exists in every retail, government, and every other establishment nation-wide.

- Where is the data that shows how many health care workers have gotten these infections on the job. Or, the data that current blood borne pathogens standards are not working.
- Without any demonstrated additional risk, airborne transmissible diseases should be dropped from the proposed regulations.

OSHA had some delayed questions related to Ebola. Responses follow:

- If you have looked at the CDC guidelines for Ebola, how would the proposed OSHA standard change how you would respond to an Ebola exposure under the blood borne pathogens standard?
  - The CDC talks about how to handle a patient who already has the Ebola virus. It refers to all skin being covered. Wearing proper PPE achieves over 95% coverage.
  - CDC refers to disinfecting "visibly contaminated surfaces." Current blood borne standards include this.
  - Note that the CDC focuses on hospital or emergency settings; not, the rural or small town office settings.

- Based upon your experiences or understanding of the response to Ebola, is there anything that the Agency should change about its current proposal?
  - Current PPE policy would have been effective against Ebola had all SOP's been followed initially when healthcare workers came in contact with the infected patient. The CDC placed more intense PPE orders in place after the patients were diagnosed and the fear hit the public. According to how the CDC says that Ebola is transmitted, current PPE should have been effective initially.
  - Once diagnosed, the Ebola patient should be transferred to an acute setting for long term setting of constant care.
  - If anything, OSHA should narrow the scope of the proposed regulations to only those acute care facilities treating highly contagious diseases like Ebola.

- Do you think the Medical Removal Protection provisions in the proposed OSHA standard should cover situations where employees have been quarantined as a result of an occupational exposure to Ebola?
  - These employees should fall under current Workers Compensation programs. The medical removal requirement bypasses state workers comp programs, introduces exorbitant and duplicative costs for small businesses that already pay workers comp premiums, and places a bone of contention between the worker and the employer that does not now exist.
  - Any such affected small business would be at risk to go out of business; thus, costing all their employees, included the sick worker, their jobs.

- Should the Agency consider creating a separate Ebola-specific standard by adapting the draft language to include only provisions related to protection from Ebola?
  - There does not appear to be any real risk from Ebola. In 1990 there were 4 reported asymptomatic cases in the United States. Then, another 4 in 2014. That is 24 years apart, with a population of 317 million people in the United States. Can the cost the implementing these new requirements be justified by OSHA?
  - From media reports, it appears that those workers contracting Ebola failed to follow current precautions. New regulations won't stop that.

- If any Ebola specific regulations should be needed, they should only relate to those acute care facilities where the individual would be treated after diagnosis.

In summary, in the materials presented as background for these proposed regulations, OSHA failed to demonstrate there is any risks to the small business health care worker. OSHA failed to adequately estimate the costs, by at least ten fold, of implementing the regulation.

Further, OSHA failed to estimate, or even consider, the enormous cost of the medical removal requirement.

Universal Precautions for blood borne pathogens appear to be adequate protections for most health care employees.

Since there were little demonstrated risks, enormous costs, few demonstrated benefits, and current precautions appear adequate, these proposed infectious diseases regulations should be withdrawn.

Thank you for the opportunity to serve,

J. Scott George, CEO

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417-466-7184 ext. 152

Paige, Lajuane M. - OSHA CTR

From: HHOGROUP@aol.com
Sent: Wednesday, November 19, 2014 8:31 AM
To: Paige, Lajuane M. - OSHA CTR
Subject: Comments

I am in Health Care we have numerous Emergency Preparedness policies - so please keep this in mind when reviewing our comments.

We are strongly suggesting that OSHA consider providing guide lines first - so local and sate agencies can co-ordinate with OSHA..

Our major issues relate to Common language - Need of OSHA to comply with WHO and CDC nomenclature.

A few dieses can be tied back to the work place - but many can not and to ask the employer indemnify the employee.

Infection Control Policy and Procedure

Staff training new employees and annually in servicing

Protective personal equipment

Disposal of medical waste

Identification and monitoring

Hazard evaluation process

Record keeping

Measures to reduce exposure including vaccinations

Exposure reporting

General Comments

The term infectious diseases must be specifically defined using recognized standards such as those employee by the WHO or CDC. The nomenclature utilized in the document is far too broad to allow for any reasonable compliance standard. For example, the common cold by definition would be an infectious disease.

When can we expect to see an in depth identification of the implementation cost of this regulation?

The term "contaminated materials" should be changed to "medical waste" throughout the document

There seems to be no recognition that "emergency preparedness" has occurred and that there are many policies and procedures that have been developed in conjunction with local health departments to meet the specific needs of communities. Somehow these regulations must recognize those individualized policies and procedures.

Perhaps OSHA should consider issuing guidelines to employers as a first step in moving to a more controlled regulatory environment. Regardless of any regulations employers do have a legal obligation to keep their employees healthy and safe while working.

Q&A Frame work document

Page 4-Vaccination provisions – what is the liability of the employer when an employee refuses to be vaccinated

The time frame for medical records duration of employment plus 30 years is excessive

Panel Issue document

Page 3 -What Employers Would have to do to comply- we need a definition for "facility".

Page 7 home health care is clearly required to comply yet the document as proposed does not reflect that care is delivered in private homes or residents. For example on page 12 Engineering controls would be out of the control of a home care provider.

Page 21 -Medical Surge Procedures have already been established by state and local communities. It would be inappropriate for OSHA to include any regulation regarding surge.

Page 23 - Vaccination issue again

Page 25 - Medical Screening and Surveillance is inconsistent with CDC recommendations particularly as it relates to TB testing. Any language on this topic should reflect current practices and guidelines.

Page 28 - Training Questions are well written and comprehensive

Outline of Key Provisions Document

Page 2 -Section 4 the language "employers would be required to consider" is confusing. Perhaps the term "guidelines" would be clearer.

Page 11 -Host employer is an unrealistic mandate.

US Department of Labor Infectious Disease Document

Page 74 --Table VI-3 does not accurately reflect the full cost of N95 respirators. Furthermore the use of this type of equipment would not be appropriate in the home health setting.

Sue Luster

President
Home Health Options Group, Inc.
3955 Pender Drive #130
Fairfax, VA 22030
703-622-3343
Fax 703-293-2932

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nursing facility association

nebraska
assisted living association

advocate. educate. support.

December 4, 2014

Mr. Robert Burt, Chair
SBAR Panel on Infectious Diseases
Occupational Safety and Health Administration
U.S. Department of Labor
200 Constitution Avenue, NW
Washington, DC 20210

Re: Written Comments on OSHA's Infectious Disease SBAR Panel

Dear Mr. Burt:

Thank you for convening and serving as Chair of OSHA's SBAR Panel on Infectious Diseases. The Nebraska Nursing Facility Association and Nebraska Assisted Living Association appreciate OSHA's consideration of the comments received and the concerns expressed by the Small Entity Representatives (SERs) throughout the process.

The Nebraska Nursing Facility Association/Nebraska Assisted Living Association (NNFA/NALA) is a private, nonprofit trade association that represents more than 400 governmental, non-profit, and for-profit nursing facilities and assisted living communities in Nebraska.

At the outset, we would like to emphasize the unique nature of the nursing facility and assisted living environment (the "long-term care industry"). The long-term care industry must navigate multiple regulatory schemes designed to protect the safety and health of employees *and* the safety and health of residents. In the long-term care industry, residents are guaranteed certain rights, which can impact how a facility is able to implement workplace safety and health rules. For residents, their rooms are their "homes" and facilities can be prohibited from taking certain actions which infringe upon how a resident is allowed to "live" in their homes. As OSHA continues to examine this rule, it is important for the Agency to specifically review how the requirements will be implemented in the long-term care industry given the unique residents-rights issues involved.

As with many of the other SERs involved in the SBAR Panel review, we have experience with OSHA's bloodborne pathogens standard and recognize that OSHA has borrowed some of the principles from that standard in this regulatory initiative. However, we have concerns as to whether OSHA has justified the need for this action in the first instance. Furthermore, we fear that several of the provisions will be difficult and burdensome to implement. We ask that OSHA review the need for the rule and many of its provisions before proceeding with a proposal.

Worker Infection Control Plan

The lynchpin of OSHA's approach in this rulemaking is the requirement that employers develop a Worker Infection Control Plan (WICP). The WICP seems similar in design to a bloodborne pathogen exposure control plan. According to the draft proposal, developing a WICP will involve identifying

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Affiliates of the Nebraska Health Care Association,
American Health Care Association, and National Center for Assisted Living

the potential sources of infection at a facility and the employees potentially exposed. It would need to be updated annually.

In addition to the WICP, there is a requirement for employers to implement a number of Standard Operating Procedures (SOPs) that are consistent with recognized and generally accepted good infection control practices. These SOPS would need to be updated as the Centers for Disease Control (CDC) or other organizations implement or change guidance in the area of infectious disease. OSHA has identified the need for numerous SOPs.

For small employers in the long-term care industry, the development and ongoing updating of SOPs will be extremely burdensome. Most small employers do not have in-house resources readily available to continually track CDC or other guidance from the public health community. OSHA's use of a process safety management (PSM) approach to this rule will place a heavy burden on small employers. Aside from the burden associated with this, small employers will have difficulty – without specific guidance from OSHA – knowing which practices need to be examined and updated.

Host-Contractor Provisions

We are also concerned about the proposed requirements for contractor safety. As set forth in the SBREFA materials, OSHA is requiring host employers to ensure that contractors, vendors, or independent healthcare practitioners adhere to infectious control procedures at least as effective as the host employer's.

While we understand OSHA's overall concern with ensuring all employers at a facility are following good hygiene practices and implementing appropriate protective measures, it is a real challenge in the long-term care environment to ensure that contractors are adhering to facilities' (or even their own) infectious disease procedures. In the long-term care industry, often contractors are specifically selected by the residents – particularly in the case of independent healthcare practitioners. It is very difficult to establish control over these individuals.

In addition, in the long-term care industry, many families will hire "sitters" to come into the facility to spend time with resident family members. These sitters are often not "employees" under the Occupational Safety and Health Act of 1970 and it will be extremely difficult for small employers to take action to ensure that these contractors are in full compliance with OSHA's proposed requirements.

Medical Screening and Medical Removal Protection

OSHA's proposed framework would require employers to provide certain vaccinations to employees as provided by recognized and generally accepted good infection control practices. In addition, medical screening and surveillance services would need to be provided to employees post exposure. In addition, if it is determined that employees must remain outside of work due to a medical condition related to workplace exposure to an infectious disease, employers must ensure that these employees maintain full pay and benefits during this time.

We have concerns regarding how these costs will be handled by small employers in the long-term care industry and would encourage OSHA to examine very closely whether workers compensation will cover certain infectious diseases. We understand that many OSHA-covered infectious diseases will not be supported by workers compensation, causing the full costs to be borne by employers.

When examining the costs of these provisions, we encourage OSHA to also consider the practical impact of medical removal protection (MRP) on small employers. Many small employers do not have large staffs to draw from to cover for work absences, particularly extended work absences. In these situations, employers may need to hire from temporary staffing agencies or make other arrangements. When determining the appropriateness of MRP, we encourage the Agency to consider the full financial burden associated with hiring a second employee, while maintaining full pay and benefits of the employee out of work on medical removal (without any offset from workers compensation).

We also request that OSHA examine the purpose of MRP in this rule *vis-à-vis* prior OSHA health standards that have required MRP. In those other standards, the Agency has required MRP based on evidence that employees may be reluctant to report illnesses or participate in medical surveillance for fear of losing pay and benefits. We ask OSHA to examine specifically if there is such evidence in the area of infectious disease in the affected industries to justify this burden before proceeding to include MRP in any proposed rule.

Cost Estimates

We appreciate OSHA's efforts to estimate the costs of the proposal. Initial review of the costs suggests that they are understated, particularly with respect to the provision and use of personal protective equipment (PPE).

As a general matter, OSHA has estimated that much of the PPE can be used multiple times throughout a shift (e.g., a facemask can be used until visibly soiled). We respectfully suggest that, for cost estimate purposes, OSHA substantially increase the number of times per shift that PPE must be changed. As a best practice, many employers have implemented single-use practices, particularly with employees with direct patient care responsibilities. We also anticipate that, for certain disease outbreaks, recognized and generally accepted infection control practices could mandate single use for PPE. We request that OSHA consider this when issuing any proposed rule.

Again, NNFA/NALA appreciates OSHA conducting the SBAR Panel review and considering the concerns of affected SERs. Should the Agency have further questions related to the proposal or its impacts on the long-term care industry, we would be happy to assist.

Sincerely,

Heath G. Boddy
President and CEO

ASCA

November 13, 2014

Bruce E. Lundegren, Assistant Chief Counsel
Office of Advocacy
US Small Business Administration
409 3rd St. SW, Washington, DC 20416

Re: US Department of Labor Infectious Diseases SER Background Document

Dear Mr. Lundegren:

On behalf of the Ambulatory Surgery Center Association (ASCA), representing the interests of more than 5,300 Medicare-certified ambulatory surgical centers (ASCs) nationwide, we appreciate the opportunity to comment on the US Occupational Safety and Health Administration's (OSHA) proposal for a new occupational safety and health rule on occupational exposure to infectious diseases. ASCs offer patients a high-quality, convenient and low-cost choice for their care. The proposed rule would add unnecessary cost and staffing requirements for ASCs, many of whom are small businesses. Our facilities are able to save the Medicare system money because they are efficient and lean. As such, we oppose the additional burdens outlined in the proposed rule for the following reasons.

Lack of Data to Support Additional Requirements

OSHA states this rule "would not only have the direct benefit of reducing occupational illness rates for covered workers, but also have the ancillary benefit of reducing illness rates for patients and other individuals, such as family members, who come into contact with covered workers." However, there is no data to confirm that exposure of healthcare workers to infectious diseases in the workplace is an issue. The rule concedes that "OSHA does not have data on the exact number of occupationally-acquired infectious diseases in the United States and other developed countries because there are no centralized surveillance systems that specifically document all occupationally-acquired infectious diseases." It is unclear why a policy would be implemented without the ability to enable healthcare facilities to measure improvement due to a lack of surveillance currently in place against which to compare results. We also have serious concerns about placing additional regulatory burdens on ASCs without clear evidence of a problem.

The proposed rule indicates that "employers whose workers are within the scope of the regulatory framework to develop and implement a written worker infection control plan (WICP) designed to prevent or minimize the transmission of infectious agents to workers." ASCs already comply with infection control standards and regulations from federal agencies, state licensing boards, and accreditation organizations. In Medicare's (CMS) Conditions for Coverage (CfCs) for ASCs, Section 416.51(b) requires facilities to "maintain an ongoing program designed to prevent, control, and investigate infections and communicable diseases. In addition, the infection control and prevention program must include documentation that the ASC has considered, selected, and implemented nationally recognized infection control guidelines." ASCs provide training and education in infection control and occupational exposure upon hire, prior to exposure, and annually. This training is presently overseen by an Infection Preventionist at the ASC.

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ASCs use nationally-recognized infection control guidelines and recommendations from organizations which include, but are not limited to, the Centers for Disease Control and Prevention (CDC), the Association for Professionals in Infection Control and Epidemiology (APIC), the Society for Healthcare Epidemiology of America (SHEA), and the Association of periOperative Registered Nurses (AORN). These guidelines assist the ASC in following key functions of their infection control program which includes but is not limited to: maintaining a sanitary environment, developing and implementing infection control activities related to ASC personnel, identifying infections, monitoring compliance with infection control policies and procedures, and evaluating the ASCs infection control program on an annual basis. ASCs are also compliant with the requirements in OSHA's standard 29CFR 1910.1030 regarding occupational exposure to Bloodborne pathogens.

ASCs also presently comply with federal agencies (CMS, OSHA, EPA) and state agencies in regards to infectious agent hazard evaluations; communication of hazard evaluation results; hand hygiene; food and cosmetics; engineering, administrative, and work practice controls and PPE; decontamination; handling, containerization, transport, or disposal of contaminated materials; occupational health services; exposure incidents; signage and labeling/color-coding; and notification of occupational exposure during transfer, transport, shipping, or receipt of sources of infectious agents.

The proposed rule states that because of "the lack of consistent and rigorous enforcement of current guidelines, certain workers are not adequately protected against the risk of occupational acquisition of infectious diseases, and OSHA believes that covering those workers under a rule as outlined in the regulatory framework would reduce their risk." As evidenced above, the ASC industry is already subject to expansive federal, state, and accrediting organization requirements regarding infection control. Adding another set of guidelines that are similar to the guidelines already being enforced by OSHA and other agencies will cause more confusion as well as added financial and staffing burdens.

One Size Does Not Fit All

The ASC industry strongly agrees with the language in the proposed rule that "Infection Control Plans Are Not and Cannot Be One Size Fits All." Since ASCs are facilities that perform elective surgical services, our facilities do not see patients with known infectious diseases. However, in the proposed rule, ASCs are being included as "ambulatory care settings" which encompasses many different entities, including primary care physicians, urgent care centers, and oncology clinics. This category is used to refer to healthcare workers in settings with a heightened risk of exposure to infectious diseases, which does not apply to the ASC setting.

An extensive medical history, including a patient's infectious disease status, is performed before the patient is admitted to the facility. Our facilities do not accept patients with known infectious diseases. If a patient does arrive at the center with an infectious disease, center personnel will isolate the patient utilizing the appropriate personal protective equipment (PPE) and transfer to a higher level of care, which would cause minimal exposure to ASC personnel. Due to this fact, ASCs don't have an airborne isolation room (AIIR) so the procedures ensuing proper operation would not apply to ASCs. Therefore, ASCs should not be designated as facilities with a

heightened risk of exposure to infectious diseases, and should not be held to this and other standards to apply to those facilities that do have an increased risk of exposure.

ASCs are Often Small Businesses with Limited Resources

The ASC industry is concerned about the cost and staffing requirements that would be needed to make vaccinations available to employees. If ASCs chose to keep the vaccines in stock, the vaccines would have to be discarded due to expiration because of underuse due to the small number of employees at ASCs. In addition, the medication refrigerator would have to be kept at a certain temperature for each vaccine, plus monitored twice daily according to CDC guidelines, which would cause extra burden for staff. Also, the ASC would have to pay for any titer(s) that would be associated with the vaccines. If the ASC prefers to send the employee to an occupational medicine/clinic for the vaccine administration, the ASC would have to pay extra staff to cover the absence of the employee.

The ASC industry also has concerns regarding medical removal protection (MRP). In the proposed rule if a worker is "removed from the job or is otherwise medically limited as a result of an exposure incident, the employer would be required to pay, to the worker, the worker's total normal earnings and to maintain the worker's seniority and all other worker rights and benefits, including the worker's job status." The first concern is determining whether the employee acquired the infectious disease at the ASC. Most infectious disease can be contracted in any public environment (gym, local store, etc.). The ASC would be financially responsible for all benefits and total normal earnings for an infectious disease that could have been acquired elsewhere. Also, if an employee is absent from work for a lengthy period of time, the ASC would have to hire a replacement for that employee which is another financial burden. When the infectious employee is deemed non-contagious in order to return to work, the ASC would have to determine the employment status of the replacement employee which could cause staffing concerns. If the infectious disease is deemed to have been acquired at the ASC, it is unclear whether or not state workers compensation laws may also apply, which can also add significant expense, particularly to small businesses.

The proposed requirement of post-exposure prophylactic treatment for influenza is also problematic. In the proposed rule, OSHA sites a CDC source who recommends that "an exposed worker needs the following post-exposure prophylactic treatment: either Oseltamivir 75 mg once a day for 10 days, or Zanamivir 10 mg (inhalation) once a day for 10 days." As articulated above with regards to infectious diseases, an employee can be exposed to influenza in any environment, inside and outside of the workplace, on any given day. Due to this, all employees could be exposed and would require ASCs to offer this treatment. In recent media publications, there has been discussion regarding the over-prescribing of antibiotics. This policy could be seen as requiring the over-medicating the employee for a possible exposure to influenza. Once again, it is simply an added expense with no clear benefit to the employee.

Summary

Ambulatory surgery centers currently comply with the standards and regulations of federal and state agencies, as well as accreditation organizations. ASCA believes the proposed rule for occupational exposure to infectious diseases is a duplication of infection control standards

already in place, and would place extra financial and staffing burdens on ASCs. We respectfully request that OSHA reconsider mandating these new requirements for the ASC setting.

Please contact Gina Throneberry at gthroneberry@ascassociation.org or (703) 836-8808 if you have any questions or need additional information.

Sincerely,

William Prentice
Chief Executive Officer

Appendix D

U.S. Department of Labor

Infectious Diseases SER Background Document

OSHA

Section I. Introduction

OSHA may propose a new occupational safety and health rule on occupational exposure to infectious diseases that would cover exposures not already addressed by the Bloodborne Pathogens standard (29 CFR 1910.1030). In 2005, the American Federation of State, County & Municipal Employees (AFSCME) petitioned OSHA for a rule addressing pandemic influenza. And in 2009, AFSCME petitioned OSHA for a rule addressing occupational exposure to infectious diseases. In response to these requests, OSHA published a variety of guidance materials addressing pandemic influenza and is now considering the need for a standard addressing the broader issue of occupational exposure to infectious diseases. OSHA has developed a regulatory framework for an infectious diseases rule that demonstrates OSHA's current thinking on the elements that such a proposed rule would contain.

OSHA's regulatory framework would cover occupational exposure to contact, droplet and airborne transmissible infectious agents during the provision of direct patient care. The ID rule would also cover occupational exposure to contact, droplet and airborne transmissible infectious agents during the performance of other covered tasks when those tasks are performed in settings where direct patient care is provided or in the following three settings where contaminated materials are handled: (1) settings where the contaminated materials originate from settings where direct patient care is provided; (2) settings where employees are working with human remains; and (3) diagnostic, research, and production laboratory facilities. (Section V provides tables showing the affected industry sectors in detail.)

The regulatory framework would cover workplaces and tasks for which enhanced infection control measures (e.g., the Center for Disease Control and Prevention's (CDC's) standard and transmission based precautions) are recommended to protect workers. OSHA would not cover workers who have exposure to infectious diseases that can be adequately addressed by common public health measures (e.g., cough/sneeze etiquette and hand hygiene); this would include those who perform retail work and teachers and other non-medical school professionals. Any rule OSHA proposes would emphasize effective and consistent infection control practices with the goal of preventing transmission of infectious diseases to workers covered by the rule. OSHA believes that a rule as outlined in the regulatory framework would not only have the direct benefit of reducing occupational illness rates for covered workers, but also have the ancillary benefit of reducing illness rates for patients and other individuals, such as family members, who come into contact with covered workers.

It is widely recognized by experts in the field of occupational safety and health that a well-structured infection control program should include: (1) identification and isolation of infectious cases; (2) immunizations for vaccine-preventable diseases; (3) standard and transmission-based

precautions; (4) training; (5) personal protective equipment; (6) management of healthcare workers' risks of exposure to infected persons, including post-exposure prophylaxis; and (7) work restrictions for exposed or infected healthcare personnel (Siegel et al., 2007). The prevention strategies listed above are set forth in guidelines, such as those of the Healthcare Infection Control Practices Advisory Committee (HICPAC), a federal advisory committee that provides advice and guidance to the CDC and to the Secretary of the Department of Health and Human Services (HHS).

CDC/HICPAC's *2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings* (Siegel et al., 2007) (2007 CDC/HICPAC guidelines) were an update of the 1996 version of these guidelines (Garner et al., 1996). CDC updated the guidelines because of a number of developments in the healthcare industry. As stated in the executive summary of the 2007 CDC/HICPAC guidelines:

> The transition of healthcare delivery from primarily acute care hospitals to other healthcare settings (e.g., home care, ambulatory care, free-standing specialty care sites, long-term care) created a need for recommendations that can be applied in all healthcare settings using common principles of infection control practice, yet can be modified to reflect setting-specific needs. Accordingly, the revised guideline addresses the spectrum of healthcare delivery settings.

Further, as stated in the 2007 CDC/HICPAC guidelines, the objectives of these guidelines are to:

> 1) provide infection control recommendations for all components of the healthcare delivery system, including hospitals, long-term care facilities, ambulatory care, home care and hospice; 2) reaffirm Standard Precautions as the foundation for preventing transmission during patient care in all healthcare settings; 3) reaffirm the importance of implementing Transmission-Based Precautions . . .; and 4) provide epidemiologically sound and, whenever possible, evidence-based recommendations.

In the United States, the CDC is recognized by the healthcare industry as the source for information on current recommendations for infection control practices in all healthcare settings, and the 2007 CDC/HICPAC guidelines contain the core recommendations central to controlling the transmission of infectious diseases. These guidelines have been endorsed by professional associations such as the Association for Professionals in Infection Control and Epidemiology (APIC) (Smith et al., 2008), the Society for Healthcare Epidemiology of America (SHEA) (Smith et al., 2008), and the Association of Operative Registered Nurses (AORN) (Tarrac, 2008).

The field of infection control is evolving as more improved methods are developed to protect patients and workers from exposure to infectious agents, and as more is learned about the transmission of specific infectious diseases. CDC therefore publishes and updates infection control guidelines both for specific healthcare settings, such as outpatient settings (CDC, 2011e;

CDC, 2011f), and for specific diseases, such as noroviruses (CDC, 2011g), as necessary to address current concerns in infection control. However, CDC bases all of these guidelines on the 2007 CDC/HICPAC guidelines, which provide the core standard and transmission-based recommended precautions to protect patients and workers from exposure to infectious agents.

Some tasks defined as other covered tasks in the regulatory framework do not fall within the scope of CDC's infection control guidelines; these tasks are largely those conducted by workers in diagnostic, research, and production laboratory facilities and those conducted by workers involved in death care. The National Institutes of Health (NIH) independently, and in collaboration with CDC, provides recommendations for protecting workers in laboratory facilities from exposure to infectious agents (CDC/NIH, 2009, NIH, 2013). Individual states have infection control requirements that apply to death care workers (see, for example, Florida Department of State, 2000, 2004).

An ID rule would require covered employers to take these kinds of guidelines into consideration in developing and implementing their own infection control programs. However, a rule would not cover occupational exposure to bloodborne diseases, which is already covered by OSHA's Bloodborne Pathogens standard (29 CFR 1910.1030). Also, while infectious diseases can be transmitted via contaminated food and water, or vectors such as rats and insects, these types of transmissions would not be covered by the rule, as OSHA does not believe that they constitute a significant route of occupational exposure for workers engaged in direct patient care and other covered tasks.

As an initial rulemaking step, and prior to the publication of a proposed rule, OSHA is convening a Small Business Advocacy Review Panel (SBAR Panel) in accordance with the Regulatory Flexibility Act, or RFA (Sections 601 through 612 of Title 5 of the United States Code). This Panel consists of members from OSHA, the Small Business Administration Office of Advocacy (SBA's Office of Advocacy, or Advocacy), and the Office of Information and Regulatory Affairs (OIRA) in the Office of Management and Budget (OMB). The SBAR Panel identifies individuals representative of affected small entities, termed Small Entity Representatives (SERs). This process enables OSHA, with the assistance of Advocacy and OIRA, to obtain advice and recommendations from SERs about the potential impacts of a rule as outlined in the regulatory framework and about alternatives to the regulatory framework that may alleviate those impacts while meeting the objectives of the OSH Act.

The SBAR Panel has several purposes under the RFA, which establishes the requirements for a Panel. First the Panel provides an opportunity early in the rulemaking process for affected small employers and SBA's Office of Advocacy to provide comment to OSHA. Second, by reviewing the provisions of the regulatory framework, estimates of the potential impacts of a rule as outlined in the regulatory framework, and alternatives to the regulatory framework, SERs and the Panel can offer recommendations to OSHA on ways to tailor rules to make them more cost effective and less burdensome for affected small employers. Third, early comment permits

identification of different regulatory alternatives the Agency might consider. Finally, the Panel, in its SBAR Panel report, can provide specific recommendations for the Agency to consider on issues such as reporting requirements, timetables of compliance, "performance" rather than "design" (or specification) standards, and whether some groups, including small employers, would be exempt from all or part of the rule.

Following the SBAR Panel, OSHA's next step, if the rulemaking process is continued, would be to publish a proposed rule in the *Federal Register*. The Preamble to the proposed rule would include an Initial Regulatory Flexibility Analysis (IRFA) to accompany the proposal in order to focus attention on the potential impacts on small businesses. The IRFA would include a description of the Panel's recommendations and OSHA's responses to those recommendations. Sections 603(b) and (c) of the RFA set out the requirements for the IRFA:

> (b)(1) a description of the reasons why action by the Agency is being considered;
>
> (b)(2) a succinct statement of the objectives of, and legal basis for, the proposed rule;
>
> (b)(3) a description of and, where feasible, an estimate of the number of small entities to which the proposed rule will apply;
>
> (b)(4) a description of the projected reporting, recordkeeping, and other compliance requirements of the proposed rule, including an estimate of the classes of small entities that will be subject to the requirements and the type of professional skills necessary for preparation of the report or record;
>
> (b)(5) an identification, to the extent practicable, of all relevant Federal rules that may duplicate, overlap, or conflict with the proposed rule; and
>
> (c) a description of any significant alternatives to the proposed rule that accomplish the stated objectives of applicable statutes and that minimize any significant economic impact of the proposed rule on small entities.

An alternative under Section 603(c) need not be unique to small entities. Rather, an alternative that meets OSHA's goals and reduces impacts for all affected entities can, and should, be considered as part of the Panel and regulatory flexibility analysis process.

OSHA is conducting this SBAR Panel early in the regulatory process in the interest of assuring that the Panel's report and recommendations can be fully considered in any subsequent rulemaking activities by the Agency. OSHA has not yet estimated the aggregate benefits and costs of a rule addressing occupational exposure to infectious diseases because the Agency is still conducting ongoing work that is necessary for such estimates. A contractor, hired by OSHA, has elicited the opinions of a group of infection control experts regarding current levels of compliance with recommended, non-mandatory infection control practices. Additionally, the contractor is developing a model to estimate the reduction in illnesses and fatalities potentially

attributable to a rule addressing occupational exposure to infectious diseases. OSHA and the contractor are also conducting additional research, including the gathering of additional data on the potential costs of such a rule and on the risk associated with exposure to infectious diseases. Thus, OSHA expects to expand its data sources, update its data, and conduct more extensive research on the costs, benefits, and impacts of such a rule from sources that are independent of the SBAR Panel process.

Under Section 609(b) of the RFA, the SBAR Panel must be provided any information that OSHA has available on issues related to paragraphs (3), (4), and (5) of Section 603(b), as well as Section 603(c), of the RFA. The SBAR Panel collects comments on these issues.

Consistent with these requirements, this document, the Small Entity Representative Background Document (the SER Background Document), provides such information to the individual SERs who have agreed to participate in this SBAR Review. The SER Background Document also satisfies the RFA's legal requirement that OSHA provide certain information to the Chief Counsel for Advocacy. OSHA has placed all references in this document in the public docket, OSHA-2010-0003, and will be happy to help SERs obtain any references they would like to see.[1]

The SER Background Document has been prepared to facilitate the SBAR Panel process. In addition to this introductory section, the SER Background Document contains the following sections:

- **Section II (pp. 7-8)** describes the legal requirements OSHA must meet if it engages in rulemaking;
- **Section III (pp. 9-26)** explains the reasons why action is being considered by OSHA;
- **Section IV (pp. 27-50)** summarizes and explains the important provisions of OSHA's regulatory framework;
- **Section V (pp. 51-58)** identifies the types of small entities that would likely be affected by a rule as outlined in the regulatory framework;
- **Section VI (pp. 59-112)** provides information on the potential impacts of a rule as outlined in the regulatory framework;
- **Section VII (pp. 113-118)** describes potentially duplicative or conflicting rules; and
- **Section VIII (pp. 119-134)** presents, for consideration by the SERs and the Panel, alternatives and/or options to the scope of, and provisions in, the regulatory framework.

Some of the most valuable contributions SERs make in the SBAR Panel process are their comments on the alternatives and/or options presented and their suggestions for other possible alternatives.

[1]All non-copyrighted references will be available online at regulations.gov in the docket for this potential rulemaking. Copyrighted materials are available for inspection through OSHA's docket office.

Appendix A contains the SBA definitions of small entities for all affected industries at the six-digit NAICS level. Appendix B contains a list of some of the relevant published infection control guidelines/regulations that are relevant to the regulatory framework.

Section II. Legal Basis for an OSHA Standard Addressing Occupational Exposure to Infectious Diseases

The Secretary of Labor promulgates and enforces occupational safety and health standards under authority granted by the Occupational Safety and Health Act of 1970 (the OSH Act).[2] OSHA must promulgate its standards by following specific procedures set forth in the OSH Act.[3]

Section 3(8) of the OSH Act defines an "occupational safety and health standard" as "a standard which requires conditions, or the adoption or use of one or more practices, means, methods, operations, or processes, reasonably necessary or appropriate to provide safe or healthful employment and places of employment."[4] This definition has been interpreted to require the Agency to make a threshold showing of "significant risk" before it can promulgate a safety or health standard.[5] The Agency has discretion to "determine, in the first instance, what it considers to be a 'significant' risk," and in making this determination, the appropriate question is whether "a reasonable person might . . . consider the risk significant and take appropriate steps to decrease or eliminate it."[6] As such, the risk requirement is "not a mathematical straitjacket" and OSHA "has no duty to calculate the exact probability of harm."[7] Courts recognize that a determination of what constitutes significant risk will be "based largely on policy considerations."[8] The Agency "is not required to support its finding that a significant risk exists with anything approaching scientific certainty[,]" and "is free to use conservative assumptions" and "risk[] error on the side of overprotection rather than under protection."[9] It is sufficient for the Agency to make a general finding of significant risk; the Agency is not required to assess relative risk or disaggregate its significant risk analyses by hazard, workplace, or industry.[10]

OSHA standards must be both technologically and economically feasible.[11] The Supreme Court has defined feasibility as "capable of being done."[12] OSHA demonstrates that a standard is

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[2]29 U.S.C. 651 *et seq*.
[3]29 U.S.C. 655.
[4]29 U.S.C. 652(8).
[5]*Indus. Union Dep't, AFL-CIO v Inst.* ("*Benzene*"), 448 U.S. 607 (1980) (plurality opinion).
[6] *Id*. at 655.
[7] *Id*.
[8] *Id*. at 655 n.62.
[9] *Id*. at 656; see also, for example, *Public Citizen Health Research Group v. Tyson* ("*Ethylene Oxide"*), 796 F.2d 1479, 1486 (D.C. Cir. 1986).
[10] See, for example, *UAW v. OSHA ("Lockout/Tagout II")*, 37 F.3d 665, 670 (D.C. Cir. 1994) (upholding OSHA's decision not to conduct individual significant risk analyses for various affected industries); *American Dental Ass'n v. Martin*, 984 F.2d 823, 827 (7th Cir. 1993) (OSHA is not required to evaluate risk "workplace by workplace"); *Associated Builders & Contractors, Inc. v. OSHA*, 862 F.2d 63, 68 (3d Cir. 1988) (noting that "the significant risk requirement must of necessity be satisfied by a general finding concerning all potentially covered industries"); *Ethylene Oxide*, 796 F.2d at 1502 n. 16 (rejecting the argument that the Secretary must find that each and every aspect of its standard eliminates a significant risk).
[11]*United Steelworkers v. Marshall* ("*Lead I*"), 647 F.2d 1189, 1264 (D.C. Cir. 1980).
[12]*Am. Textile Mfrs. Inst. v. Donovan* ("*Cotton Dust*"), 452 U.S. 490, 508-09 (1981).

technologically feasible "by pointing to technology that is either already in use or has been conceived and is reasonably capable of experimental refinement and distribution within the standard's deadlines."[13] In determining the economic feasibility of a standard, OSHA must consider the cost of compliance on an industry, rather than on individual employers. The "practical question" in an economic feasibility analysis "is whether the standard threatens the competitive stability of an industry . . . or whether any intra-industry or inter-industry discrimination in the standard might wreck such stability or lead to undue concentration."[14]

Section 6(b)(5) of the Act provides that, in promulgating a standard dealing with toxic materials or harmful physical agents, the Agency must "set the standard which most adequately assures, to the extent feasible, on the basis of the best available evidence, that no employee will suffer material impairment of health or functional capacity."[15] Thus, the OSH Act does not call for OSHA to use benefit-cost analysis as a basis for rulemaking.[16] Instead, OSHA must reduce significant risk to the extent technologically and economically feasible without regard to a balancing of costs and benefits.

[13]*American Iron and Steel Inst. v. OSHA*, 939 F.2d 975, 980 (D.C. Cir. 1991) (*per curiam*) (internal citation omitted).
[14]*Lead I*, 647 F.2d at 1265.
[15]29 U.S.C. 655(b)(5).
[16]*Cotton Dust*, 452 U.S. at 509.

Section III. Reasons Why Action by the Agency is Being Considered

Infectious agents cause both healthcare-associated infections (HAIs) and occupationally-acquired infections in healthcare workers (HCWs). HAIs are recognized as a serious and costly problem in the U.S. healthcare system. According to the CDC, there are 1.7 million HAIs leading to approximately 99,000 patient deaths and $20 billion in additional healthcare costs in the U.S. system each year (CDC, 2013a). Preventing the spread of infectious diseases in healthcare and related settings benefits workers, as well as patients, given that there is a well-recognized link between patient safety and healthcare worker safety and that integration of patient and worker safety initiatives has been shown to improve both patient outcomes and worker protection (TJC, 2012).

OSHA does not have a standard that addresses occupational exposure to infectious agents transmitted by contact, droplet and airborne routes. OSHA's Bloodborne Pathogens standard (29 CFR 1910.1030) only covers infectious agents transmitted by the bloodborne route. Precautions used for bloodborne pathogens (termed universal precautions[17]) are not sufficient to protect people from infectious agents transmitted by the contact, droplet, and airborne routes. The Agency has been, and continues to be, concerned about occupational exposure to infectious diseases not addressed by the Agency's Bloodborne Pathogens standard. OSHA documented occupational exposure to, and infection with, *Mycobacterium tuberculosis* (TB) in its notice of proposed rulemaking entitled, "Occupational Exposure to Tuberculosis; Proposed Rule" (62 FR 54160, October 17, 1997). Though OSHA has not promulgated a final rule on TB, the Agency did issue a compliance directive addressing occupational exposure to TB. OSHA remains concerned about occupational exposure to TB, as well as numerous other infectious diseases, multidrug-resistant and totally drug-resistant infectious agents, and new and emerging infectious diseases (e.g., severe acute respiratory syndrome (SARS), 2009 H1N1 pandemic influenza, Middle East Respiratory Syndrome (MERS), and H7N9 avian influenza).

Infectious agents pose a unique hazard because, unlike chemical hazards: 1) Each infectious agent replicates within infected individuals; and 2) Infected individuals can transmit the agent to other individuals, who can then transmit it to additional people and so on, with exponential spread of the disease possible from expanding rounds of transmission. SARS, for example, spread from China to numerous other countries in a matter of months, ending with more than 8,000 infections and approximately 800 deaths (World Health Organization (WHO), 2004a).

On May 6, 2010, OSHA published a request for information (RFI) on infectious diseases in health care, laboratory, and other associated work settings, and in July 2011, the Agency held

[17]"Standard Precautions" is now the term generally used by the healthcare community and encompasses universal precautions with a few additional elements.

two stakeholder meetings to further discuss the issue.[18] Stakeholder comments in response to the RFI and a subsequent review of the literature (some of which is discussed in this section of the SER Background Document) indicate that workers providing direct patient care and performing other covered tasks (as those terms are defined in the regulatory framework) are at risk of harm from occupational exposure to infectious agents, and that implementing recognized and generally accepted good infection control practices reduces the risk of transmission of infectious agents to these workers.

OSHA does not have data on the exact number of occupationally-acquired infectious diseases in the United States and other developed countries because there are no centralized surveillance systems that specifically document all occupationally-acquired infectious diseases. This type of data also suffers from underreporting. For example, in the U.S., Singh (2011) and Sewell (1995) noted that underreporting of laboratory-associated infections is widely recognized and is in large part due to a lack of a systematic reporting system at the state, federal, or professional-society level that monitors these incidents. In another example, Harding & Byers (2006) state that "our ability to accurately quantify laboratory-associated infections (LAIs) is hampered by an indifference to and, frequently, an unwillingness to report these incidents". Despite this recognized underreporting, these authors determined from the literature on LAIs in a number of countries, that1,448 symptomatic LAIs, along with 36 deaths and 17 secondary infections had been documented over the 26-year period from 1979-2004. In an additional example from the Netherlands and the United Kingdom, Haagsma et al. (2012) state that "only a small number of work-related infectious diseases are reported to the designated registration systems." This is consistent with a review by Azaroff et al. (2002), where the authors state that documentation of the incidence of work-related injuries, illnesses, and fatalities in diverse workplaces is "fragmentary, unreliable, and inconsistent." The authors conclude that the actual incidence of work-related injuries, illnesses, and fatalities is underestimated by as much as several hundred percent. There are a number of reasons for underreporting, including: difficulty attributing illnesses to workplace contact; workers continuing to report to work despite being ill; workplace incentives to keep reported illness and injury numbers low; workers utilizing their private insurance for treatment over workers' compensation or employee health centers; and workers' fear of losing their jobs as a consequence of reporting exposures to their superiors.

Illness data reported by the Bureau of Labor Statistics (BLS) is likely subject to these under-reporting issues. For example, there were only 420 influenza cases, and only about 2,000 cases of workplace-related infectious and parasitic diseases, reported in the BLS Occupational Injuries and Illnesses and Fatal Injuries Profiles in 2012 (BLS, 2012).[19] Given the millions of cases of

[18]The public comments on the RFI and a summary of the stakeholder meetings can be accessed at www.regulations.gov (Docket# OSHA-2010-0003 is available at: http://www.regulations.gov/#!docketDetail;D=OSHA-2010-0003).

[19] In the BLS classification system, cases of influenza and cases of workplace-related infectious and parasitic diseases are grouped separately.

influenza that occur yearly in the U.S., it is very unlikely that only 420 cases would have been occupationally acquired in 2012. At the beginning of the 2009 H1N1 influenza pandemic, for example, CDC reported that 50 percent of the initial cases (13 of 26) identified in healthcare workers were deemed to have been acquired in a healthcare setting (CDC, 2009).

BLS recognizes that occupationally-acquired illnesses are underreported. According to BLS, the Statistics of Occupational Illnesses and Injuries (SOII) Survey measures the "number of new work-related illness cases that are recognized, diagnosed, and reported during the year" (BLS, 2007). However, "[i]n contrast [to] the overwhelming majority of the reported new illnesses," which are "easier to directly relate to workplace activity (for example, contact dermatitis or carpal tunnel syndrome)," there are "[s]ome conditions…[that] are difficult to relate to the workplace and are not adequately recognized and reported" (Id.).

As noted above, the United States does not have a surveillance system to document occupational exposure to infectious diseases. The limited surveillance information that is available on occupational exposure to infectious diseases among HCWs is mostly related to HCWs in hospitals. Some data exists from the National Surveillance System for Healthcare Workers (NaSH), which was a voluntary surveillance system developed by CDC to systematically collect information important to the prevention of occupational exposures and infections among HCWs. The NaSH consisted of data collection modules for monitoring and managing immunization and tuberculin skin-testing programs, and recording exposures to blood and body fluids, vaccine-preventable diseases, and tuberculosis. The only module that received even modest participation by hospitals was the module for recording exposures to blood and body fluids. Participation in this module grew from five hospitals in 1995 to 64 facilities in 2000, but decreased to 18 in 2007. The number of occupational exposures ranged from a low of 378 exposures in five hospitals in 1995 to a high of 4,334 occupational exposures in 64 hospitals in 2000. A tiny fraction of the total number of hospitals in the U.S. participated, and those that participated were mainly large, teaching hospitals in urban settings (CDC, 2011h).

Data on worker exposures and infections in non-hospital settings include surveys of employees, employers and/or public health agencies and information collected in outbreak investigations. For example, a survey of home healthcare providers found that 5.9 percent of workers had received treatment for lab-confirmed healthcare-associated bacterial infections (most commonly Methicillin-resistant *Staphylococcus aureus* (MRSA) or *Clostridium difficile*) and nearly 60 percent of the providers reported that their healthcare establishment did not have a written policy that covered infection control procedures recommended for dealing with antibiotic-resistant infections (Kenneley, 2012).

There are also numerous peer-reviewed journal articles that document occupationally-acquired illnesses and outbreaks in healthcare and related settings. Based on that evidence (discussed below), OSHA believes that the cases of occupationally-acquired illnesses reported in the SOII,

to OSHA, or through the workers' compensation system, seriously underestimate the true number of workplace-acquired illnesses resulting from contact with infectious agents.

OSHA is evaluating a large number of peer-reviewed journal articles relating to occupational exposure to infectious agents. The evidence thus far examined shows that there is a sustained prevalence of work-related infectious diseases in healthcare, laboratory, and associated work settings. These infectious diseases are caused by agents that are transmissible to humans by different routes, including the contact, droplet and airborne routes. A myriad of studies continues to document illnesses in HCWs resulting from occupational exposure to infectious agents. Some examples of the Agency's findings of peer-reviewed manuscripts on this topic are listed below.[20]

- Norovirus[21] – Primary transmission route is contact: In 2003, eighty-four workers in a long-term care facility contracted norovirus during an outbreak in Pennsylvania (Wu et al., 2005). More recently, a norovirus outbreak affected ninety patients and 265 HCWs in a hospital, with cases clustered in the coronary care and psychiatry units. Thirteen affected HCWs required emergency department visits or hospitalization (Johnston et al., 2007).
- Adenovirus infections[22] – Primary transmission route is droplet: In 2007, eight workers in an intensive care unit (ICU) in Texas were infected with adenovirus after caring for a patient suffering from the disease (Yun & Prakash, 2008). Similarly, from April through June 2007, fifteen health care trainees at one military hospital in Texas were hospitalized for pneumonia due to adenovirus that appeared to be occupationally-acquired (Lessa et al., 2009).
- Mumps[23] – Primary transmission route is droplet: In April through May 2006, seven workers at a tertiary care hospital contracted mumps during an outbreak in the facility. This outbreak led to fifty-nine employees missing a total of 282 work days (an average of 4.8 days per worker) due to having contracted mumps, being non-immune, or awaiting symptom evaluation or laboratory test results (Bonebrake et al., 2010).
- Pertussis[24] – Primary transmission route is droplet: A three-month pertussis outbreak in a community hospital in 1999 resulted in twelve of fifty-three HCWs in the surgical unit being infected with pertussis (Pascual et al., 2006). In 2003, ten HCWs at a Hematology-Oncology care unit in New Hampshire were infected with pertussis (Boulay et al., 2006) and eight workers at two different hospitals in Washington state contracted pertussis in 2004 (Baggett et al., 2007).

[20]Although many infectious agents can be transmitted via more than a single route, only the primary transmission route is listed.
[21]Gastroenteritis can be caused by norovirus.
[22]A number of diseases, including gastroenteritis, conjunctivitis, and pneumonia, can be caused by adenoviruses.
[23]Mumps is caused by a Rubulavirus.
[24]Pertussis (whooping cough) is caused by the bacterium *Bordetella pertussis*.

- Tuberculosis (TB) – Primary transmission route is airborne: A 2011 report on exposure to TB at a medical center in Arizona concluded that 18 employees had a newly positive TB skin test and one employee was diagnosed with active TB (de Perio & Niemeier, 2012). In a TB outbreak case in Nevada, a woman and her recently-delivered twins died from TB, and 61 people who had contact with the woman and/or her twins tested positive for TB infections (2 active, 59 latent). Of the active cases, 1 (50 percent) was a HCW. Of the latent cases, 21/59 (36 percent) were HCWs (Southern Nevada Health District, 2013). In a latent TB infection, the person is infected, but not symptomatic, and may or may not go on to have an active infection. If a person with latent TB infection gets appropriate treatment, however, it is much less likely the person will progress to an active TB infection. The high incidence of multi-drug resistant strains of TB amplifies the concern. A recent antibiotic resistance threat report by CDC classifies drug-resistant TB as a "serious" health threat in the United States (CDC, 2013b).

The peer-reviewed literature also suggests that HCWs are especially susceptible to exposures during the early stages of the emergence of novel infectious agents or novel strains of known infectious agents. Workers in laboratories that are tasked with the identification of the infectious agent causing the outbreak are similarly susceptible to exposures. In these cases, it is very likely that both the HCWs and laboratory workers that become infected with these novel agents have been occupationally-exposed rather than exposed in the community. Examples of such outbreaks are listed below.

- Severe Acute Respiratory Syndrome (SARS)[25] – Primary transmission route is droplet: Occupational exposure to SARS at a hospital in Toronto, Canada resulted in 42.5 percent of the HCWs who were exposed while performing their job duties becoming infected with the SARS virus (Ofner-Agostini et al., 2008). As of the end of 2003, the World Health Organization (WHO) reported that, of the 8,096 SARS cases reported worldwide, 21 percent occurred in HCWs (WHO, 2004a). Since the end of the SARS pandemic, the majority of reported SARS-CoV infections have occurred in laboratory workers, or individuals who had close contact with infected laboratory workers (WHO, 2003; WHO, 2004b; WHO, 2004c). At least thirteen individuals (six laboratory workers and seven individuals who had contact with those workers) contracted laboratory-associated SARS-CoV infections after WHO declared the end of the SARS pandemic (Liang et al., 2004).
- H1N1 pandemic influenza[26] – Primary transmission route is droplet: Near the beginning of the 2009 H1N1 pandemic, state health departments reported forty-eight cases of confirmed or probable cases of H1N1 infection in HCWs (CDC, 2009). Early in the

[25]Severe Acute Respiratory Syndrome is caused by the SARS coronavirus. As an emerging disease for which the transmission route(s) was unknown, airborne precautions were initially used to handle SARS.
[26]Influenza (flu) is caused by influenza A and B viruses. The 2009 strain of the influenza A H1N1 subtype caused the last influenza pandemic. Pandemic influenza refers to a worldwide epidemic caused by a new strain of influenza for which humans have little immunity and that, therefore, can spread quickly from human-to-human.

pandemic it was easier to identify the cases that were occupationally-related because there were not yet many cases in the community. Of the 26 cases where the source of infection could be identified, CDC determined that 13 (50 percent) of the cases were occupationally-acquired.

- Middle Eastern Respiratory Syndrome (MERS)[27] – Primary transmission route is not yet identified: WHO estimated that more than 25 percent (109/402) of individuals infected with MERS over a two-month period (April 11 – June 9, 2014) were HCWs (WHO, 2014a). Although MERS does not appear to be readily transmitted from person-to-person, many of the cases among both patients and HCWs have been acquired in healthcare settings (Zumla and Hui, 2014). The two MERS cases that have occurred in the United States as of May 2014 were HCWs who were infected in other countries and subsequently traveled into and around the United States while symptomatic. MERS testing done by Indiana and Florida Public Health Departments determined that 53 HCWs (Indiana) and 23 HCWs (Florida) who were exposed to the two infectious patients prior to implementation of isolation precautions were negative for MERS (CDC, 2014a; NBC, 2014a).
- Ebola – Primary transmission is through direct contact with a sick person's blood or body fluids or materials that have been contaminated with Ebola virus. WHO warns in an August 11, 2014 statement that "Ebola virus disease in West Africa continues to evolve in alarming ways, with no immediate end in sight," noting that 170 HCWs have been infected so far, with 80 of those HCWs dying (WHO, 2014b). Two HCWs from the U.S. who were infected in West Africa were transported back to the U.S. and were treated under high containment conditions and released (NBC, 2014b). Of high concern are people who do not know they are infected traveling into other countries via air travel. CDC has recently stated that it is possible that infectious diseases such as Ebola will spread to the U.S. due to the nature of global airline travel (Frieden, 2014) and outlines how U.S. hospitals should prepare for possible Ebola cases including the stringent precautions that should be used for suspected cases (Medscape.com, 2014).

While the patients who are the most ill with infectious diseases are most likely being treated in hospitals, there are several reasons why HCWs in ambulatory care settings are at particular risk of exposure to infectious diseases:

- Many patients with infectious diseases are treated in ambulatory care settings during the early stages of the disease while they are asymptomatic or have mild symptoms. Depending on the infectious agent's incubation period (i.e., the time between intitial infection and the first expression of symptoms) as well as the severity of the illness, people can be contagious for days, weeks or even longer without knowing that they have an infection that can be transmitted to others.

[27] MERS is caused by a coronavirus that is distinct from the coronavirus that caused the SARS outbreak.

- Primary care doctors and those in other ambulatory settings routinely see patients who may be colonized with infectious agents such as MRSA and Streptococcus. Although these colonized patients are not necessarily infected with the agent, the agent can be transmited to providers. The providers may then become colonized or infected.
- An increasing number of patients who are ill and symptomatic with an infectious disease are getting initial treatment at clinics that have urgent care or immediate care services, rather than being treated at hospital emergency rooms.
- Many patients with "childhood" illnesses such as measles, mumps and pertussis are being treated at clinics, not hospitals, unless they have severe cases. Currently, outbreaks of measles, mumps and pertussis are occurring in various countries, including the U.S.

While information on occupational exposures and infections in HCWs in ambulatory care settings is limited, data from outbreak investigations show that HCWs in these settings are exposed to infectious diseases. Examples of occupational exposure to infectious agents and HCW infections in ambulatory care settings include:

- Soft tissue and skin infections (SSTIs) – A study of skin infections treated in U.S. physicians' offices between 1993 and 2005 estimates that there were 6.3 million SSTIs, including those caused by MRSA, diagnosed annually during this time period (Pallin et al., 2014). Occupationally-acquired MRSA infections have been documented at ambulatory care settings including oncology, dental, and pediatric clinics, with a HCW fatality from MRSA at one pediatric clinic (Carpenter et al., 2008; Kassis et al., 2011; Roberts et al., 2011).
- Norovirus gastroenteritis – Based upon information obtained from insurance claim databases, a modeling study estimated that over an eight year period from 2001-2009, norovirus contributed to approximately 400,000 Emergency Department visits and 1.7 million office visits annually. This study concluded that norovirus is a substantial cause of gastroenteritis-related visits to ambulatory care facilities. (Gastanaduy, et al., 2013).
- Epidemic keratoconjunctivitis (EKV) – Outbreaks of highly contagious adenovirus eye infections in a neonatal intensive care unit (NICU) and twelve outpatient clinics in four states were reported to CDC during 2008-2010. Of the 212 cases that were associated with the outpatient clinics, 10 were HCWs. (CDC, 2013).
- TB – In a dental clinic in Washington state, a dental hygienist developed active TB and worked for several months while infectious, likely transmitting TB to a coworker and possibly also to several patients (Merte et al., 2014).
- Pertussis –A study of pediatric HCW exposure to and infection with pertussis showed that 1,193 confirmed HCW exposures were associated with 219 index cases[28], 7 of which were HCWs. The authors concluded that occupational exposures to pertussis occur frequently in pediatric healthcare settings (Kuncio et al., 2014).

[28] An index case is the first patient that indicates the existence of an outbreak.

Because HCWs are exposed to infectious diseases in a variety of settings, it is important for employers in all such settings to implement infection control practices. Good infection control practices are laid out in a number of non-mandatory guidelines (e.g., CDC/HICPAC guidelines) and are recognized and generally accepted by the industry. But evidence shows that many employers do not consistently adopt or rigorously enforce these guidelines, leaving both workers and patients at risk of contracting infectious diseases. When these practices are consistently and rigorously followed, they have proven effective at preventing the spread of infections. Some case examples are provided in Section C, below. Due to the lack of consistent and rigorous enforcement of current guidelines, certain workers are not adequately protected against the risk of occupational acquisition of infectious diseases, and OSHA believes that covering those workers under a rule as outlined in the regulatory framework would reduce their risk. The Agency believes that effective enforcement would result in more consistent and rigorous adherence to guidelines, and thus safer environments for both workers and patients.

As explained in Section II, Legal Basis for an OSHA Standard Addressing Occupational Exposure to Infectious Diseases, the Agency is required by statute to show that a rule is reasonably necessary and appropriate to provide a safe and healthful workplace. This has been interpreted to require OSHA to make a finding of significant risk before it promulgates a new standard. In evaluating significant risk, the Agency asks whether a reasonable person might regard the risk of harm to be significant and take steps to decrease or eliminate it. OSHA can find significant risk based on reasoning well-accepted by leading public health authorities and supported by the available scientific evidence showing that there is occupational exposure to broad categories of hazardous agents or work conditions that endanger workers in the absence of protections (e.g., Hazardous Chemicals in Laboratory Standard (55 Fed. Reg. 3300, 3302-06 (Jan. 31, 1990)), Hazard Communication Standard (59 Fed. Reg. 6126, 6131-32, 6136-40 (Feb. 9, 1994); 48 Fed. Reg. 53280, 53320-21 (Nov. 25, 1983)), Personal Protective Equipment Standard (59 Fed. Reg. 16334, 16335 (Apr. 6, 1994))). Below is a summary of the evidence showing that: (A) There is a well-recognized risk to workers associated with exposure to infectious agents during the provision of direct patient care and/or performance of other covered tasks; (B) Current infection control guidelines are non-mandatory, are not consistently and rigorously followed, and therefore are not sufficient to adequately reduce the risk of transmission of infectious agents to workers who provide direct patient care and/or perform other covered tasks; and (C) Following recognized and generally accepted good infection control practices considerably reduces the risk of transmission of infectious agents to workers providing direct patient care and/or performing other covered tasks.

OSHA plans to rely in part on study data documenting the occurrence of occupationally-acquired infectious disease among health care workers in work settings where the incidence of disease has been adequately investigated. The Agency is continuing to analyze the available information and

has not yet made any final determinations regarding risk; OSHA is interested in feedback from small entity representatives on the evidence presented below.

(A) There is a well-recognized risk to workers associated with exposure to infectious agents during the provision of direct patient care and/or performance of other covered tasks.

The risk associated with exposure to infectious agents during the provision of direct patient care and performance of other covered tasks has been known and documented for some time. Occupational risks are documented and discussed in guidelines of the CDC's HICPAC, a federal advisory committee that provides advice and guidance to the CDC on the practice of healthcare infection control in U.S. healthcare facilities. CDC/HICPAC's *2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings* (Siegel et al., 2007) and *Guideline for Infection Control in Health Care Personnel, 1998* (Bolyard et al., 1998) both highlight the risks to workers from exposure to infectious agents In its 1998 guidelines, the CDC/HICPAC wrote that its guidance for mitigating infectious disease risks applied to all workers in healthcare settings who have the "potential for exposure to infectious materials, including body substances, contaminated medical supplies and equipment, contaminated environmental surfaces, or contaminated air," and that these workers:

> may include but are not limited to emergency medical service personnel, dental personnel, laboratory personnel, autopsy personnel, nurses, nursing assistants, physicians, technicians, therapists, pharmacists, students and trainees, contractual staff not employed by the health care facility, and persons not directly involved in patient care but potentially exposed to infectious agents (e.g., clerical, dietary, housekeeping, maintenance, and volunteer personnel).

The two CDC/HICPAC guidelines support the existence of risks associated with occupational exposure to infectious agents and infectious agent transmission from patient to worker, worker to patient, and worker to worker. The guidelines recommend appropriate precautions to prevent such exposure and transmissions and the resulting diseases. The Joint Commission (TJC), recognizing the link between patient safety and healthcare worker safety, recently issued a 171-page monograph entitled, *Improving Patient and Worker Safety: Opportunities for Synergy, Collaboration and Innovation* (TJC, 2012). TJC's monograph notes that HCWs experience some of the highest rates of nonfatal occupational illness and injury—exceeding even construction and manufacturing industries. The monograph outlines how integration of patient and worker safety initiatives results in both improved patient outcomes and worker protection.

OSHA believes that the 1998 and 2007 CDC/HICPAC guidelines, along with other authoritative guidance documents (e.g., CDC/NIH, 2009), and hundreds of peer-reviewed publications (some of which are cited in this document), demonstrate a well-recognized risk of occupational

exposure to infectious agents for workers providing direct patient care and/or performing other covered tasks.

These workers include physicians, nurses, emergency medical technicians, transport personnel, phlebotomists, and other patient-care staff that routinely have hands-on and face-to-face contact (i.e., direct patient care) with infected patients in facilities such as hospitals, urgent care clinics, physicians' offices (e.g., general practitioners/pediatricians), school infirmaries, and workplace occupational health clinics where sick or injured workers go for treatment (Siegel et al., 2007: section I.D). Healthcare workers are also at risk in less traditional healthcare settings where exposures to infectious agents are likely to occur (Siegel et al., 2007; section I.D.2). These settings include: home care settings where services are provided to patients often too ill to seek treatment outside of the home (Siegel et al., 2007; section I.D.2.c); nursing homes and other extended-care facilities where infections are common due to the long-term care of an elderly infirm population (Siegel et al., 2007; section I.D.2.a); and outpatient surgical, infusion treatment, and dialysis centers where the procedures employed pose increased opportunity for the spread of infectious agents (Siegel et al., 2007; section I.D.2.b). Healthcare workers in these ambulatory care and long-term care facilities are likely to be using invasive devices and equipment, such as catheters, vascular lines, and breathing and feeding tubes, that can facilitate the transmission of infectious disease.

As individuals harboring infectious agents may infect others while they are asymptomatic, the 2007 CDC/HICPAC guidelines express a concern about HCWs being exposed to infectious diseases even when they provide direct patient care to patients not known to be infectious (Siegel et al., 2007: section I.D). These occupational exposures can occur in professions that routinely engage in hands-on and face-to-face contact with patients, such as dentistry, ophthalmology/optometry, physical therapy, podiatry, and radiography. The risk to workers in settings that provide direct patient care may vary depending on frequency, duration and intensity of contact with the infected individuals. For example, a nurse that has frequent, intense contact with infected patients in a hospital or nursing home may be at relatively greater risk of contracting an infectious disease than a dental hygienist or optometrist who likely interacts with fewer infected patients.

In addition to concerns about the risk of occupational exposure to infectious diseases when workers provide direct patient care, the CDC and NIH recognize the risk of occupational exposure to infectious disease in biomedical and research laboratories that handle infectious agents (CDC/NIH, 2009). Likewise, laboratory and animal workers are at risk of occupational exposure to infectious agents in production laboratories that are engaged in the development and testing of vaccines against infectious agents and treatments for infectious diseases. Technicians that collect and process specimens contaminated with infectious agents in a clinical laboratory are also at risk of disease. Workers in death care settings (e.g., medical examiner's offices, morgues, and mortuaries) are routinely exposed to tissues and body parts that may be contaminated with infectious agents. In addition, workers that provide environmental services in

hospitals and long-term health care facilities, such as laundry, housekeeping, and waste handling (i.e. "other covered tasks" under the regulatory framework) may also come in contact with surfaces and other materials contaminated with infectious agents. Finally, workers involved in cleaning, repairing, and maintaining contaminated medical equipment are also at risk of occupational exposure to infectious agents.

The major goal of infection control is to prevent transmission of infectious diseases to patients and HCWs. This fundamental approach is set forth in the CDC/HICPAC guidelines (e.g., Bolyard et al., 1998; Siegel et al., 2007), which are comprehensive guidelines for infection prevention and control that are recognized both nationally and internationally. The guidelines address: the identification and isolation of infectious cases; immunizations for vaccine-preventable diseases; standard and transmission-based precautions; training; personal protective equipment (PPE); the management of HCWs' risk of exposure to infected persons, including post-exposure prophylaxis; and work restrictions for exposed or infected healthcare personnel.

The CDC/HICPAC guidelines for standard and transmission-based precautions are widely recognized by experts in the field of occupational safety and health, generally accepted, often cited as an efficient means to address infectious agent hazards, and directly applicable to the prevention of occupationally-acquired infections. In 2007, the CDC/HICPAC updated and modified its 1996 guidelines (Garner, 1996), in part, to accommodate changes in the healthcare industry, e.g., to specifically target the growing shift of healthcare delivery from primarily acute care hospitals to other diverse healthcare settings, including home care and ambulatory care settings, and to address the need for recommendations that could be applied to all healthcare settings (Siegel et al., 2007). Thus, OSHA has reason to believe that these guidelines are directly applicable, or readily adaptable, to the direct patient care and associated tasks that are addressed in the regulatory framework (also see prior discussion on the applicability of the CDC/HICPAC guidelines).

OSHA believes that the majority of employers that would be subject to a rule as outlined in the regulatory framework are familiar with, and have adopted at some level, infection control programs that are generally consistent with the CDC/HICPAC guidelines.[29] OSHA also finds that a large number of employers with workers performing other covered tasks, as that term is defined in the regulatory framework (for example, maintenance and housekeeping in healthcare settings), operate in facilities that have some level of infection control in order to meet professional association or other accreditation requirements. OSHA has compiled additional infection control guidelines and regulations, including guidelines that apply to settings, such as mortuaries and laboratories, in which only other covered tasks are performed. A list of the guidelines and regulations OSHA has compiled and analyzed is contained in Appendix B to this SER Background Document. OSHA would be interested in hearing from small entity

[29]The draft results of the Expert Panel elicitation verify that many employers have at least some elements of an infection control plan in place already. See Section VI: Description of Potential Impacts of a Rule as Outlined in the Regulatory framework for further discussion and the results of that Panel.

representatives regarding any additional guidelines or regulations they believe the Agency should consider.

(B) Current infection control guidelines are non-mandatory, are not consistently and rigorously followed, and therefore are not sufficient to adequately reduce the risk of transmission of infectious agents to workers who provide direct patient care and/or perform other covered tasks.

Some stakeholders asserted, in response to OSHA's RFI, that adequate worker protection is achieved through adherence to Centers for Medicare and Medicaid Services (CMS) regulations. CMS regulations condition a provider's participation in Medicare or Medicaid on the provider's implementation of an infection control program.[30] CMS regulations only cover providers that accept or collect payments from Medicare or Medicaid. CMS requires a certification, which involves an inspection covering infection control procedures as they affect patient safety for settings such as hospitals, nursing homes, home health agencies, hospices and some ambulatory care facilities such as rural health care clinics and ambulatory surgery centers. However, most physicians' offices and many kinds of clinics are not subject to CMS accreditation requirements. Additionally, healthcare providers need not, and some healthcare providers do not, accept Medicare and/or Medicaid. Furthermore, CMS regulations do not cover some workplaces, particularly workplaces where other covered tasks (but not direct patient care) are performed (e.g., medical equipment reprocessing facilities and research and production laboratory facilities).

In addition, OSHA has in place, enforcement mechanisms that CMS does not have and that would work in concert with CMS to achieve an even greater level of compliance. Compliance with the CMS regulations is generally validated through periodic accreditation surveys of facilities by CMS-approved accreditation organizations, including TJC, state survey agencies, and other accrediting organizations (e.g., Accreditation Association for Ambulatory Health Care (AAAHC)).

Evidence OSHA has examined thus far indicates that, notwithstanding the CMS regulations, many employers receiving Medicare and Medicaid funding are not fully conforming to nationally recognized infection control practices and guidelines. OSHA has, at its disposal, enforcement mechanisms that CMS does not have. For example, OSHA can respond to complaints, conduct random unannounced inspections, and conduct worksite inspections in response to complaints filed by workers. OSHA believes that the failure of employers to

[30]See, e.g., 42 CFR 482.42 (hospitals), 483.65 (long term care facilities), 483.470(l) (intermediate care facilities for individuals with intellectual disabilities), 485.62(b) (outpatient rehabilitation facilities). CMS interpretive guidelines say that to meet this condition, providers should ensure that their infection control programs conform to nationally-recognized infection control practices and guidelines, such as the CDC/HICPAC guidelines. See, e.g., CMS State Operations Manual App. A – Survey Protocol, Regulations and Interpretive Guidelines for Hospitals, App. PP - Guidance to Surveyors for Long Term Care Facilities, App. J - Guidance to Surveyors: Intermediate Care Facilities for Persons With Mental Retardation (CMS, 2013a).

routinely and rigorously comply with recognized and generally accepted good infection control practices can be ameliorated through a joint effort between OSHA and CMS. CMS has been validating compliance through periodic accreditation surveys alongside OSHA's enforcement of its existing Bloodborne Pathogens standard for over twenty years. This has led to significant declines in bloodborne diseases among healthcare workers. OSHA believes that a similar joint effort with CMS focused on protecting workers from exposure to infectious agents transmitted by routes other than the bloodborne route would also be successful in improving infection control practices and providing additional protection to workers.

The lack of compliance with recommended infection control procedures has been recognized by the CDC, the Institute of Medicine (IOM), and the WHO, and has been documented in numerous peer-reviewed scientific publications. For example, when discussing HCW adherence to infection control guidelines in its 2007 guidance, CDC/HICPAC found (Siegel et al., 2007, pages 45-46):

> Adherence to recommended infection control practices decreases transmission of infectious agents in healthcare settings. However, several observational studies have shown limited adherence to recommended practices by healthcare personnel. Observed adherence to universal precautions ranged from 43% to 89%. However, the degree of adherence depended frequently on the practice that was assessed and, for glove use, the circumstance in which they were used. Appropriate glove use has ranged from a low of 15% to a high of 82%…Differences in observed adherence have been reported among occupational groups in the same healthcare facility and between experienced and non-experienced professionals. In surveys of health care personnel, self-reported adherence was generally higher than that reported in observational studies. Furthermore, where an observational component was included with a self-reported survey, self-perceived adherence was often greater than observed adherence. Among nurses and physicians, increasing years of experience is a negative predictor of adherence.

OSHA has found ample evidence of non-compliance with recommended guidelines in a number of areas including: hand hygiene, respiratory protective measures, hazard analyses, and appropriate laboratory infection control practices. The Agency details its findings below.

Hand Hygiene

Perhaps the most basic, and important, element of infection control is proper hand hygiene. Nonetheless, consistent and rigorous adherence to such a practice has been a challenge since Ignaz Semmelweis first identified its importance in 1847 (Semmelweis, 1861). There is ample guidance on the subject, most recently the 2009 WHO *Guidelines on Hand Hygiene in Health Care* (WHO, 2009). This guidance document provides HCWs, hospital administrators and

health authorities with a thorough review of evidence on hand hygiene in healthcare and specific recommendations to improve practices and reduce transmission of pathogenic microorganisms to patients and workers in healthcare settings. Chou et al. (2010) emphasized that despite the fact that hand hygiene is the best method of preventing transmission of infections in health care, compliance is usually suboptimal. Likewise, Allegranzi & Pittet (2009) published an extensive literature review that documents the widespread lack of compliance with proper hand hygiene procedures. In 2009, Turnberg et al. also published a study that surveyed nurses and doctors from five medical facilities, documenting the lack of compliance with both hand hygiene and respiratory protection guidelines. The study found that only 33 percent of 156 doctors, and only 43 percent of 266 nurses, reported practicing five recommended hand hygiene measures.

Respiratory Protective Measures

Turnberg et al. (2008) reported significant gaps in adherence to recommendations for the control of respiratory infections in a study that surveyed 630 workers (187 medical practitioners; 277 nurses and nurse aides; 82 allied professionals; and 84 administrative staff) at five medical centers in 2005. The study found shortcomings in overall personal and institutional use of CDC recommended practices, including the failure to comply with posted signs and with patient masking and separation, hand hygiene, and PPE practices. That study also identified deficiencies in staff training and written procedures. And in the same 2009 Turnberg et al. study referenced in the paragraph above, the authors found that only 8 percent of 177 doctors, and only 25 percent of 249 nurses, reported using recommended respiratory protection.

The IOM noted the lack of compliance with recommended infection control practices in its report on respiratory protective measures for HCWs exposed to pandemic influenza (IOM, 2009). The IOM concluded that:

> [A]lthough workers are aware of expert guidance and the risk they face, they often do not wear PPE when faced with conditions requiring its use. Such noncompliance is also seen in low rates of hand hygiene and use of gloves, respirators, and eye protection. To improve the compliance rates and thereby improve worker protection, a "culture of safety" for workers must be established in all healthcare organizations evidenced by senior leadership commitment.

Hazard Evaluations

Studies also indicate that many employers are not engaging in appropriate infectious agent hazard evaluations. Examples of occupationally-acquired infectious diseases resulting from inadequate infectious agent hazard evaluations include the following:

- Bacterial meningitis[31]: A report published in CDC's Morbidity and Mortality Weekly Report (MMWR) outlined the occupational transmission of *Neisseria meningitidis* to a police officer and a respiratory therapist in the course of their job duties (CDC, 2010a). The hospital emergency room personnel did not diagnose the patient with suspected meningococcal disease.
- Cowpox virus infection: The first known human case of laboratory-acquired cowpox virus infection recently occurred in the United States. Determination of the causative agent and the application of proper control and remediation measures were delayed because of an incomplete initial patient history that excluded the patient's occupation (McCollum et al., 2012).

These incidents are examples of many in the literature that underscore that HCWs must conduct a thorough infectious agent hazard evaluation. Infectious diseases are commonly not diagnosed definitively until after HCWs have been exposed. Performing thorough hazard evaluations improve the likelihood that the appropriate infection control procedures will be implemented for a particular infectious disease, even before the exact diagnosis has been made.

Laboratory-Acquired Infections (LAIs)

Lack of adherence to infection control measures is not limited to HCWs engaged in direct patient care (Harding and Byers, 2006). The failure to consistently use proper PPE, working with cultures outside of biological safety cabinets, and allowing unvaccinated workers to handle highly infectious materials have all led to illnesses among laboratory workers. Examples of LAIs include:

- Brucellosis[32]: In 2006, two laboratory workers in two separate laboratories became ill with brucellosis after working with specimens at their workplaces (CDC, 2008).
- MRSA infections: Two laboratory-acquired infections of MRSA were reported in laboratory workers in a European laboratory (Gosbell et al., 2003).

In some cases, the failure to follow infection control measures has even led to the deaths of laboratory workers. Examples of fatalities resulting from a lack of worker compliance with appropriate precautions include:

- Bacterial meningitis: CDC's MMWR reported a number of cases of transmission of *Neisseria meningitidis* to laboratory workers from patient samples, resulting in a fatality rate of 50 percent in the 16 cases cited (CDC, 2002a). After concluding its investigation into the death of a research laboratory worker from a meningitis infection, OSHA issued

[31]Meningitis can be caused by infection with viruses, bacteria, and other micro-organisms. Many species of bacteria, including *Neisseria meningitidis* can cause meningitis.
[32]Brucellosis or Undulant Fever is caused by various species of bacteria of the genus *Brucella*, including *B. abortus, B. canis, B. melitensis,* and *B. suis*. Brucellosis is the most commonly reported laboratory-acquired infection.

a notice of unsafe and unhealthful working conditions to the medical center that employed the laboratory worker (OSHA, 2013a).

- Plague[33]: Attenuated *Yersinia pestis* infected and killed a 60-year old laboratory worker who wasn't following proper infection control practices (CDC, 2011a).

(C) Following recognized and generally accepted good infection control practices considerably reduces the risk of transmission of infectious agents to workers providing direct patient care and/or performing other covered tasks.

The CDC/HICPAC guidelines describe an approach to mitigating the risk from infectious agents through the use of a comprehensive infection control program employing standard and transmission-based precautions. CDC/HICPAC (Siegel et al., 2007) concluded that "adherence to recommended infection control practices decreases transmission of infectious agents in healthcare settings." OSHA believes that the guidelines provide both compelling and ample evidence to support the efficacy of such an approach.

The peer-reviewed literature is replete with studies of outbreaks of infectious diseases, often in hospitals or long term care facilities. In these studies, facilities that experienced an outbreak took corrective action by rigorously following recommended standard and transmission-based precautions. Once these precautions were implemented, studies showed that the risk and incidence of transmission was considerably lowered. Examples of successful reduction and/or elimination of infection risks by taking corrective actions include:

- *Clostridium difficile* infection[34]: Post-discharge and daily disinfection of inpatient rooms using bleach wipes was associated with a reduction in the incidence of hospital-acquired *Clostridium difficile* in patients on two hospital units (Orenstein et al., 2011).
- Norovirus: Poor cleaning techniques and delayed diagnoses of norovirus-infected patients resulted in increased transmission in a long-term care facility (Wu et al., 2005). Implementation of the following infection control practices eliminated the spread of norovirus within the facility: surveillance of patients; furloughing of infected workers; adherence of HCWs to contact precautions; proper use of PPE; hand hygiene; and extensive cleaning and decontamination.
- SARS: A SARS outbreak in one hospital in Hong Kong was stopped by implementing airborne and contact precautions, as well as programs for the early recognition, prompt isolation and appropriate treatment of infected individuals (Lee et al., 2003).

[33]Plague is caused by the bacterium *Yersenia pestis*. Attenuated strains are less virulent ones that are often handled with a lower level of safety precautions.
[34]Gastroenteritis can be caused by the bacterium *Clostridium difficile*. Epidemic strains of *Clostridium difficile* that are resistant to some antibiotics have resulted in an increasing number of healthcare-acquired and community-acquired infections.

- VRE[35]: Improved post-discharge and daily cleaning in a medical ICU reduced vancomycin-resistant *Enterococcus* (VRE) contamination of the environment and HCWs' hands, and reduced VRE cross-transmission (Hayden et al., 2006).

It should be noted that the literature often does not conclusively tie the origin of the outbreak in question to a facility's failure to routinely and rigorously follow recommended infection control practices. It is difficult to definitively prove causation in individual studies, which may have size or other limitations. Yet, there are many studies that conclude that outbreaks frequently arise in situations where some recommended infection control practice(s) are not being used, and demonstrate that the outbreaks end after more rigorous implementation of those missing practices. For this reason, OSHA believes that the evidence supports the position that many outbreaks can be prevented or minimized with correct infection control practices.

Reduced Risks to Patients Translates to Reduced Risks to HCWs

Several of the studies cited in this section found that following recommended infection control practices decreased risk to patients, without explicitly mentioning the decreased risk to HCWs. Recognized and generally accepted good infection control practices, such as administrative controls, work practice controls, engineering controls, and PPE, are, by their very nature, designed to decrease the risk of transmission of infectious diseases. It is a reasonable inference that study conclusions demonstrating risk reduction when recommended infection control practices are fully implemented apply equally to all individuals, whether they are patients, HCWs, or other workers that would be covered by a rule as outlined in the regulatory framework.

The Joint Commission published a monograph in 2012 entitled "Improving Patient and Worker Safety-Opportunities for Synergy, Collaboration and Innovation." The monograph was designed to "bridge safety-related concepts and topics that are often singled out within the specific disciplines of patient safety/quality improvement and occupational health and safety." By citing case studies that demonstrate hazards that affect patients, it emphasizes that these same hazards may also affect workers. It also states that "safety must include both patient and worker safety simultaneously, since staff working conditions are related to patient safety as well as occupational safety."

[35]Enteritis can be caused by various species of bacteria of the genus *Enterococcus*, including *E. faecalis* and *E. faecium*. Vancomycin-resistant Enterococci (VRE) are of special concern since vancomycin is considered an antibiotic of last resort.

OSHA's Bloodborne Pathogens Standard Reduces Risk to HCWs for Diseases Caused by Bloodborne Pathogens

Based in part on OSHA's experience with the Bloodborne Pathogens standard (29 CFR 1910.1030), OSHA believes that mandatory requirements and OSHA oversight will substantially reduce the risk of infectious diseases for affected workers. The Agency's past experience with human immunodeficiency virus (HIV) and hepatitis B virus (HBV) showed that, even though recommendations for control of these agents were previously in existence, promulgation of the Agency's Bloodborne Pathogens standard significantly improved worker safety and health. Surveillance data by Mahoney et al. (1997) documented a dramatic decline in the incidence of hepatitis B infections among HCWs, explaining that "[t]he decline in incidence of HBV infection since 1990 may be related to publication of the blood-borne pathogens standard by the Occupational Health and Safety Administration (sic) and the increase in vaccination coverage attributable to the Occupational Health and Safety Administration (sic)." Similarly, the CDC reported that, while there have been a total of 57 documented cases of occupational HIV transmission to HCWs in the United States, no confirmed cases have been reported since 1999 (CDC, 2011b). While this 12-year absence of confirmed occupational transmission cannot be completely attributed to promulgation of the Bloodborne Pathogens standard, the standard likely played a key role in preventing HIV infections in HCWs.

Recent analysis of the sharps safety provisions of the Bloodborne Pathogens standard (as mandated by the Needlestick Safety and Prevention Act (NSPA) - Pub. L. 106-430) by the International Healthcare Worker Safety Center at the University of Virginia found the provisions highly effective (Phillips et al., 2012). They found that there was a trend toward increasing rates of injuries before the legislation was enacted, which was followed by a drop of about 38 percent (95 percent confidence interval, 35 to 41 percent) in 2001, after the NSPA took effect. Subsequent injury rates, through 2005, remained well below pre-NSPA rates. Phillips et al. concluded that the revisions to the Bloodborne Pathogens standard contributed to the decline in percutaneous injuries among U.S. hospital workers, and support the concept that well-crafted standards supported by effective enforcement can result in a safer work environment and workforce.

Therefore, OSHA believes that the current non-mandatory approach to assuring appropriate implementation of infection control guidelines is not sufficient to adequately protect workers with occupational exposure to infectious diseases and that a rule as outlined in the regulatory framework is necessary to compel employers to follow recognized and generally accepted good infection control practices.

Section IV. Description of the Important Components in the Regulatory framework

Introduction

OSHA presents, in its regulatory framework, a potential programmatic approach to the protection of workers from occupational exposure to infectious diseases. The regulatory framework represents, in its entirety, OSHA's preferred alternative. The elements in the regulatory framework do not represent a list of provisions that OSHA may or may not include but instead represent all of the provisions the Agency believes, at this point, would constitute the best, most protective rule while providing the most flexibility and minimizing the burden on affected entities. While this framework represents OSHA's initial thinking, the Agency is still considering a number of alternatives and options (see Section VIII of this SER Background Document) and is open to considering additional alternatives or options that the SERs may present. OSHA welcomes feedback on all of the elements included in the regulatory framework.

The approach laid out in the regulatory framework would require employers to implement recognized and generally accepted good infection control practices such as those outlined in CDC infection control guidelines, CMS regulations, and CDC/National Institutes of Health (NIH) *Biosafety in Microbiological and Biomedical Laboratories* guidance. A typical OSHA program standard affords employers substantial flexibility in determining the best way to tailor protective measures to their workplaces, and, like most program standards, OSHA would require, among other things:

- an exposure determination;
- a written exposure control plan (referred to as a worker infection control plan (WICP) in the regulatory framework);
- methods of compliance (e.g., engineering,[36] administrative,[37] and work practice[38] controls, and PPE[39]);

[36]The regulatory framework defines engineering controls as measures that reduce, isolate, or remove the infectious agents' hazard from the workplace. Examples of engineering controls would include, but would not be limited to, airborne infection isolation rooms (AIIRs) and physical barriers, such as sneeze guards.

[37]The regulatory framework defines administrative controls as managerial measures that reduce the risk of transmission of, or infection by, infectious agents. Examples of administrative controls would include, but would not be limited to: promoting and providing vaccination; enforcing exclusion of ill employees from the workplace; setting up triage stations and separate areas for patients with suspected or confirmed infectious disease when they enter a healthcare facility; and assigning dedicated staff to minimize the number of employees exposed to those with a particular suspected or confirmed infectious disease.

[38]The regulatory framework defines work practice controls as measures designed to reduce the likelihood of transmission of infectious agents by specifying the manner of performing particular work tasks. Examples of work practice controls would include, but would not be limited to: performing tasks in a manner that minimizes generation of droplets or aerosols of infectious agents and practicing appropriate hand hygiene and respiratory hygiene/cough etiquette.

[39]The regulatory framework defines personal protective equipment (PPE) as specialized clothing or equipment worn by an employee for protection against a hazard. General work clothes (e.g., uniforms, pants, shirts or blouses) not intended to function as protection against a hazard would not be considered PPE.

- medical screening, surveillance, and vaccinations;
- employee training; and
- recordkeeping.

Numerous studies (see Section III of this SER Background Document) find that fully implemented infection control plans are effective at reducing transmission of infectious agents and illnesses in both patients and workers. OSHA believes that many employers of workers with occupational exposure to infectious agents already have some (if not most) infection control plan elements in place and that the remainder usually have at least some familiarity with the elements introduced in the regulatory framework.

Moreover, responses to OSHA's RFI on infectious diseases (75 FR 24835, May 6, 2010)[40] and early site visits to healthcare facilities suggest that even very small employers can, and often do, implement infection control plan elements, and that small employers could successfully apply the programmatic elements in the regulatory framework. Thus, for many small employers, complying with a rule like the regulatory framework could simply involve:

- Evaluating their current written plan for completeness and adding missing elements;
- Identifying improvements needed in the implementation of their written plan and ensuring the elements of the plan are fully and rigorously followed;
- Verifying that employee health provisions, including vaccinations, are implemented and up-to-date; and
- Modifying their existing infection control training materials and using these modified materials to train employees in any areas where deficiencies in the existing program or in the implementation of the existing program have been identified.

There are at least two factors that could minimize the burden of compliance with a rule like the regulatory framework on some employers. First, all employers with employees who have occupational exposure to blood and other potentially infectious materials (as defined in the Bloodborne Pathogens (BBP) standard, 29 CFR 1910.1030) must already adhere to the BBP standard. These employers include most of the employers that would also be covered by a rule as outlined in the regulatory framework. Therefore, these employers should already be adhering to many of the types of practices that would be required by a rule as outlined in the regulatory framework to the extent these types of practices are already required by the BBP standard. For example, the BBP standard requires precautions such as hand hygiene, decontamination, exposure incident investigations, and hazard signage and labeling, which are also part of Standard Precautions. According to the regulatory framework, Standard Precautions are the "minimum infection control practices that apply to all direct patient care, regardless of suspected or confirmed infection status of the patient, in any setting where healthcare is provided." In

[40]For example, see the following comments to the RFI, available under docket number OSHA-2010-0003 at Regulations.gov: OSHA-2010-0003-0021; OSHA-2010-0003-0022; OSHA-2010-0003-0064; OSHA-2010-0003-0173; and OSHA-2010-0003-0179.

addition to Standard Precautions, in some cases, transmission-based precautions would need to be implemented based on the hazard evaluation(s).

Second, OSHA wants to stress that each employer covered by the regulatory framework would only be tasked with developing and implementing a Worker Infection Control Plan (WICP) that is tailored to their specific work setting. The complexity of the WICP would largely be dictated by the size of the setting as well as the diversity and nature of job duties performed in that setting. For example, a larger setting such as a hospital would necessarily have a more complex WICP than a small setting such as a physician's or dentist's office.

For ambulatory care settings, the 2011 outpatient settings checklist (CDC, 2011f) demonstrates that most of the precautions that are recommended fall under Standard Precautions with transmission-based precautions implemented as needed. The next section explains why WICPs are not and cannot be "One Size Fits All".

Infection Control Plans (Including WICPs That Would be Required Under An OSHA Rule) Are Not and Cannot Be "One Size Fits All"

The basic elements of infection control practices for healthcare and related settings are laid out in the 2007 CDC/HICPAC guidance document and other guidance documents (e.g., BMBL and the NIH Guidelines for laboratories). Not surprisingly, the guidance documents recommend similar basic practices (e.g., hand hygiene, decontamination of infected materials and surfaces) for different settings. However, how these infection control practices are implemented in different settings and under different conditions will be affected by a number of factors.

- Sources and magnitude of worker exposure to infectious agents varies by setting.
  - In settings that provide direct patient care, appropriate precautions should be in place to protect workers from exposure to patients known or suspected to be infected or colonized with disease agents.
  - In all settings (including settings that provide direct patient care, morgues, laundries and laboratories), appropriate precautions should be in place to protect workers from exposure to infectious materials (e.g., contaminated materials and surfaces should be appropriately disinfected).
  - In hospitals, nursing homes and laboratories, there are longer exposures to infectious patients/contaminated materials.
  - In ambulatory care settings, worker exposures to infectious patients are frequently of shorter duration.
- Characteristics of patient populations vary by setting.
  - Immunocompromised patients, who are more susceptible to infectious diseases and are contagious for longer periods of time, are most likely to be seen in hospitals, nursing homes and specific types of ambulatory care settings (e.g., oncology clinics).
  - More severely ill infectious patients are treated in hospitals.

    - A greater number of infectious patients are seen in ambulatory care settings than in hospitals, though clinic patients frequently have mild or moderate symptoms.
- Characteristics of infectious agent(s), which affect level(s) of worker exposure, vary by setting.
    - The agent's route(s) of transmission will determine the types of precautions required (e.g., in settings that provide direct patient care, whether Standard Precautions are sufficient or transmission-based precautions (contact, droplet and/or airborne) will also need to be implemented).
- The severity of the disease due to the virulence of the infectious agent(s) is different for different agents. Individuals who have exposure to an infectious agent(s) that causes severe disease (e.g., active TB) are more likely to be treated in a hospital than in an ambulatory care setting.
- Types of infectious agents and diseases encountered vary by setting.
    - In hospitals and nursing homes, pneumonia, caused by a number of different infectious agents, is often seen.
    - In pediatric and family clinics, childhood infectious diseases such as mumps, measles, and pertussis are often seen.
    - In research laboratories, many different types of infectious agents capable of causing many different types of diseases are handled.

The 2007 CDC/HICPAC guidelines (which focus on settings that provide direct patient care) take all these various factors into consideration and recommend different ways to implement infection control practices that are appropriate for different types of settings. Examples of their recommendations (see pages 77-90 of the 2007 CDC/HICPAC guidelines) by setting, discussed below, include patient placement and patient transport using Standard Precautions versus transmission-based precautions.

Patient Placement - Standard Precautions

The potential for transmission of infectious agents should be considered when making patient-placement decisions. Place patients who pose a risk of transmission to others in a single-patient room, when available. Determine patient placement based on the following principles:

- Route(s) of transmission of the known or suspected infectious agent
- Risk factors for transmission from the infected patient
- Risk factors for adverse outcomes resulting from a healthcare-acquired infection(s) in other patients in the area or room being considered for patient-placement
- Availability of single-patient rooms
- Patient options for room-sharing (e.g., cohorting patients with the same infection)

Patient Placement - Contact Precautions

Acute care hospitals

Place patients in a single-patient room, when available. If single-patient rooms are in short supply, the following factors should be considered when making decisions on patient placement:

- Prioritize patients with conditions that may facilitate transmission (e.g., uncontained drainage, stool incontinence) for single-patient room placement.
- Place together in the same room (cohort) patients who are infected or colonized with the same infectious agent.
- Change protective attire and perform hand hygiene between contact with patients in the same room, regardless of whether one or both patients are on Contact Precautions.

Long-term care and other residential settings

Decisions regarding patient placement should be made on a case-by-case basis, balancing exposure to other patients in the room, the presence of factors that increase the likelihood of transmission, and the potential adverse psychological impact on the infected or colonized patient.

Ambulatory settings

Place patients in an examination room or cubicle as soon as possible.

Patient Placement - Droplet Precautions

Acute care hospitals

Place patients who require Droplet Precautions in a single-patient room when available. When single-patient rooms are in short supply, apply the following principles for making decisions on patient placement:

- Prioritize patients who have excessive cough and sputum production for single-patient room placement.
- Place together in the same room (cohort) patients who are infected with the same infectious agent and are suitable roommates.
- Change protective attire and perform hand hygiene between contact with patients in the same room, regardless of whether one patient or both patients are on Droplet Precautions.

Long-term care and other residential settings

Make decisions regarding patient placement on a case-by-case basis after considering exposure to other patients in the room and available alternatives.

Ambulatory settings

Place patients who require Droplet Precautions in an examination room or cubicle as soon as possible. Instruct patients to follow recommendations for Respiratory Hygiene/Cough Etiquette (which are available at www.cdc.gov/flu/professionals/infectioncontrol/resphygiene.htm).

Patient Placement - Airborne Precautions

Acute care hospitals and long-term care settings

Place patients who require Airborne Precautions in an AIIR that has been constructed in accordance with current AIIR guidelines.

- When an AIIR is not available, transfer the patient to a facility that has an available AIIR.
- In the event of an outbreak or exposure involving large numbers of patients who require Airborne Precautions:
  - Consult infection control professionals before patient placement to determine the safety of alternative rooms that do not meet engineering requirements for an AIIR.
  - Place together (cohort) patients who are presumed to have the same infection (based on clinical presentation and diagnosis when known) in areas of the facility that are away from other patients, especially patients who are at increased risk for infection (e.g., immunocompromised patients).
  - Use temporary portable solutions (e.g., exhaust fan) to create a negative pressure environment in the converted area of the facility. Discharge air directly to the outside, away from people and air intakes, or direct all the air through HEPA filters before it is introduced to other air spaces.

Ambulatory settings

Develop systems (e.g., triage, signage) to identify patients with known or suspected infections that require Airborne Precautions upon entry into ambulatory settings.

- Place the patient in an AIIR as soon as possible.
- If an AIIR is not available, place a surgical mask on the patient and place him/her in an examination room. Once the patient leaves, the room should remain vacant for the appropriate time, generally one hour, to allow for a full exchange of air.
- Instruct patients with a known or suspected airborne infection to wear a surgical mask and observe Respiratory Hygiene/Cough Etiquette.
- Once in an AIIR, the mask may be removed; the mask should remain on if the patient is not in an AIIR.

Patient Transport – Standard Precautions

No special practices are recommended for transport of patients who are being handled under Standard Precautions.

Patient Transport - Contact Precautions

Acute care hospitals and long-term care and other residential settings

Limit transport and movement of patients outside of the room to medically-necessary purposes.

In any healthcare setting

When transport or movement is necessary,

- Ensure that infected or colonized areas of the patient's body are contained and covered.
- Remove and dispose of contaminated PPE and perform hand hygiene prior to transporting patients on Contact Precautions.
- Don clean PPE to handle the patient at the transport destination.

Patient Transport - Droplet Precautions

Acute care hospitals and long-term care and other residential settings

Limit transport and movement of patients outside of the room to medically-necessary purposes.

In any healthcare setting

When transport or movement is necessary, instruct patient to wear a surgical mask and follow Respiratory Hygiene/Cough Etiquette.

Patient Transport - Airborne Precautions

Acute care hospitals and long-term care and other residential settings

Limit transport and movement of patients outside of the room to medically-necessary purposes.

When transport or movement outside an AIIR is necessary:

- Instruct patients to wear a surgical mask, if possible, and observe Respiratory Hygiene/Cough Etiquette.
- For patients with skin lesions associated with varicella or smallpox or draining skin lesions caused by *M. tuberculosis*, cover the affected areas to prevent aerosolization or contact with the infectious agent in skin lesions.

Laboratories

Diagnostic laboratory facilities (e.g., clinical laboratories), research laboratory facilities, and production laboratory facilities are unique work environments that may pose special infectious disease risks to persons in or near them. Key documents that detail biological safety practices in laboratory facilities include: Biosafety in Microbiological and Biomedical Laboratories (CDC/NIH. 2009), NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH, 2013) and [CDC, 2012c]. The precautions in research and production laboratory facilities vary from those used in healthcare settings because laboratory workers are exposed to infectious materials rather than infectious patients. Workers in clinical laboratories can be exposed both to infectious materials and infectious patients. CDC/NIH recommends standard microbiological practices as well as practices for specific biosafety levels and disease agent-specific precautions (CDC/NIH. 2009),

One example of a difference between laboratory facilities and healthcare settings providing direct patient care is the type(s) of engineering controls used. Engineering controls recommended for laboratory facilities such as biosafety cabinets, laboratory hoods, and other laboratory design and containment measures are designed to protect the worker from exposure to infectious materials. In contrast, the types of engineering controls (e.g., AIIRs in hospitals) used in healthcare settings are designed to protect workers from exposure to infectious patients and contaminated materials.

The remainder of this section provides a broad overview of the regulatory framework and highlights some of its major elements.

Scope

Per the regulatory framework, OSHA would require that an infectious diseases rule apply to employers within federal OSHA's jurisdiction and include firms engaged in general industry sectors. If a rule is promulgated, states with OSHA-approved State Plans would be required to adopt an equivalent "at least as effective" standard covering both the private sector and state and local government workers, as applicable.[41]

Because infectious agents pose serious hazards to workers performing many types of tasks, per the regulatory framework, an infectious diseases rule would generally cover any worker with occupational exposure when that worker performs certain tasks described in the regulatory framework. An infectious diseases rule would not be limited to covering workers providing healthcare services only, or to covering specific workplaces or work settings only. An employer's workplace would fall within the scope of an infectious diseases rule if: (1) the employer's workers provide direct patient care (a term that is defined in the following paragraphs) or perform other covered tasks (a term that is also defined in detail in the following paragraphs); and (2) those workers have occupational exposure (i.e., exposure which is or should

[41]There are 27 States and territories with OSHA-approved plans, 5 of which are limited in coverage to public employees only.

be reasonably anticipated to sources of infectious agents resulting from a worker's execution of job duties that involve the provision of direct patient care or the performance of other covered tasks). OSHA notes that, under the regulatory framework, a worker would have "occupational exposure" even if that worker is subject only to the potential for being exposed to infectious agents during the performance of job duties that involve the provision of direct patient care or the performance of other covered tasks, so long as that potential is or should be reasonably anticipated.

Per the regulatory framework, OSHA would exclude occupational exposure as defined in OSHA's Bloodborne Pathogens standard (29 CFR 1910.1030).

OSHA anticipates that employees working in settings to which the CDC/HICPAC guidelines apply (or to which guidelines for particular settings or medical specialties that are based upon the CDC/HICPAC guidelines apply), as well as employees working in other settings where there is occupational exposure, would fall within the scope of an infectious diseases rule. The employer would be required to determine whether its workers are covered during its development of a written infection control plan (discussed in further detail later in this section). Most small employers are used to working under guidelines and regulations that address infection control, such as those issued by CDC, NIH, CMS, and OSHA (e.g., the Bloodborne Pathogens standard). (See Appendix B of this document for a partial list of guidelines and regulations currently in place that address infection control in a variety of settings). As a result, the Agency does not believe that small employers would have difficulty determining whether their employees have occupational exposure during the provision of direct patient care or performance of other covered tasks.

The regulatory framework defines "direct patient care" as job duties that involve the provision of healthcare services with hands-on or face-to-face contact with patients, while acting under a license, certification, or registration to provide healthcare services within a legally permitted scope of practice, or while acting under the supervision of a licensed, certified, or registered employee. Nurses, physicians, physical and occupational therapists, paramedics, and emergency responders are examples of the types of workers who perform direct patient care. A pharmacist performing duties that involve hands-on contact with patients (e.g., administering vaccinations) is another example of a worker who performs direct patient care. However, a worker who provides first aid only would not be considered to provide direct patient care for the purposes of the regulatory framework. OSHA believes that general public health measures are adequate to protect workers who provide first aid only from the types of infectious agents covered by the regulatory framework, and that it would not be necessary to impose the burden of implementing and maintaining a comprehensive infection control plan for such workplace exposures.

Moreover, coming into hands-on or face-to-face contact with another individual would not necessarily constitute direct patient care. Personal trainers at gyms and cosmetologists may have hands-on or face-to-face contact with other individuals, but they are outside of the scope of the

regulatory framework, either because they are not licensed/certified/registered to provide healthcare services, or because they are not delivering healthcare services to patients. OSHA believes, at this stage, that exposures in these types of settings are more properly addressed by general public health measures.

"Other covered tasks" is defined in the regulatory framework as job duties that do not involve direct patient care but still involve occupational exposure in settings where direct patient care is provided, or occupational exposure to contaminated materials originating from settings where direct patient care is provided or to human remains. In addition, other covered tasks involve occupational exposure to contaminated materials in diagnostic, research or production facilities. Examples of other covered tasks would include: providing patient support services (e.g., triage reception, housekeeping, food services, facility maintenance); handling, transporting, receiving or processing contaminated materials (e.g., laundering healthcare linens, transporting medical specimens, disposing of medical waste, reprocessing medical equipment); maintaining, servicing or repairing contaminated medical equipment; conducting autopsies (e.g., in medical examiners' offices); performing mortuary services; manipulating and analyzing cultures, specimens, and human remains that may contain infectious agents in diagnostic, research and production facilities; and dispensing medications and/or medical supplies in settings where direct patient care is provided.

While the scope of the regulatory framework is defined by the types of job tasks performed in a facility, and not by the industry classification(s) of the facility, OSHA has identified a number of industries where direct patient care and/or other covered tasks could be performed. OSHA has preliminarily estimated that direct patient care would be provided in, among other industries: hospitals; long-term care facilities and nursing homes; ambulatory care centers, including doctors' offices and dentists' offices; ambulatory surgical centers; medical clinics embedded in schools, correctional facilities, or industrial settings; home healthcare; and medical emergency delivery services (e.g., ambulances). Other covered tasks could be performed in all of the previously mentioned industries where direct patient care is provided, plus, among other industries: diagnostic, research, and production laboratory facilities; morgues and mortuaries; laundry facilities that handle linens from healthcare settings; medical waste collection and disposal facilities; medical equipment reprocessing facilities; and durable medical equipment supply companies that rent reusable equipment such as hospital beds and wheelchairs. Section V of this SER Background Document presents the industries that OSHA anticipates would likely be covered by an infectious diseases rule, and describes their characteristics, in more detail.

OSHA does not intend for the regulatory framework to cover veterinarians and veterinary technologists, technicians, or assistants, except when these workers perform duties defined as other covered tasks. For example, animal caregivers would be covered if they work in a research facility that handles infectious agents that can be transmitted to humans via contact, droplet or airborne route(s) or materials contaminated with such infectious agents.

Per the regulatory framework, an infectious diseases rule would not include in its scope certain job tasks, such as the tasks of prison guards and teachers, that are not other covered tasks. In addition, there are certain job classifications, for example flight attendants, that would not be covered because workers in those classifications generally do not provide direct patient care or perform other covered tasks. The tasks covered under the regulatory framework – unlike the typical duties of workers such as prison guards, teachers and flight attendants – would generally be subject to the standard and transmission-based precautions laid out in the CDC/HICPAC guidelines. Although many of the programmatic elements of the regulatory framework are already in place for the tasks covered under the regulatory framework, this is not generally the case for the tasks of prison guards, teachers and flight attendants. Note that under the regulatory framework, workers such as prison guards and teachers would be covered if they perform other covered tasks (e.g., a prison guard working in an embedded prison clinic).

OSHA is not suggesting that prison guards, teachers, and flight attendants not covered under the regulatory framework have no occupational exposure. Rather, it is the Agency's belief that such exposures are more appropriately addressed through general public health approaches and OSHA's Bloodborne Pathogens standard, rather than through the infection control measures envisaged in the regulatory framework. OSHA notes that it will continue to examine these job classifications carefully, and may explore ways to specifically address the infectious disease hazards associated with these job classifications in the future.

Under the regulatory framework, direct patient care is defined, in part, as job duties involving hands-on or face-to-face contact with patients. An exception to this definition states that pharmacists who provide hands-on care (e.g., administer vaccinations) provide direct patient care, while those who perform duties that involve face-to-face contact only (e.g., dispense medications) do not provide direct patient care. Pharmacists who are dispensing medications and/or medical supplies in settings where direct patient care is provided, however, are performing other covered tasks and therefore fall under the scope of the regulatory framework if they have occupational exposure. OSHA believes, based on the evidence it has thus far analyzed, that general public health measures are adequate to protect pharmacists who neither provide direct patient care nor perform other covered tasks, as defined by the regulatory framework.

Per the regulatory framework, an infectious diseases rule would not apply to occupational exposures that are already covered by the Bloodborne Pathogens standard, 29 CFR 1910.1030. All other forms of occupational exposure to infectious agents that are transmissible to humans would be covered by an infectious diseases rule. The Agency expects that many employers would likely develop a unified infection control plan that addresses both occupational exposures to bloodborne hazards and to other sources of infectious agents.

OSHA notes that, unless otherwise stated in the regulatory framework, covered employers would also have to comply with other applicable provisions in Part 1910, such as the Respiratory

Protection standard (§1910.134), the Personal Protective Equipment standards (Subpart I); and the Specifications for Accident Prevention Signs and Tags standard (§1910.145).

Worker Infection Control Plan (WICP)

Per the regulatory framework, OSHA would require employers whose workers are within the scope of the regulatory framework to develop and implement a written worker infection control plan (WICP) designed to prevent or minimize the transmission of infectious agents to workers. The written WICP is the foundation of the regulatory framework. Because infection control must be practiced by everyone, it is imperative that workers are aware of and trained on the provisions in place in their workplaces. Having the WICP in written form is also essential to determine if the components of the plan have been implemented. OSHA believes that many employers of workers with occupational exposure have already developed WICPs for their workplaces and that these plans would fulfill most, if not all of, the requirements for a WICP, as specified under the regulatory framework. However, employers could choose to modify current elements or develop additional elements for their current infection control programs to help them better manage their programs, and to demonstrate that they are implementing and maintaining all elements of their programs.

According to the regulatory framework, OSHA would require that the WICP contain an exposure determination; identifying information regarding the plan administrator and the person(s) responsible for the daily management of the WICP; and the standard operating procedures (SOPs)[42] outlined in the regulatory framework (described in more detail in the discussion of Standard Operating Procedures Development and Implementation, below). With respect to the exposure determination, OSHA would require that the employer compile a list of all job categories in the workplace where all or some of the employees have occupational exposure during the provision of direct patient care and/or performance of other covered tasks. For example, in a hospital, an employer would include in its exposure determination job categories such as registered nurses, physicians, radiological technicians, and respiratory therapists, because some or all personnel in those categories have occupational exposure; a hospital probably would not include in its exposure determination job classifications such as accounting and HR, so long as no personnel in those categories have occupational exposure. OSHA would require that the exposure determination be made without regard to the use of PPE for the following reasons. 1) Sometimes exposures occur to people who are not directly working with the hazardous material and may not routinely use PPE. For these workers, part of the exposure determination process would involve assessing whether these workers should also use PPE and if so, what PPE would be appropriate; 2) In addition, several conditions must be met for PPE to effectively lessen exposures. The employee must be trained to use the PPE properly each time the task is performed, the PPE must fit properly and be appropriate for the task and finally the PPE must be

[42]The regulatory framework defines "standard operating procedure" as an organizational directive that establishes a standard course of action to accomplish a task or goal.

free of physical flaws that could compromise safety. If even one of these conditions is not fully met, protection cannot be assured. Therefore, all tasks that entail occupational exposure need to be included in the exposure determination, regardless of the PPE used, so that the workers who perform such tasks will be properly protected. OSHA does not anticipate that the preparation of the exposure determination would be burdensome for most employers.

Because of the continual emergence of new research and technology related to the prevention of occupational illness due to infectious agents, OSHA would require that employers (with input from non-managerial workers with occupational exposure) review and update their WICPs at least annually, and whenever necessary to reflect changes in occupational exposure, and that employers establish and maintain records of the reviews. These provisions would be similar to requirements in OSHA's Bloodborne Pathogens standard (§§1910.1030(c)(1)(iv), (c)(1)(v)).

Without such updates and reviews, there is a risk of the WICP becoming static and documented elements, such as SOPs, becoming out of date. In most settings where workers are exposed to infectious agents, changes in technology, new or emerging infectious agents, changes in job tasks, procedures, and job classifications, and other changes occur markedly over time. Each change in the work setting has the potential to create new occupational hazards that may need to be addressed and brought under control, or the potential to make one or more elements of the WICP outdated. OSHA's intent is that each establishment's WICP be structured so that it can evolve and change to meet new circumstances and needs. The Agency believes this would be assured by the WICP review process in the regulatory framework. Further, providing workers with opportunities to participate in the implementation and evaluation of the WICP is critical to ensuring that the plan is successful and effective. Involving workers allows employers to tap into the knowledge and insight that workers have about infectious agents, infection control practices, how work is conducted, and potential solutions to infection control issues.

Finally, per the regulatory framework, an infectious diseases rule would contain provisions that host employers (e.g., hospitals) would implement to protect their workers from infectious agent hazards. Under such a rule, OSHA would require that the host employer require that contractors, vendors, and licensed independent practitioners with privileges, at a minimum, adhere to infection control practices consistent with the host employer's WICP. OSHA would also generally require the host employer to ensure that its WICP is followed by each of its employees, even when instructions from a contractor, vendor or licensed independent practitioner with privileges are contrary to the host employer's WICP. Under such a rule, the host employer would allow its employees to follow contrary instructions from a contractor, vendor or licensed independent practitioner with privileges if the host employer could show that not following the contrary instructions would be a greater hazard to a patient(s) or an employee(s), or that following the contrary instructions is consistent with recognized and generally accepted good infection control practices. In concert with these provisions, OSHA would require that host employers ensure that a copy of the WICP is provided and accessible to workers, contractors, vendors, and licensed independent practitioners with privileges.

Standard Operating Procedures Development and Implementation

Per Section 4 of the regulatory framework, OSHA would generally require employers having a worker(s) covered by an infectious diseases rule to develop, implement, and update written SOPs that are consistent with recognized and generally accepted good infection control practices relevant to the occupational exposures encountered by employees during their job tasks. To determine whether SOPs are consistent with such practices, OSHA would require that employers consider both applicable regulations, such as federal, state and local regulations, and current guidelines, such as those issued by the CDC, CDC/HICPAC, and NIH.[43] In the absence of such regulations and guidelines, OSHA would require that employers consider current guidance issued by professional organizations and accrediting bodies. Moreover, OSHA would require that employers develop, implement, and update written SOPs that are consistent with applicable requirements in Part 1910 (e.g., requirements contained in 29 CFR 1910.134, and 29 CFR 1910 Subpart I); and, if a recognized and generally accepted good infection control practice conflicts with an applicable requirement in Part 1910, employers would need to incorporate into its SOPs, and implement, the Part 1910 requirement.

SOPs for all employers: A rule based on the regulatory framework would require the SOPs for all employers in the scope of the regulatory framework to contain at least procedures for:

- Infectious agent hazard evaluations;
- Communication of hazard evaluation results;
- Hand hygiene;
- Food and cosmetics;
- Engineering, administrative, and work practice controls and PPE;
- Decontamination;
- Handling, containerization, transport, or disposal of contaminated materials;
- Occupational health services;
- Exposure incidents;
- Signage and labeling/color-coding; and
- Notification of occupational exposure during transfer, transport, shipping, or receipt of sources of infectious agents.

Below, OSHA highlights some of the SOPs for all affected work settings covered under the regulatory framework.

Per the regulatory framework, OSHA would require the employer to establish and implement procedures for the conduct of timely infectious agent hazard evaluations to promptly identify

[43]The regulatory framework provides that, when conducting research on infection control practices, employers may consider research protocols that are not consistent with recognized and generally accepted good infection control practices, provided those protocols have been approved by an institutional review board and adequately address worker protection as a component of the overall protection of the human subjects.

suspected or confirmed sources of infectious agents that are present in the work setting. An effective hazard evaluation would anticipate a range of infectious agent hazards and appropriately link those hazards with standard and transmission-based precautions. In a healthcare setting, such an evaluation might include an assessment of a patient's infectious status based upon symptoms reported at scheduling and intake/admittance and/or a healthcare provider's index of suspicion based upon the provider's interactions with the patient. If the regulatory framework develops into a proposed rule, the Agency might include in that proposed rule a non-mandatory appendix that would explain how employers can conduct infectious agent hazard evaluations in different settings. OSHA would not require the hazard evaluations to be written documents, but would permit the hazard evaluations to be incorporated into routine activities, such as triage, scheduling, intake, or a preliminary assessment by a healthcare worker.

Per the regulatory framework, OSHA would require the employer to establish and implement procedures to ensure that handwashing facilities are available and accessible, and for following recognized and generally accepted good infection control practices for hand hygiene.

Per the regulatory framework, OSHA would require the employer to establish and implement procedures for the use of engineering, administrative, and work practice controls, and would require the employer to establish and implement procedures for the provision and use of PPE (e.g. gloves, gowns, laboratory coats, protective eyewear, face shields, facemasks, and respirators). OSHA would require that employers establish and implement SOPs in accordance with recognized and generally accepted good infection control practices, and thereby tailor their SOPs to their specific work settings and to the specific risks typically encountered in their workplaces. As such, OSHA notes in the regulatory framework that the Agency might permit adherence to the required hierarchy of controls, such as that required by 29 CFR 1910.134(a)(1), to be modified in accordance with recognized and generally accepted good infection control practices. Thus, for example, OSHA would permit an employer not to use certain engineering controls (e.g., airborne infection isolation rooms (AIIRs)) if it is consistent with recognized and generally accepted good infection control practices to use some combination of alternative engineering controls, administrative controls, work practice controls and PPE instead.

OSHA wrote the regulatory framework in this manner because OSHA recognizes that infection control practices normally rely upon a multi-layered and overlapping strategy of employing engineering, administrative, and work practice controls, as well as PPE. Moreover, the regulatory framework is consistent with OSHA's understanding that most workplaces outside of hospitals do not have AIIRs.

Per the regulatory framework, OSHA would require the employer to establish and implement procedures for regular examination of existing engineering controls, and for maintaining or replacing existing engineering controls to ensure that engineering controls function properly and, thus, provide protection to workers as intended. OSHA would require the employer to establish

and implement procedures to prevent or minimize the generation of droplets or aerosols of infectious agents.

Per the regulatory framework, OSHA would require the employer to establish and implement procedures for decontamination of contaminated materials (i.e., contaminated items and/or surfaces) and contaminated equipment. The Agency chose not to specify particular disinfectants or procedures for decontamination under the regulatory framework, as OSHA would require SOPs that are consistent with recognized and generally accepted good infection control practices relevant to their work setting. OSHA also believes that specifying particular disinfectants and procedures could have the effect of limiting the use of new products and of discouraging the development of new information relative to adequate decontamination.

Per the regulatory framework, OSHA would require the employer to establish and implement procedures to provide occupational health services, including screening, surveillance, vaccinations and vaccination regimens (e.g., doses, intervals), post-exposure treatment and follow-up, and medical removal protection, that are consistent with recognized and generally accepted good infection control practices. Such potential requirements are discussed later in this section of this SER Background Document.

Per the regulatory framework, OSHA would require the employer to establish and implement procedures to investigate the circumstances surrounding each exposure incident, which is defined as a specific event in which a worker has been exposed to a suspected or confirmed source of an infectious agent(s), either without the benefit of the infection control practices that would be required by OSHA, or where the infection control practices that would be required by OSHA may not have adequately protected the worker from the exposure. These procedures would involve determining the cause of the incident, and whether existing policies, procedures, or training need to be revised to prevent future exposure incidents. For example, during an exposure incident investigation, a Physician or other Licensed Healthcare Professional (PLHCP) may conclude that a patient exposed a worker to a suspected or confirmed source of an infectious agent and that proper implementation of the employer's infection control practices may not have adequately protected the worker from the exposure. The exposure incident investigation will assist the employer in revising its SOPs to more fully protect workers and will help the employer identify which workers may need to receive occupational health services (which, again, are discussed below).

Additional SOPs for Direct Patient Care: Per the regulatory framework, OSHA would require employers whose workers provide direct patient care to develop, implement, and update, in addition to the SOPs for all affected work settings, SOPs that contain at least procedures for:

- Patient scheduling and intake/admittance;

- Standard Precautions;[44]
- Contact precautions;[45]
- Droplet precautions;[46]
- Airborne precautions;[47]
- Patient transport;
- Medical surge procedures; and
- Ensuring any other employee protection precautions necessary to address specific infectious diseases or circumstances.

Below, OSHA highlights some of the provisions in the regulatory framework addressing SOPs for employers whose workers provide direct patient care.

OSHA has concerns that workers exposed to airborne transmissible infectious diseases are not being adequately protected. Therefore, the regulatory framework includes provisions for the development, implementation, and update of SOPs associated with airborne precautions.

Per the regulatory framework, OSHA would require procedures for the temporary isolation and inter-facility transfer of an individual with a suspected or confirmed airborne-transmissible infectious disease if the employer's healthcare setting does not have an available AIIR. OSHA recognizes that there are certain situations where transfer may not be appropriate and notes that transfer would not be required if: a transfer would be medically detrimental to the individual's health; it is not medically necessary for the individual to remain in the healthcare facility (e.g., it is appropriate to send the individual home); or an AIIR becomes available at the facility.

Per the regulatory framework, OSHA would require procedures for ensuring proper AIIR operation if the employer's healthcare setting has an AIIR, including procedures for ensuring that each AIIR, associated ducting, and filtration are constructed, operated, and maintained so that they maintain negative pressure, achieve sufficient air changes per hour, properly exhaust contaminated air, and function to prevent or minimize transmission of infectious agents, and for ensuring that, when in use, each AIIR is monitored daily for maintenance of negative pressure.

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[44]The regulatory framework defines "Standard Precautions" as the minimum infection control practices that apply to all direct patient care, regardless of suspected or confirmed infection status of the patient, in any setting where healthcare is provided.

[45]The regulatory framework defines "contact precautions" as infection control practices designed to prevent or minimize transmission of infectious agents spread by direct contact (i.e., infectious agent transmission from one infected individual to another individual without a contaminated intermediate item, surface, or individual) or indirect contact (i.e., infectious agent transmission through a contaminated intermediate item, surface, or individual) with an item, surface, or individual contaminated with, such an agent(s).

[46]The regulatory framework defines "droplet precautions" as infection control practices designed to prevent or minimize transmission of infectious agents spread through direct contact of droplets containing the infectious agent with an individual's respiratory or mucous membranes.

[47]The regulatory framework defines "airborne precautions" as infection control practices designed to prevent or minimize transmission of infectious agents that remain infectious over time and distance (e.g., between or across rooms; through ventilation systems) when suspended in the air.

OSHA believes that these procedures would ensure that AIIRs function properly when they are needed.

As stated, the Respiratory Protection standard (29 CFR 1910.134) would generally apply to the use of respirators by workers performing tasks covered by a rule as outlined in the regulatory framework. Per the regulatory framework, OSHA would require employers to establish and implement procedures for workers to use respiratory protection: when entering areas, rooms, or homes where individuals have been isolated; when transporting individuals with suspected or confirmed infectious disease in an enclosed vehicle; during aerosol-generating procedures; during maintenance of air systems or equipment reasonably likely to contain airborne-transmissible infectious agents; and whenever the infectious agent hazard evaluation indicates that respiratory protection is necessary for worker protection.[48] OSHA would also require employers to establish and implement procedures to ensure that facemasks are not used to provide respiratory protection when the use of respirators is required under 29 CFR 1910.134.

Per the regulatory framework, OSHA would require SOPs for any other worker protection precautions that are necessary to address specific infectious diseases or circumstances for direct patient care. As explained earlier, OSHA would generally require employers having a worker(s) covered by a rule as outlined in the regulatory framework to develop, implement, and update SOPs that are consistent with recognized and generally accepted good infection control practices relevant to their work setting. Such a rule would thus be performance-based. Nonetheless, OSHA chose to explicitly address some specific worker protection precautions in the regulatory framework because OSHA views these particular precautions as especially important for a good infection control program, and OSHA therefore wants to emphasize these precautions directly in the regulatory framework. However, OSHA would require employers to establish and implement SOPs not specifically addressed in the regulatory framework to ensure that their infection control programs are consistent with recognized and generally accepted good infection control practices relevant to their work settings. Employers would generally be able to determine whether their SOPs are consistent with such practices by considering both applicable regulations, such as federal, state and local regulations, and current guidelines, such as those issued by the CDC, CDC/HICPAC, and NIH, and, in the absence of such regulations and guidelines, guidance issued by professional organizations and accrediting bodies.

Additional SOPs for Other Covered Tasks: Per the regulatory framework, OSHA would require employers whose workers perform other covered tasks to develop, implement, and update SOPs, in addition to the SOPs for all affected work settings, that, at a minimum, contain procedures for:

- The handling and intake of contaminated materials;

[48]This list of procedures in the regulatory framework is non-exclusive (i.e., OSHA would require the employer to establish and implement procedures that would include, but would not be limited to, the procedures listed in the regulatory framework).

- The use of control measures necessary to prevent or minimize transmission of infectious agents;
- Implementing, in diagnostic, research, and production facilities, standard microbiological practices and any special practices for handling infectious agent(s) of a specific biosafety level, in addition to the other procedures outlined for other covered tasks; and
- Ensuring any other employee protection precautions necessary to address specific infectious diseases or circumstances.

Below, OSHA highlights some of the provisions in the regulatory framework addressing SOPs for employers whose workers perform other covered tasks.

Diagnostic laboratory facilities (e.g., clinical laboratories), research laboratory facilities, and production laboratory facilities are unique work environments that may pose special infectious disease risks to persons in or near them. In fact, CDC/NIH publishes guidelines specifically for biosafety in microbiological and biomedical laboratories (CDC/NIH, 2009). In addition, NIH's *Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (NIH, 2013) includes guidance on safe handling of recombinant and synthetic infectious agents. To ensure that workers in diagnostic, research, and production facilities are adequately protected, OSHA would require that employers of workers in these types of facilities include in their SOPs procedures for the implementation of standard microbiological practices and any special practices for handling infectious agent(s) of a specific biosafety level.

To this end, per the regulatory framework, OSHA would require the employer to establish and implement procedures to ensure the use of appropriate engineering controls (i.e. engineering controls that are necessary to ensure consistency with recognized and generally accepted good infection control practices). Appropriate engineering controls would include such controls as biosafety cabinets, laboratory hoods, and other laboratory design and containment measures. Per the regulatory framework, OSHA would also require the employer to establish and implement procedures to ensure that these engineering controls are appropriately constructed, operated, and maintained (e.g., proper air flow, exhaust air filtration, double access doors, special design requirements for Biosafety Level 3 and 4 facilities). Finally, OSHA would require the employer to establish and implement procedures necessary to address uncontrolled releases of infectious agents, including mitigation of such releases and prompt reporting of such incidents to appropriate authorities (e.g., federal, state, and local authorities).

Per the regulatory framework, OSHA would require SOPs for any other worker protection precautions that are necessary to address specific infectious diseases or circumstances for other covered tasks. OSHA discussed the rationale for this provision earlier in this section of the SER Background Document when discussing the analogous provision for SOPs related to direct patient care.

Medical Screening, Surveillance, and Vaccination

Early intervention, through testing, appropriate prophylaxis, and vaccination of occupationally exposed workers, can reduce the risk of infection among workers and patients. Moreover, since a single unprotected occupational exposure may result in an infection, post-exposure evaluation and follow-up after each exposure incident can mitigate the impact of the infection on the worker and can also help prevent additional infections of other workers and patients. Per the regulatory framework, OSHA would require employers to make medical screening, surveillance, and vaccinations available to each worker who falls within the scope of an infectious diseases rule, and to promptly provide a confidential post-exposure medical evaluation and appropriate follow-up to each worker who has had an exposure incident. In addition, OSHA would require the employer to make a confidential medical evaluation and appropriate follow-up available to each worker referred for such services following medical screening/surveillance. Similar requirements can be found in other OSHA standards, such as the Bloodborne Pathogens standard (§1910.1030), the Lead standard (§1910.1025), and the Chromium (VI) standard (§1910.1026).

Below, OSHA highlights some of the provisions in Section 5 of the regulatory framework.

Per the regulatory framework, OSHA would set forth specific requirements for vaccinations. Vaccination is generally considered an important component of an effective infection control program. The regulatory framework explains that an employer would be required to make available vaccinations and associated vaccination regimens (e.g., doses, intervals) that are consistent with recognized and generally accepted good infection control practices relevant to the occupational exposures encountered during the job tasks of the employee. The employer of a worker(s) in a research or production laboratory facility would be required to make available to that worker(s) any vaccinations specified in the employer's WICP, or determined by a PLHCP to be medically appropriate for a particular worker. For all other workers who fall under the scope of an infectious diseases rule, OSHA would require the employer, at a minimum, to make the following vaccinations available to each worker:

- Influenza (Seasonal and Pandemic);
- Measles, Mumps and Rubella (MMR);
- Tetanus, Diphtheria, and Pertussis (Tdap);
- Varicella; and
- Any other vaccination(s) that is specified in the employer's WICP, or determined by a PLHCP to be medically appropriate for a particular worker.

OSHA is interested in feedback from SERs on whether employees with occupational exposure at diagnostic laboratory facilities, like employees at research and production facilities, should be offered targeted vaccinations only, or whether they, like other employees that would be covered under a rule as outlined in the regulatory framework, should be offered the minimum set of

vaccinations listed above. OSHA believes that at least some employees in diagnostic laboratory facilities work with samples containing unidentified potentially infectious agents and, therefore, should be offered the minimum set (unlike workers in research and production laboratory settings, where the infectious agents to which workers have occupational exposure are known).

OSHA's aim in the regulatory framework is to promote and encourage worker cooperation in the vaccination program by ensuring that the employer offers appropriate vaccinations at no cost to employees and provides appropriate educational material on the benefits and risks of such vaccinations (the latter aim is described under Section 6, Training). Per the regulatory framework, OSHA would permit workers to decline required vaccinations, but, in such cases, the employer would be required to obtain and retain a signed declination statement and to make the vaccination available to any worker who decides to accept the vaccination after initially declining it. These provisions would encourage greater participation in the vaccination program by reiterating that a worker declining vaccination remains at a greater risk of acquiring infectious diseases than vaccinated workers, would benefit the employer by making it easier to determine vaccination status during the investigation of an exposure incident (e.g., because of the provision that would require signed declinations), and would allow resources to be directed toward improving the acceptance rate of the vaccination program.

Per the regulatory framework, OSHA would cover medical removal protection (MRP). The employer would be required to follow a PLHCP's recommendations concerning modifications or restrictions to a worker's job duties, or precautionary removal of a worker from the workplace (e.g., to protect patients or coworkers). When a worker has been removed from the job or is otherwise medically limited as a result of an exposure incident, the employer would be required to pay, to the worker, the worker's total normal earnings and to maintain the worker's seniority and all other worker rights and benefits, including the worker's job status. A rule that would require employers to provide MRP benefits would encourage employee participation in (and therefore increase the effectiveness of) the medical surveillance program that would be required by such a rule by ensuring that reporting symptoms or health conditions to the PLHCP would not result in loss of job or pay.

Per the regulatory framework, OSHA would permit several limitations on MRP benefits. Per the regulatory framework, OSHA would not require MRP benefits for those workers removed from their jobs or otherwise medically limited as a result of occupational exposure to the common cold or influenza, with one exception. In research and production laboratory facilities, if a worker is removed from the job or otherwise medically limited as a result of an exposure incident to any infectious agent with which the employee is working (including the common cold or influenza viruses), OSHA would require the employer to provide MRP benefits to the worker. Per the regulatory framework, OSHA would require the employer to provide medical removal benefits only until the worker is determined to be noninfectious or is otherwise able to return to normal duties, and, in any case, OSHA would limit the required provision of benefits to a period not exceeding 18 months. Any potential obligation to provide MRP benefits to a removed or

restricted worker would also be reduced to the extent that the worker receives compensation for earnings lost during the period of removal either from a publicly or employer-funded compensation program, or from employment with another employer made possible by virtue of the worker's removal. Finally, even if MRP benefits are not required in a particular case, under the regulatory framework, the employer would not be precluded from offering administrative or sick leave for medical removal of a worker.

Based on the regulatory framework, the employer would be required to ensure that employees' medical records are kept confidential and not disclosed or reported, without the employee's written consent, to any person within or outside the workplace, except as would be required by OSHA or as may be required by law. Regarding privacy issues under HIPAA regulations, OSHA's assessment is that as long as the information disclosed to employers by PLHCPs is limited to findings concerning a work-related illness or injury or workplace-related medical surveillance, and that the employee is given notice of such disclosure, that the regulatory framework's requirements for employers to receive, maintain, and possibly disclose employee health information are not in conflict with HIPAA.

Training

Section 6 of the regulatory framework covers worker training. Worker training is critical to the success of any infection control program. Unless workers have sufficient knowledge and understanding of the program, including how to recognize hazards and protect themselves, the intent and effectiveness of the program will be undermined. Per the regulatory framework, OSHA would require the employer to provide training as follows: initially, prior to the time of assignment to tasks where occupational exposure may take place; annually thereafter, not to exceed 12 months from the previous training; and supplemental training to address specific deficiencies. Both initial and periodic worker training are recognized as important components of an effective infection control program. Initial training provides information that workers need to protect themselves against occupational exposures to hazards, while periodic training refreshes worker knowledge, reinforces the importance of the infection control program, and provides a means of introducing new information and procedures (which is especially important in the infectious disease realm, given the likelihood of changes in technology, the possibility for the appearance of new or emerging infectious agents, and other changes that occur markedly over time).

To ensure that the employer's training program is adequate and meaningful, OSHA would require that the program: be overseen or conducted by a person knowledgeable in the program's subject matter as it relates to the workers' workplace; consist of material appropriate in content and vocabulary to the educational level, literacy, and language of workers; and provide an opportunity for interactive questions and answers with a person knowledgeable in the program's subject matter as it relates to the workplace.

The provisions for worker training in the regulatory framework are performance-oriented, listing categories of information that would be provided to workers, including, among other elements: a general explanation of the epidemiology and symptoms of common infectious diseases, including the signs and symptoms of infectious diseases that require further medical evaluation; an explanation of the modes of transmission of infectious agents and applicable infection control practices (e.g., standard and transmission-based precautions) so that the worker can recognize tasks and other activities that may involve occupational exposure and take precautionary measures; information on vaccines that will be made available to the worker, including their efficacy, contraindications, likelihood and severity of possible adverse health effects, method of administration, the benefits of being vaccinated, and that the vaccines and vaccinations will be offered at reasonable times and places at no cost to the worker; an explanation of the employer's WICP and the means by which the worker can obtain a copy of the plan; training on all of the SOPs developed as part of the WICP that are applicable to the worker's duties; an explanation of the use and limitations of engineering, work practice, and administrative controls; and information on the types, proper use, limitations, location, handling, decontamination, removal, and disposal of PPE.

OSHA believes that the approach taken in the regulatory framework would ensure that important information is communicated to workers that will enable workers to understand the hazards associated with infectious agents, while, at the same time, allowing employers the most flexible approach to providing training.

Recordkeeping

Like OSHA's Bloodborne Pathogens standard (29 CFR 1910.1030), per the regulatory framework, OSHA would require a recordkeeping element in an infectious diseases rule. Per Section 7 of the regulatory framework, OSHA would require the employer to maintain medical records and exposure incident records for at least the duration of employment, plus 30 years. Maintenance of records for 30 years is currently a provision in the BBP standard. Like some of the diseases covered by the BBP standard (i.e., HIV and Hepatitis B), infectious diseases that would be covered under the ID rule may also have chronic, long-term effects such as cancer, negative reproductive consequences, and organ damage (e.g., lung damage from TB).

In addition, the employer would be required to retain records of WICP reviews for three years. The maintenance of WICP review records is important for employers to assure that they have addressed prior concerns as part of the continuous improvement process. The maintenance of exposure incident records would allow the employer to document elements such as the work setting and work task(s) being performed when the exposure incident(s) occurred, which would, in turn, allow the employer to focus efforts on decreasing or eliminating specific circumstances or routes of occupational exposures. The maintenance of medical records is essential to permit proper evaluation of the worker's immune status and proper healthcare management following an exposure incident. And the maintenance of all three types of records is important to allow

compliance with the potential obligation in the regulatory framework to make such records available to workers and OSHA upon request.

Cost and Availability

Per the regulatory framework, OSHA would require that the implementation of all requirements be at no cost to the worker, that all time required by a worker to comply, including time for training, medical evaluations/procedures, and reasonable travel time (as appropriate), be considered compensable time, and that any required medical evaluations and procedures (including vaccinations and post-exposure evaluation and follow-up) and training be made available to the worker at reasonable times and places. OSHA believes that requiring employers to pay workers for the time associated with compliance with a rule as outlined in the regulatory framework, and giving workers reasonable opportunities to participate in medical evaluations and procedures and training, will help encourage worker participation in (and therefore increase the effectiveness of) a rule as outlined in the regulatory framework, and would help OSHA to ensure that employers are making good faith efforts to comply.

Section V. Description of the Entities, Establishments, and Employees Likely to be Affected by a Rule as Outlined in the Regulatory framework

Introduction

In this section of the SER Background Document, OSHA provides preliminary estimates of the number of affected entities, establishments, and employees for the industries that have settings that would be affected by a rule as outlined in the regulatory framework. The term "entity" describes a legal for-profit business, a non-profit organization, or a local governmental unit, whereas the term "establishment" describes a particular site of economic activity. Some entities own and operate more than one establishment.

As discussed in Section IV of this SER Background Document, OSHA would cover settings where direct patient care is provided and settings where other covered tasks are performed. The Agency has translated the settings where these tasks will be performed into the following four categories: (1) settings where direct patient care is provided; (2) settings where there are contaminated materials originating from settings where direct patient care is provided; (3) settings where there is exposure to human remains; and (4) diagnostic, research, and production laboratory facilities, where there is exposure to contaminated materials.

This analysis focused on worker tasks and the industries where those tasks that would expose workers to infectious agents would be performed.[49] This method accounts for the fact that an establishment may employ both workers who perform direct patient care and workers who perform other covered tasks (as those terms are used in the regulatory framework). For example, in hospital settings, doctors and nurses provide direct patient care, while custodial workers perform other covered tasks.

Finally, this analysis accounts only for entities that have employees. Entities that do not have employees (e.g., self-employed individuals) are not covered by OSHA.[50]

OSHA requests comments on the preliminary estimates in this section with respect to two issues. First, has OSHA stated clearly in the regulatory framework who would be covered by a rule as outlined in the regulatory framework, or would additional clarification of scope terms such as, "direct patient care", "other covered tasks", and "occupational exposure", be needed? Second, is the scope of worker tasks that would be covered appropriate? Should OSHA cover more types of worker tasks than are envisioned in the regulatory framework? Alternatively, should OSHA cover fewer worker tasks?

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[49] The setting "First Aid & Emergency Care" does not include settings where the only relevant task performed by employees is solely the provision of first aid by workers who are not medical caregivers. Pursuant to the regulatory framework, employees who are not medical personnel but who provide first aid only are not considered to provide direct patient care.

[50] This section of the SER Background Document lists OSHA's estimates, without describing in detail how OSHA derived those estimates. OSHA will provide SERs with a fuller description of its analysis upon request.

Criteria for Determining Whether For-Profit Businesses, Non-Profit Organizations, and Governmental Units are Small Entities

There are three types of small entities under the RFA: (1) small businesses; (2) small non-profit organizations; and (3) small governmental jurisdictions. The Small Business Administration (SBA) uses the North American Industry Classification System (NAICS) as a basis for determining whether businesses are small for given industries. SBA size criteria vary by industry, but are usually based on either number of employees or revenue.[51] A small non-profit organization is any not-for-profit enterprise that is independently owned and operated and not dominant in its field. Finally, a small governmental jurisdiction is a government of a city, county, town, township, village, school district, or special district with a population of less than 50,000.

Table V-1 displays size criteria, derived from SBA definitions, for for-profit entities that OSHA believes would be affected by a rule as outlined in the regulatory framework.

For the purposes of the analysis in Table V-1, OSHA grouped entities into aggregate categories made up of entities that are performing similar types of healthcare services or other covered tasks. These aggregated settings include entities from various NAICS industries. Since each six-digit NAICS industry has its own threshold for being considered a small entity by SBA, the SBA size criteria often appear as ranges in Table V-1. The SBA criteria and corresponding OSHA-estimated employee size thresholds by six-digit NAICS industry are presented in Appendix A at the end of this document. (OSHA converted the SBA revenue criteria for for-profit entities to an equivalent employee size threshold, as shown in Table V-1.)[52]

The SBA criteria and corresponding OSHA-derived employee size thresholds are more fully documented in Appendix A at the end of this document.

[51] *See* 13 CFR § 121.201. These other measures are sometimes product output measures.

[52] For those industries with a revenue criterion, OSHA calculated the average revenue for each employment size class in the Census data and identified the largest size class where average revenue is less than the SBA definition. Only one SBA criterion listed in Appendix A is based on neither revenue nor number of employees. That SBA criterion is based on megawatt hours, and is associated with the Electric Power Generation, Transmission, and Distribution Industry only.

Table V-1. SBA Size Definitions for For-Profit Entities by Setting				
Setting	**SBA size criteria based on revenue (range, if applicable) ($millions)**	**SBA size criteria based on other criteria**	**SBA size criteria based on number of employees (range, if applicable)**	**SBA Criteria converted to employees (range, if applicable)**
Offices of Physicians	$10			100
Offices of Dentists	$7			100
Other Patient Care	$2 - 35.5			10 - 500
First Aid & Emergency Care	$7 - 30			100 - 500
Hospitals	$7 - 34.5			100 - 500
Nursing Homes	$7 - 13.5			500
Home Healthcare	$7 - 13.5			100 - 500
Laboratories	$12 - 13.5		500	100 - 500
Embedded Clinics in Schools	$7			100 - 500
Embedded Clinics in Correctional Facilities	$35.5			500
Morgue/Mortuaries	$7			100
Embedded Clinics in Industry	$7 - 25.5	4 million megawatt hours	100 - 1,500	100 - 1,500
Medical Equipment Activities	$7			20 - 100
Waste Collection & Handling & Commercial Laundries	$12.5 - 35.5			100 - 500

Note: There are some ranges in the SBA criteria above because some settings contain multiple NAICS industries with non-identical size or revenue thresholds.

Source: OSHA, Directorate of Standards and Guidance, Office of Regulatory Analysis, based on SBA, 2010 and Census Bureau, 2007.

Affected Entities and Establishments

Table V-2 presents OSHA's preliminary estimate of the number of affected entities, establishments, small entities, and very small entities (i.e., entities with fewer than 20 employees) for each type of setting presented above. This preliminary estimate shows that, out of an estimated 637,000 entities that would be affected by a rule as outlined in the regulatory framework, approximately 625,000 are SBA-defined small entities and approximately 555,000 are very small entities. Moreover, approximately 217,000 of the affected SBA-defined small entities are non-profit.

Table V-2. Total Affected Entities and Establishments by Size and Setting				
Setting	All Entities	All Establishments	SBA Defined Small Entities	Entities With Fewer Than 20 Employees
Offices of Physicians				
Private For-Profit and Government-Owned	182,128	209,792	179,417	164,521
Non-Profit	8,954	10,314	8,954	8,088
Offices of Dentists				
Private For-Profit and Government-Owned	119,758	127,530	119,570	116,053
Non-Profit	426	454	426	413
Other Patient Care				
Private For-Profit and Government-Owned	45,656	54,067	44,183	40,487
Non-Profit	7,090	10,187	7,090	6,288
First Aid & Emergency Care				
Private For-Profit and Government-Owned	2,653	3,579	2,375	1,736
Non-Profit	1,016	1,474	1,016	665
Hospitals				
Private For-Profit and Government-Owned	2,240	3,919	338	276
Non-Profit	1,773	2,992	1,773	218
Long Term Care and Nursing Homes				
Private For-Profit and Government-Owned	22,010	41,410	20,026	11,012
Non-Profit	12,368	31,771	12,368	6,188
Home Healthcare				
Private For-Profit and Government-Owned	16,155	24,000	14,062	14,175
Non-Profit	179,486	181,214	179,486	157,491
Laboratories				
Private For-Profit and Government-Owned	4,351	6,421	4,020	3,396
Non-Profit	288	398	288	225
Embedded Clinics in Schools				
Private For-Profit and Government-Owned	3,014	10,200	2,217	1,420
Non-Profit	4,574	5,229	4,574	2,155
Embedded Clinics in Correctional Facilities				
Private For-Profit and Government-Owned	599	962	386	223
Non-Profit	0	0	0	0
Morgue/Mortuaries				
Private For-Profit and Government-Owned	9,628	12,420	9,416	8,934
Non-Profit	1,338	1,744	1,338	1,241
Embedded Clinics in Industry				
Private For-Profit and Government-Owned	2,320	2,960	2,198	1,845
Non-Profit	3	5	3	3
Medical Equipment Activities				
Private For-Profit and Government-Owned	3,459	7,635	3,311	3,041
Non-Profit	5	11	5	4
Waste Collection & Handling & Commercial Laundries				
Private For-Profit and Government-Owned	6,140	7,736	5,918	5,163
Non-Profit	33	40	33	28
Total				
Private For-Profit and Government-Owned	**420,111**	**512,631**	**407,439**	**372,280**
Non-Profit	**217,354**	**245,833**	**217,354**	**183,006**
Total - All	**637,465**	**758,464**	**624,793**	**555,286**

Note: OSHA assumes that all non-profits are small entities by SBA criteria.
Totals may not equal the sum of the components due to rounding

Source: OSHA, Directorate of Standards and Guidance, Office of Regulatory Analysis, based on Census Bureau, 2007, Census Bureau, 2009, and BLS, 2010.

Affected Employees

Tables V-3a, V-3b, and V-3c present, by size and setting, OSHA's preliminary estimates of the number of employees that would be affected by a rule as outlined in the regulatory framework, including employees that provide direct patient care and employees that perform other covered tasks, and the total number of employees in both groups (i.e., the total number of employees that would be affected by a rule as outlined in the regulatory framework). As shown in Table V-3c, OSHA preliminarily estimates that approximately 9 million employees would be affected by a rule as outlined in the regulatory framework, and that of these, about 5.8 million are employed by SBA-defined small entities. These preliminary estimates show that approximately 2.2 million workers in SBA-defined for-profit small entities and small government entities provide direct patient care, while an additional 203,000 workers in those entities are engaged in other covered tasks (as those terms are used in the regulatory framework). The Agency preliminarily estimates that approximately 3 million workers provide direct patient care, and 300,000 workers perform other covered tasks, at SBA-defined small, non-profit entities. OSHA preliminarily estimates that 1.5 million workers are employed by entities with fewer than 20 employees, where approximately 1.3 million workers provide direct patient care, while about 140,000 perform other covered tasks.

Table V-3a. Number of Affected Employees Providing Direct Patient Care by Size Classification and			
	Number of Employees at:		
Setting	All Entities	SBA Defined Small Entities	Entities with Fewer than 20 Employees
Offices of Physicians			
Private For-Profit and Government-Owned	1,049,598	655,817	460,179
Non-Profit	175,473	175,473	76,933
Offices of Dentists			
Private For-Profit and Government-Owned	543,261	506,956	476,988
Non-Profit	3,401	3,401	2,986
Other Patient Care			
Private For-Profit and Government-Owned	393,261	167,746	71,485
Non-Profit	133,689	133,689	24,301
First Aid & Emergency Care			
Private For-Profit and Government-Owned	88,881	34,338	14,740
Non-Profit	29,317	29,317	4,862
Hospitals			
Private For-Profit and Government-Owned	1,135,344	60,518	266
Non-Profit	1,995,594	1,995,594	468
Long Term Care and Nursing Homes			
Private For-Profit and Government-Owned	1,112,497	543,940	92,543
Non-Profit	594,079	594,079	49,419
Home Healthcare			
Private For-Profit and Government-Owned	504,525	233,617	37,976
Non-Profit	130,573	130,573	9,828
Embedded Clinics in Schools			
Private For-Profit and Government-Owned	39,908	4,245	3,367
Non-Profit	13,000	13,000	1,097
Embedded Clinics in Correctional Facilities			
Private For-Profit and Government-Owned	10,440	282	85
Non-Profit	0	0	0
Embedded Clinics in Industry			
Private For-Profit and Government-Owned	4,101	2,007	453
Non-Profit	25	25	3
Medical Equipment Activities			
Private For-Profit and Government-Owned	3,890	1,425	2,937
Non-Profit	0	0	0
Waste Collection & Handling & Commercial Laundries			
Private For-Profit and Government-Owned	1,135	487	348
Non-Profit	7	7	2
Total Direct Patient Care			
Private For-Profit and Government-Owned	**4,886,841**	**2,211,378**	**1,161,368**
Non-Profit	**3,075,159**	**3,075,159**	**169,900**
Total Direct Patient Care - All	**7,962,000**	**5,286,537**	**1,331,268**

Note: Totals may not equal the sum of the components due to rounding.
Source: see Table V-3c.

Table V-3b. Number of Affected Employees Performing Other Covered Tasks by Size and Setting			
	Number of Employees at:		
Setting	All Entities	SBA Defined Small Entities	Entities with Fewer than 20 Employees
Offices of Physicians			
Private For-Profit and Government-Owned	11,312	6,358	4,959
Non-Profit	1,891	1,891	829
Offices of Dentists			
Private For-Profit and Government-Owned	5,147	4,800	4,519
Non-Profit	32	32	28
Other Patient Care			
Private For-Profit and Government-Owned	59,862	19,756	3,247
Non-Profit	698	698	38
First Aid & Emergency Care			
Private For-Profit and Government-Owned	233	38	38
Non-Profit	80	80	13
Hospitals			
Private For-Profit and Government-Owned	151,699	18,341	36
Non-Profit	208,618	208,618	49
Long Term Care and Nursing Homes			
Private For-Profit and Government-Owned	128,767	33,314	6,396
Non-Profit	56,804	56,804	2,822
Home Healthcare			
Private For-Profit and Government-Owned	1,910	528	263
Non-Profit	974	974	134
Laboratories			
Private For-Profit and Government-Owned	196,383	43,253	36,668
Non-Profit	25,270	25,270	4,718
Embedded Clinics in Schools			
Private For-Profit and Government-Owned	48	204	4
Non-Profit	352	352	32
Embedded Clinics in Correctional Facilities			
Private For-Profit and Government-Owned	4,368	800	264
Non-Profit	0	0	0
Morgue/Mortuaries			
Private For-Profit and Government-Owned	63,319	47,468	46,387
Non-Profit	6,987	6,987	5,119
Embedded Clinics in Industry			
Private For-Profit and Government-Owned	7,556	2,314	1,511
Non-Profit	4	4	1
Medical Equipment Activities			
Private For-Profit and Government-Owned	21,298	7,682	15,126
Non-Profit	2	2	1
Waste Collection & Handling & Commercial Laundries			
Private For-Profit and Government-Owned	48,439	18,466	11,738
Non-Profit	168	168	41
Total Other Covered Tasks			
Private For-Profit and Government-Owned	**700,340**	**203,323**	**131,156**
Non-Profit	**301,880**	**301,880**	**13,825**
Total Other Covered Tasks - All	**1,002,220**	**505,203**	**144,981**

Note: Totals may not equal the sum of the components due to rounding.
Source: see Table V-3c.

Table V-3c. Total Affected Employees by Size and Setting			
	Number of Employees at:		
Setting	All Entities	SBA Defined Small Entities	Entities with Fewer than 20 Employees
Total Affected Employees			
Private For-Profit and Government-Owned	**5,587,181**	**2,414,701**	**1,292,524**
Non-Profit	**3,377,040**	**3,377,040**	**183,725**
Total Affected Employees - All	**8,964,221**	**5,791,741**	**1,476,249**

Note: Totals may not equal the sum of the components due to rounding.

Source: OSHA, Directorate of Standards and Guidance, Office of Regulatory Analysis, based on Census Bureau, 2007, Census Bureau, 2009, and BLS, 2010.

Section VI. Description of Potential Impacts of a Rule as Outlined in the Regulatory framework

A. Introduction

In this section, OSHA presents preliminary estimates of potential impacts on employers who would be required to come into compliance with the provisions of a rule as outlined in the regulatory framework. Here and throughout this SBAR Panel process, the Agency will not be presenting aggregate costs but, instead, will be focusing on potential impacts presented in their simplest and most natural units of measure—sometimes as dollars and sometimes as time requirements. The potential impacts of concern here are those of a single item or action, such as a worker receiving a vaccination. In this example, there would be two relevant impacts: (1) the cost of a single dose of the vaccine, reported in dollars; and (2) the time necessary for a nurse to provide, and the worker to receive, the vaccine, reported in minutes or hours. Such impacts help generalize the discussion because many unit costs do not vary by setting or establishment size.

While the unit costs may be the same for various types and sizes of settings, the total costs will be highly dependent on the type of facility and on the number and types of infectious agents a given facility would typically encounter. Some of the costs would be incurred one time, up front for all facilities (e.g., developing a WICP or written respiratory protection program if the facility currently does not have one), but many of the costs (e.g., hand hygiene or PPE use) are based on the number of interactions workers have with infectious patients or materials. In addition, the flexibility inherent in a program standard allows employers whose facilities generally do not treat infectious patients to take simple steps to deal with such patients. For example, a small podiatrist's or dentist's office could simply require patients presenting with flu-like symptoms or symptoms of a respiratory illness to reschedule their appointments, rather than implement full droplet and/or airborne precautions for their workers. (The offices would, however, still be required to institute Standard Precautions for their workers). Some of these various compliance methods were addressed in Section IV of this document, and, throughout this section, OSHA will discuss how the total costs of a provision might vary based on the type or size of a facility.

For the purposes of the SBREFA process and panel, OSHA developed preliminary estimates of unit costs for almost all items in the regulatory framework that would result in costs to employers if those items were included in a rule. As mentioned above, these unit costs account for the cost or time for a single item to be purchased or for a single action to be taken. In developing these estimates, OSHA based unit costs on those actions and costs the Agency preliminarily determined an employer would need to undertake or bear to comply with the regulatory framework. OSHA assigned costs in either dollars, for items that would need to be purchased, or in time, where an action would need to be taken. OSHA preliminarily concludes that some provisions of the regulatory framework would not have associated costs because, for example,

the Agency believes that a provision is already standard practice or that complying with a provision would require only a modification of current practices without requiring additional time or resources. OSHA presents a summary table, Table VI-9, that shows all estimated unit costs at the end of this section.

In addition to preliminary estimates of unit costs, OSHA developed preliminary estimates of levels of current compliance with many of the provisions of a rule as outlined in the regulatory framework. These estimates are discussed in more detail throughout this section of the SER Background Document.

1. Preliminary Estimates of Unit Costs

An employer's total costs will depend on: the number of employees the employer has that would be affected under the scope of a rule as outlined in the regulatory framework; the number of times certain procedures would need to be completed or the number of nondurable items (such as gloves, soap, or vaccines) employees would need to use to comply with a rule as outlined in the regulatory framework; the hours that would be needed to ensure that contractors, vendors, and licensed independent practitioners with privileges, at a minimum, adhere to infection control practices consistent with the employer's WICP (assuming the employer is a host employer); and the extent to which the employer is already in compliance with provisions in the regulatory framework. OSHA is still in the process of developing estimates for these elements. Most importantly, the Agency has not yet made a preliminary determination as to the number of workers who would be subject to the requirements of any given potential provisions (i.e. how many workers will need to be vaccinated or how many workers will receive respirator fit-testing). Because the work to develop key estimates is still in progress, OSHA will not be presenting total costs as a part of this SER Background Document.

2. Preliminary Estimates of Current Compliance

The preliminary analysis in this section of the SER Background Document summarizes preliminary evidence of current baseline compliance in settings that would be subject to a rule as outlined in the regulatory framework. The source of this data is a Draft Report on the Expert Elicitation on Infectious Disease Control in Healthcare and Other Settings (hereafter "Draft Report on Current Compliance" or "Draft Report"), conducted by OSHA's contractor, Eastern Research Group, Inc. ("ERG"), in 2013. As with other non-copyrighted references in this SER Background Document, the Draft Report is available online under docket number OSHA-2010-0003.[53]

[53] The categorization of settings used in the Draft Report differs slightly from that presented in Section V, Description of the Entities, Establishments, and Employees Likely to be Affected by a Rule as Outlined in the regulatory framework, in this SER Background Document. Please see Table VI-10 at the end of this section of the SER Background Document for the categorization used in the Draft Report on Current Compliance. For more information, please see the full Draft Report.

ERG prepared the Draft Report by eliciting opinions from a panel of experts on infection control about the levels of current compliance with many of the provisions outlined in the regulatory framework. While the Draft Report has assisted OSHA in establishing preliminary estimates of current compliance, the Agency is still reviewing these estimates and is interested in any feedback the SERs may have on the levels of current compliance presented throughout this section of the SER Background Document. If OSHA engages in rulemaking, it will take any such feedback into consideration in preparing a preliminary estimate of baseline compliance and total costs to industry.

OSHA's preliminary estimates of current levels of compliance, presented in this section of the SER Background Document, are the average of the experts' responses, which were weighted based on the experts' self-reported confidence levels. The experts were asked to judge their levels of confidence in their answers to both the overall questions and the occupational settings at issue in the questions, and those levels of confidence were used to give proportionally more weight to answers given by more confident respondents (see Section 2.2.6 of the Draft Report). While the range of answers varied widely on many questions and for many settings (see Appendix A to the Draft Report), the weighted average and the median were relatively close. As stated above, OSHA has made no final determination on current levels of compliance and seeks additional feedback from the SERs on the preliminary estimates of levels of compliance presented in this section of the SER Background Document.

OSHA discusses specific estimates of baseline compliance in relevant parts of this section of the SER Background Document. See Table VI-10, at the end of this section of the SER Background Document, for more details regarding OSHA's preliminary estimates of compliance. And as stated earlier, ERG's full Draft Report is available in the docket.

3. Request for Feedback

OSHA encourages the SERs to comment on all elements of this preliminary cost analysis, including the preliminary estimates presented here and any estimates not presented because the Agency is still in the process of developing them. OSHA solicits comments about the following issues:

- Are the unit costs that are presented in this section of the SER Background Document reasonable?

- Are there types of costs, actions, or items that the Agency is either over- or under-estimating, or that the Agency has failed to consider at all?

- Are the Agency's preliminary estimates of the actions that an employer would be required to undertake to comply with individual provisions in the regulatory framework consistent with the understanding of the SERs?

- Are the Agency's preliminary estimates of current compliance consistent with what the SER's have observed in their own industries?

- Are the Agency's preliminary determinations with respect to the provisions of the regulatory framework for which most employers would not incur additional costs, over and above current practice, consistent with the understanding of the SERs? If not, what additional costs, over and above current practice, would employers need to bear to comply with the relevant provisions of a rule as outlined in the regulatory framework?

- Are there any potential provisions for which OSHA has presented cost estimates that the SERs believe would not require employers to undertake additional actions or incur additional costs, over and above current practice?

OSHA will solicit further comment on specific cost issues throughout this section of the SER Background Document, but also welcomes comments on issues not specifically addressed. OSHA considers the feedback and information provided by the SERs to be a very important part of the development of the preliminary economic analysis and the initial regulatory flexibility analysis and welcomes all comments.

B. Potential Impacts of Provisions in the Regulatory framework

1. Worker Infection Control Plan (WICP)

Per the regulatory framework, OSHA would require employers to develop written WICPs designed to prevent or minimize the transmission of infectious agents to each worker. The WICP could be part of a larger plan, such as one addressing patient safety or bloodborne pathogens, but, in such cases, the WICP would need to be a cohesive document, in and of itself, or there would need to be a guiding document that identifies the elements of the larger plan that comprise the WICP.

OSHA would require that the WICP include a write-up of the following elements:

- The name and title of, and contact information for, the plan administrator responsible for WICP implementation and oversight;
- The name of the person(s) responsible for the daily management of the WICP;
- An exposure determination; and
- The SOPs for the employer's work setting(s).

OSHA would require employers to review and update the WICP at least annually, and to share the WICP with contractors, vendors, licensed, independent practitioners with privileges, and the employer's workers.

As shown in Table VI-1, below, OSHA preliminarily estimates that the time required initially to complete a written WICP ranges from 20 hours for lower risk work settings to 40 hours for higher risk work settings. Lower risk work settings are work settings, such as embedded clinics in schools and industry and medical equipment handling and reprocessing facilities, that have fewer types of healthcare workers and where workers either have fewer encounters with potentially infectious patients or are potentially exposed to fewer types of infectious agents. Higher risk work settings are work settings, such as hospitals and other patient care settings, that have the most types of healthcare workers and where workers have more encounters with potentially infectious patients and are potentially exposed to the widest range of possible infectious agents.

The estimates presented here and below in Table VI-1 with respect to initial development of the WICP are based on the median estimates of the time necessary to prepare a WICP, as estimated by the expert panel on current compliance. These time estimates assume that employers would be formulating a WICP from start to finish and do not take into account the fact that some employers currently have WICPs that would be either partially or fully in compliance with a rule as outlined in the regulatory framework. One participant in the panel initially suggested that it would take a hospital 2,880 hours to develop a WICP, but reduced this response to 480 hours in a second round of questioning (see Section 4.1 of the Draft Report). The remaining experts reported that facilities could augment or tweak available templates to fit their particular settings (*Id.*). Given the availability of infection control plans for purchase, OSHA believes the preliminary estimates in Table VI-1 are reasonable, but the Agency is still developing the estimates and would be interested in feedback from the SERs on the issue.

As shown in Table VI-1, OSHA preliminarily estimates that the time necessary to review and update a WICP annually, and to share the WICP with all affected parties, would range from four hours for lower risk work settings to sixteen hours for the highest risk industry—hospitals. As with the preliminary estimates of WICP development time, these estimates are based on the responses of the expert panel.

Table VI-1		
Worker Infection Control Plan		
Estimated Compliance Burden per Establishment in Hours		
Setting	Initial Development	Annual review and update
Offices of Physicians	24	6
Offices of Dentists	20	4
Other Patient Care	40	8
First Aid & Emergency Care	20	4
Hospitals	40	16
Long Term Care and Nursing Homes	40	8
Home Healthcare	40	8
Laboratories	40	8
Embedded Clinics in Schools	20	4
Embedded Clinics in Correctional Facilities	20	4
Morgue/Mortuaries	20	4
Embedded Clinics in Industry	20	4
Medical Equipment Activities	20	4
Waste Collection & Handling & Commercial Laundries	20	4

Source: Office of Regulatory Analysis, OSHA, based on ERG, 2013.

Costs related to developing and updating a WICP would be incurred by all facilities not currently in compliance with this potential provision. As shown in Table VI-1, different types of settings would have different costs, a variability that is based on the number of patients, the volume of infectious materials handled, and the number of types of infectious diseases that might be encountered, in different types of settings. Some facilities may have even lower costs to develop their plans than the costs shown in Table VI-1 if their workers do not have reasonably anticipated exposure to certain types of infectious diseases. For example, an employer would only incur costs to develop a plan related to contact-transmissible diseases if the employer reasonably anticipates that workers would be exposed to contact-transmissible diseases.

Based on the estimates of the experts questioned by OSHA's contractor, the Agency preliminarily estimates that about 94 percent of hospitals, 90 percent of long term care facilities and nursing homes, and 90 percent of laboratories have a written WICP (see Table VI-10 and Draft Report). On the other hand, just 39 percent of establishments in "other occupational settings," which includes morgues and mortuaries, waste collection and handling services, and laundry services, are preliminarily estimated to have a written WICP (*Id.*). Finally, between about 40 and 60 percent of establishments in the other settings examined are preliminarily estimated to have a written WICP (*Id.*).

Also, based on the estimates of the experts questioned by OSHA's contractor, the Agency preliminarily estimates that most hospitals (77 percent) and laboratories (70 percent), as well as a majority of nursing home and long-term care facilities (63 percent), review their WICPs on an annual basis (*Id.*). A smaller percentage of physicians' offices (16 percent), dentists' offices (18 percent), and "other occupational settings" (12 percent) are preliminarily estimated to review their WICPs annually. OSHA welcomes feedback from the SERs on these preliminary estimates of current levels of compliance (*Id.*).

2. Implementation of Standard Operating Procedures ("SOPs")

OSHA is presenting the potential impacts for implementation of the elements of the SOPs laid out in the regulatory framework. Under a rule as outlined in the regulatory framework, individual employers would not incur costs associated with all of these elements since the SOPs each employer develops would be dependent on the types of risk seen in that employer's work setting(s). For example, a dentist's office would not incur costs to maintain an airborne infection isolation room (AIIR) since this type of establishment would not have one. Where OSHA has estimated that only certain settings are affected by a given provision in the regulatory framework, the unit costs are presented for those settings only. In addition, OSHA has preliminarily found that the implementation of some of these procedures will involve changes in work practices without additional time or equipment costs, other than those costs associated with incorporating these new work practices into a WICP, which is addressed above, and training on these new work practices, which is addressed below.

a. SOPs For All Affected Work Settings

Per the regulatory framework, all employers would be required to develop and implement certain SOPs, including SOPs on:

Infectious Agent Hazard Evaluations and Communication of Hazard Evaluation Results

Per the regulatory framework, OSHA would require employers to implement SOPs for the conduct of infectious agent hazard evaluations to identify suspected or confirmed sources of infectious agents. Based on OSHA's current thinking, the hazard evaluation would not need to be a written document and could be incorporated into routine activities, such as triage and patient scheduling. OSHA would require the employer to communicate the results of the hazard evaluation and the status of any suspected or confirmed sources of infectious agents to the person(s) responsible for implementing appropriate worker protection precautions.

OSHA preliminarily concludes that performing an infectious agent hazard evaluation, and communicating the results of that evaluation, as those potential provisions are laid out in the regulatory framework, would not take additional time over existing practice, and could be accomplished by modifying current job duties. Additional training (discussed later in this section of the SER Background Document) would provide workers with the background

knowledge and procedures necessary to perform evaluations and communicate results in the course of their normal job duties.

Moreover, per the Draft Report of Current Compliance, and as shown in Table VI-10, OSHA preliminarily estimates that 81 percent of hospitals, and 79 percent of long-term care facilities and nursing homes, already conduct infectious agent hazard evaluations. OSHA also preliminarily estimates that only 20 percent of establishments in "other occupational settings," which includes morgues and mortuaries and waste handling and laundry services, only 28 percent of dentists' offices and between about 40 and 60 percent of establishments in the remaining settings already conduct these activities. As mentioned previously, OSHA considers these estimates to be preliminary and is interested in incorporating feedback from the SERs on current levels of compliance in preparing final estimates for the preliminary economic analysis.

OSHA is interested in any information the SERs have on this issue. OSHA also asks the following:

- How are hazard evaluations currently performed and how are those results communicated to the relevant parties?
- Would conducting a hazard evaluation, as described both above and in Section IV of this document, require additional time above that preliminarily estimated by OSHA?
- To what extent are facilities currently complying with this potential requirement?

Hand Hygiene

Per the regulatory framework, OSHA would require employers to have SOPs to ensure that handwashing facilities are available and accessible, and that recognized and generally accepted good infection control practices for hand hygiene are followed. CDC recommendations on hand hygiene vary depending on the specific circumstances. In general, CDC recommends handwashing with soap and water, or if handwashing facilities are not available, using alcohol-based hand sanitizers containing at least 60 percent alcohol (CDC, 2013c). In situations where healthcare workers (HCWs) are routinely providing care to numerous patients, CDC recommends, in the absence of visible soiling of hands, using approved alcohol-based hand sanitizers rather than soap and water (CDC, 2002a). Using such hand sanitizers improves hand hygiene compliance due to their convenience and lower levels of associated dermatitis. In laboratories, however, CDC/NIH recommends handwashing with soap and water (CDC/NIH, 2009).

OSHA preliminarily estimates, based on WHO recommendations (WHO 2011a, WHO 2011b), that proper hand hygiene using soap and water washing takes 50 seconds of a worker's time, and that hand hygiene using an alcohol-based hand sanitizer in an effective manner takes 25 seconds of a worker's time. These times are estimated to be consistent across all settings within the scope of the regulatory framework.

While the time necessary to perform hand hygiene is consistent across facilities, the total costs of implementing SOPs for hand hygiene would vary based on the number of employees, the number of patients with which those employees interact on a daily basis (or, for workers handling infectious materials, the number of times gloves are removed during a work shift), and the type of hand hygiene (soap and water or alcohol-based) employed. Hand hygiene should be performed at a minimum before and after each patient encounter and, under some circumstances, at additional times during a patient encounter (for example, after contact with blood, body fluids, or contaminated surfaces (even if gloves are worn) or before invasive procedures) or, for workers who are handling hazardous or potentially hazardous materials like medical waste or linens, hand hygiene should be performed at a minimum after gloves are removed and anytime ungloved hands come into contact with known or suspected contaminated materials. Second, since alcohol-based hand rubs take less time for employees to use and the dispensers can be easily mounted in most settings, employers may, in certain situations, be able to achieve compliance with this potential provision in a less costly manner.

In small facilities that have only a few employees who interact directly with patients, the number of times hand hygiene is performed, and therefore the cost of implementing SOPs for hand hygiene, would be considerably lower than the corresponding numbers for large providers with many employees and patients. Likewise, in settings where other covered tasks are performed, like laundry facilities, waste handling facilities, or laboratories, the costs for hand hygiene would depend on the number of employees. As a result, a smaller facility would have lower total costs. The cost to individual facilities will also depend on the extent to which workers are currently performing hand hygiene. If the workers in a given facility are always, or almost always, performing appropriate hand hygiene, the additional costs to comply with a rule based on OSHA's regulatory framework would be low compared to the higher costs in a comparably-sized facility where workers do not currently perform appropriate hand hygiene.

Per the Draft Report on Current Compliance, and as shown in Table VI-10, OSHA preliminarily estimates that workers in laboratories have the highest baseline compliance rate (practicing proper hand hygiene 80 percent of the time), that workers in "other occupational settings," including morgues and mortuaries and waste handling and laundry services, have the lowest baseline compliance rate (practicing proper hand hygiene 34 percent of the time), and that workers in the remaining settings practice proper hand hygiene about 50 to 60 percent of the time. The Agency welcomes feedback from the SERs on these preliminary estimates of current compliance.

Food and Cosmetics

Per the regulatory framework, OSHA would require implementation of procedures for restricting, to areas where there is no occupational exposure during provision of direct patient care and/or performance of other covered tasks, activities such as eating, drinking, smoking, applying cosmetics or lip balm, handling contact lenses, and storing food and drink.

OSHA preliminarily concludes that such restrictions are standard practice in all healthcare facilities and in facilities that handle potentially contaminated waste and, therefore, that employers would not incur costs to comply with this provision in a rule as outlined in the regulatory framework.

The Agency is interested in any feedback on this issue the SERs may have to offer. Do the SERs agree with OSHA's determination that there are no costs associated with this potential provision? What additional actions, if any, would employers need to take, or what costs might they incur, to comply with this potential provision?

Engineering Controls

Per the regulatory framework, OSHA would require employers to implement procedures to examine existing engineering controls on a regular schedule and to ensure that those controls are maintained or replaced to ensure their effectiveness and thereby provide their intended protections. OSHA would also require that employers that have healthcare settings with airborne infection isolation rooms (AIIRs) implement procedures for ensuring proper AIIR operation. These would include procedures for ensuring that each AIIR, associated ducting, and filtration are constructed, operated, and maintained so that they maintain negative pressure, achieve sufficient air changes per hour, properly exhaust contaminated air, and function to prevent or minimize transmission of infectious agents, and for ensuring that, when in use, each AIIR is monitored daily for maintenance of negative pressure. Finally, in diagnostic, research, and production laboratory facilities, OSHA would require procedures to ensure the appropriate construction, operation, and maintenance (e.g., proper air flow, exhaust air filtration, double access doors, special design requirements for Biosafety Level 3 and 4 facilities) of engineering controls (such as biosafety cabinets (BSCs), laboratory hoods, and other laboratory design and containment measures).

OSHA has preliminarily estimated that certain types of engineering controls currently used to control the spread of infectious agents (e.g., AIIRs, autopsy suites, and BSCs) may need to be upgraded or improved by some establishments to comply with a rule as outlined in the regulatory framework. The Agency does not anticipate that such a rule would result in the installation of new or additional engineering controls. And OSHA expects that many of the sectors affected by a rule as outlined in the regulatory framework would not incur costs related to upgrading or improving engineering controls because many facilities do not have these types of controls and would not need them to comply with a rule as outlined in the regulatory framework.

For the purposes of this preliminary analysis, OSHA is estimating the cost of upgrading and maintaining AIIRs, autopsy suites, and BSCs. These estimates include one-time costs to upgrade

or perform major maintenance in order to bring existing AIIRs, autopsy suites, and BSCs into compliance with accepted engineering or other recognized and accepted standards and yearly costs thereafter for facilities to continue to maintain those controls in working order. Under a rule as outlined in the regulatory framework, these potential upgrading and maintenance costs would only be incurred by facilities that (1) have these types of engineering controls and (2) are not currently maintaining those controls to the proper standards.

Based on analyses performed in conjunction with OSHA's proposed rule addressing occupational exposure to tuberculosis (TB), 64 FR 54160 (Oct. 17, 1997), the Agency preliminarily estimates that, for those facilities that would need to do so, there would be a one-time cost of $7,217 to upgrade an AIIR so that it functions properly (e.g., maintains negative air pressure relative to the surrounding areas, completes the recommended number of hourly air exchanges). This is based on an estimated cost of approximately $48 per square foot to purchase and install material, including ducting, fans, and HEPA filters, in an average isolation room measuring 150 square feet (WCG, 1994, updated to 2012 dollars). OSHA also preliminarily estimates that it will cost $866 annually for facilities that are not properly maintaining their existing AIIRs to do so (an estimated 12 percent of the cost of upgrading an AIIR). This maintenance cost would be incurred annually and represents the cost to facilities to properly maintain their AIIRs during a given year. The provisions of a rule as outlined in the regulatory framework would not require facilities that do not have AIIRs to install them, and OSHA expects that costs associated with upgrading and maintaining AIIRs would only apply to hospitals, and that some percentage of facilities would not incur costs relating to upgrading or maintaining AIIRs because they either do not have AIIRs or are already properly maintaining them.

OSHA also preliminarily concludes that some funeral homes, morgues and mortuaries, and hospitals would need to upgrade their autopsy suites to comply with a rule based on the regulatory framework. The Agency preliminarily estimates that these upgrades will cost $14,435 per facility, which includes the installation of HEPA filtration, if necessary, and upgrading ventilation systems to achieve adequate negative pressure (WCG, 1994, updated to 2012 dollars) and represents a one-time cost for facilities that would need to bring their existing autopsy suites into compliance with existing engineering standards or other applicable guidelines or specifications. In addition to those upgrades, OSHA estimates that facilities not currently maintaining their autopsy suites would incur annual maintenance costs of $1,732 annually (estimated at 12 percent of the cost of upgrading an autopsy suite). OSHA preliminarily concludes that only hospitals, morgues, and mortuaries have autopsy suites and some of these establishments would incur such costs. The remaining establishments are preliminarily believed to be maintaining their autopsy suites to industry standards.

Finally, OSHA preliminarily concludes that some diagnostic, research, and production laboratory facilities – including clinical laboratories which can be located within a hospital – would need to

upgrade and properly maintain their existing BSCs. The Agency preliminarily estimates that it would cost $809 initially for a BSC to be upgraded properly and $97 for a BSC to be maintained properly (OSHA, 1997, updated to 2012 dollars). The initial cost represents a one-time cost for facilities that would need to upgrade or perform major maintenance on their existing equipment in order to bring it into compliance with existing applicable guidelines or standards. The annual cost would be incurred each year by facilities in order to continue to properly maintain their upgraded equipment. Establishments whose BSCs are currently being maintained properly would not incur any additional maintenance costs associated with a rule as outlined in the regulatory framework. OSHA preliminarily concludes that only hospitals and diagnostic, research, and production laboratory facilities will have BSCs.

OSHA summarizes the unit costs associated with engineering controls in Table VI-2, below.

Table VI-2

Engineering Controls

Setting	One-time Airborne Infection Isolation Room Upgrades	Annual Airborne Infection Isolation Room Maintenance	One-time Autopsy Suite Upgrades	Annual Autopsy Suite Maintenance	One-time Biological Safety Cabinet Upgrades	Annual Biological Safety Cabinet Maintenance
Hospitals	$7,217	$866	$14,435	$1,732	$809	$97
Laboratories	--	--	--	--	$809	$97
Morgue/Mortuaries	--	--	$14,435	$1,732	--	--

Source: Washington Consulting Group, 1994; OSHA, 1997; updated to 2012 dollars.

Because of the flexibility of the regulatory framework, a facility with an AIIR that does not want to upgrade and maintain that room would not need to do so as long as the facility does not use the room for isolation purposes. (However, per the regulatory framework, this facility would need to develop SOPs for the temporary isolation and inter-facility transfer of individuals with suspected or confirmed airborne infectious diseases to facilities with functional AIIRs.) Likewise, a laboratory that does not wish to upgrade and maintain its BSCs would not need to do so as long as the facility does not use the BSC for infectious agent containment purposes. Instead, the facility could use the certified BSCs at a different laboratory for certain steps in a procedure they are performing, use alternative containment (such as a fume hood) where appropriate, or redesign experiments to use materials and/or procedures that do not call for containment in a BSC.

Based on the Draft Report on Current Compliance, and as shown in Table VI-10, OSHA preliminarily estimates that most hospitals (83 percent) that have AIIRs properly maintain them. OSHA also preliminarily estimates that 91 percent of hospitals and 94 percent of laboratory facilities that have BSCs properly maintain them. Finally, OSHA preliminarily estimates that 83

percent of hospitals and 58 percent of morgues and mortuaries that have autopsy suites properly maintain them. OSHA considers these estimates to be preliminary and welcomes any feedback the SERs can offer on current compliance. This feedback would assist OSHA in developing estimates for the proposed rule, if OSHA engages rulemaking.

OSHA also asks the following:

Are facilities or sectors currently using any types of engineering controls that have not been discussed in this section of the SER Background Document to control the spread of infectious agents?

- Do SERs interpret the provisions as outlined in the regulatory framework as potentially requiring facilities to install new, rather than to upgrade and maintain existing, engineering controls? For example, do SERs believe that there are instances where a facility's WICP, when written to the specifications in the regulatory framework, would result in those facilities needing to install engineering controls (either those listed above or those not identified by OSHA) to comply with a rule as outlined in the regulatory framework?

Administrative and Work Practice Controls

Per the regulatory framework, OSHA would require that employers implement procedures for the use of administrative and work practice controls to minimize transmission of, and infection by, infectious agents. As discussed below, OSHA has preliminarily concluded that some administrative controls and most work practice controls necessary to minimize transmission of, and infection by, infectious agents can be achieved through modification of current practices and that compliance with a rule as outlined in the regulatory framework would result in no additional costs to employers. As always, the Agency welcomes feedback from the SERs on this determination. Are there controls – either administrative or work practice - that OSHA has not considered that would need to be implemented to comply with a rule based on the regulatory framework? If so, would these controls result in additional time or materials costs to the affected facilities?

Per the regulatory framework, administrative controls would include, but are not limited to: promoting and providing vaccinations; enforcing the exclusion of ill employees from the workplace; setting up triage stations and separate areas for patients with suspected or confirmed infectious diseases when they enter the facility; and assigning dedicated staff to patients with suspected or confirmed infectious diseases to minimize the number of employees exposed. While OSHA preliminarily concludes that, under a rule as outlined in the regulatory framework, there would be costs associated with promoting and providing vaccinations and enforcing the exclusion of ill employees from the workplace, OSHA discusses these costs later in this section of the SER Background Document. The Agency preliminarily concludes that setting up triage

stations and separate areas for patients with suspected or confirmed infectious diseases when they enter a healthcare facility, and implementing administrative controls related to staffing, may require modifications in the way tasks are performed, but should not take additional time or resources.

Per the regulatory framework, work practice controls would include, but are not limited to, performing tasks in a manner that minimizes generation of droplets or aerosols of infectious agents and practicing appropriate hand hygiene and respiratory hygiene/cough etiquette. See the discussion, earlier in this section of the SER Background Document, regarding OSHA's preliminarily estimates of the costs associated with hand hygiene. OSHA preliminarily concludes that other work practice controls can be implemented through modifications in current practices and that these modifications would not require additional time or materials over current practices.

Personal Protective Equipment

Per the regulatory framework, OSHA would require that employers implement procedures to provide, make readily accessible, and ensure that each employee uses appropriate PPE (such as, but not limited to, gloves, gowns, laboratory coats, face shields, facemasks, and respirators). Compliance with the PPE provisions described in the regulatory framework would involve the selection of the correct type of PPE for each specific type of situation, the implementation of procedures for the correct donning and removal of PPE, the provision of designated containers for disposable PPE or reusable PPE, and the implementation of procedures for the laundering of PPE (e.g., lab coats, scrubs). The potential costs for a provision on developing (as opposed to implementing) PPE guidelines (with the exception of developing and establishing a respiratory protection program) are covered by the earlier discussion of the costs associated with developing a WICP, and any training related to the proper selection or use of PPE is addressed as part of the training discussion later in this section of the SER Background Document. The potential costs associated with respiratory protection programs are addressed below, under the heading "Respiratory Protection."

The total cost to establishments to provide PPE would vary based on the type of infectious agents that may be encountered in the workplace, and the number of encounters workers will have with sources of infectious agents during a given period. In settings where employees do not routinely see patients with infectious diseases, facilities could have extremely low costs for this potential provision. Such employers could reduce costs even more by further reducing employee exposure. For instance, if dentists' offices or ophthalmologists' offices require that patients displaying flu-like symptoms or symptoms of a respiratory illness reschedule their appointments, the offices would not need to provide PPE as droplet and/or airborne precautions for their workers (although they would still need to provide PPE to institute the Standard Precautions that

would be required under a rule as outlined in the regulatory framework and to comply with OSHA's Bloodborne Pathogens standard (to the extent that standard is applicable)).

The cost of implementing SOPs for PPE provision and use will also vary by the size of a facility and by the number of patients that the facility sees. A small practice with few employees and low patient volume may have very low costs for PPE while a large hospital with hundreds of workers and patients on any given day may have much higher costs for PPE. Standard Precautions should be used in all healthcare settings. In ambulatory care settings, many patients who are more severely ill with symptoms for which transmission-based precautions are appropriate are routinely transferred to hospitals or other similar settings. The additional gloves required for transmission-based precautions, therefore, would not be needed as often in ambulatory care settings; as a result, the overall cost of gloves would be lower in these facilities.

While the per-facility cost of implementing the SOPs for employer's providing PPE and the use of PPE will vary by facility type and size, the per-unit cost of PPE should be comparable across establishments and work settings. OSHA preliminarily estimates that a pair of disposable gloves costs $0.16 (Staples.com, 2013) and would need to be donned by each worker prior to contact with each new patient and any time gloves become visibly soiled or before contact with potentially infectious materials. Facemasks (e.g., surgical masks), which are needed for protection against suspected or confirmed cases of droplet transmissible diseases, cost $0.13 per piece (GlobalCareMarket.com, 2013), and can be worn by an employee until visibly soiled (one surgical mask estimated to be used per work shift). N95 respirators, which are needed for protection against airborne transmissible diseases and during aerosol generating procedures, can be purchased for $0.33 each (Amazon.com, 2013), and, like facemasks, can be worn until visibly soiled, (one N95 respirator estimated to be used per work shift). Disposable gowns cost $2.42 each (Grainger, 2013a) and need to be used when workers are working inside isolation rooms or when there is risk of the worker's skin or clothing becoming contaminated (e.g., during aerosol generating procedures, during some laboratory procedures, or while handling infectious waste or laundry). Disposable face shields can be purchased for $4.55 (Grainger, 2013b) and are needed mainly when workers are potentially exposed to droplet spray and when workers are performing aerosol-generating activities in settings where direct patient care is provided and where other covered tasks (such as medical equipment reprocessing or in laboratories) are performed. Finally, protective eyewear can be purchased for $2.05 per pair (Uline.com, 2013) and is used primarily when workers are potentially exposed to splashes or sprays and when performing aerosol-generating activities. Table VI-3 below details the estimated per-unit costs of PPE.

Table VI-3		
Personal Protective Equipment		
Estimated Per Unit Cost		
Item	Cost	
Gloves (pair)	$0.16	[1]
Facemasks (e.g., surgical mask)	$0.13	[2]
N95 respirators	$0.33	[3]
Gowns	$2.42	[4]
Face Shield	$4.55	[5]
Protective eyewear (e.g., safety glasses, safety goggles)	$2.05	[6]

Source: [1] Staples.com, 2013; [2] GlobalcareMarket.com, 2013;
[3] Amazon.com, 2013; [4] Grainger, 2013a;
[5] Grainger, 2013b; [6] Uline.com, 2013.

Employers will only need to provide PPE appropriate to their facility. If a facility does not perform aerosol generating procedures or have patients in isolation rooms, that facility would not need to provide PPE needed for those circumstances.

According to the Draft Report on Current Compliance, and as shown in Table VI-10, employees in laboratories are estimated to be using PPE, where appropriate, 86 percent of the time, with employees in hospitals and dentists' offices also estimated to have a relatively high level of compliance at 76 percent each. Employees in "other occupational settings," including morgues and mortuaries and waste handling, and laundry services, are estimated to be using PPE, when appropriate, just 35 percent of the time, and workers in the remaining settings are estimated to be using appropriate PPE between 40 and 60 percent of the time.

In addition to welcoming feedback on both unit costs and current levels of compliance, OSHA is interested in the number of encounters a worker would have in a given time period that would require the use of PPE, the number of items of PPE used in a given time period (for example, how many pairs of gloves would a worker need during a work shift), and the number of ***additional*** encounters that would require the use of PPE under a rule based on the regulatory framework (for example, how many additional times would a worker need to use gloves, above and beyond what is currently used, as a result of a rule based on the regulatory framework). The Agency welcomes any information that would assist in estimating the additional PPE needs that would result from the promulgation of a rule as outlined in the regulatory framework that would be above the preliminary compliance rates shown above.

Respiratory Protection

This section presents potential costs for establishing a respiratory protection program (other than costs for providing respirators, which have been described above). Under a rule based on the regulatory framework, employers would generally have to develop, establish, and implement procedures that are consistent with OSHA's Respiratory Protection standard (29 CFR 1910.134). At present, OSHA has not made any determination about the extent to which compliant respiratory protection programs are currently in place at establishments potentially affected by a rule based on the regulatory framework, but the Agency presents its preliminary estimates, based on the Draft Report on Current Compliance, at the end of the present discussion on respirators.

According to OSHA's Respiratory Protection standard, employers whose workers are required to wear respirators during the course of their job duties must establish a written respiratory protection program (OSHA, 1998). A respiratory protection program must contain the following elements:

- Procedures for selecting respirators;
- Medical evaluations of employees required to use respirators;
- Fit testing procedures;
- Procedures for proper use of respirators in routine and reasonably foreseeable emergency situations;
- Procedures and schedules for cleaning, disinfecting, storing, inspecting, repairing, discarding, and otherwise maintaining respirators;
- Procedures to ensure adequate air quality, quantity, and flow of breathing air for atmosphere-supplying respirators;
- Training of employees in the respiratory hazards and proper use of respirators; and
- Procedures for regularly evaluating the effectiveness of the program.

In this section, OSHA is evaluating the potential costs for program establishment and implementation, medical evaluation, fit testing, and training. OSHA believes, at this time, that facilities subject to a rule as outlined in the regulatory framework would use disposable N95 respirators only, and therefore would not need to clean or disinfect their respirators, nor would they need to ensure adequate air quality, quantity and flow of breathing air, since they would not be using atmosphere-supplying respirators. Potential recordkeeping costs are addressed, separately, in the discussion of potential recordkeeping costs.

Based on OSHA's Respiratory Protection information collection request (ICR), OSHA estimates that an infection control professional at a high risk establishment would take eight hours to develop a written respiratory protection program initially, and four hours annually to maintain the program (OSHA, 2011). And the Agency estimates that an infection control professional at a low risk establishment would take four hours to develop a written program initially, and two

hours to maintain the program annually (OSHA, 2011). As stated below, OSHA expects that the per-facility cost to develop and implement a respiratory protection program will vary by setting and facility size. While OSHA has not currently made any determination as to which settings and facilities potentially affected by a rule based on the regulatory framework would be high risk and which would be low risk, the Agency welcomes any feedback the SERs may have on the issue.

The Respiratory Protection standard requires employers to provide a medical evaluation to determine the employee's ability to use a respirator before the employee is fit tested or required to use the respirator in the workplace (OSHA, 1998). The medical evaluation may be done in the form of a medical questionnaire that is included in an appendix to the Respiratory Protection standard. The questionnaire is completed by the employee and reviewed by a PLHCP for certain answers that would indicate that the employee needs to be further evaluated by a medical professional. Although some workers who undergo the medical evaluation would require a follow-up medical examination that must include any medical tests, consultations, or diagnostic procedures that a PLHCP deems necessary, most initial medical evaluations do not require a follow-up medical examination. Moreover, employers must provide additional medical re-evaluations to workers under specific conditions, such as where: a symptom is displayed by the employee; there is a change in workplace conditions that may result in a substantial increase in the physiological burden on the employee; the respiratory protection program administrator or a manager or a PLHCP notices a need for reevaluation; or fit testing reveals an issue (OSHA, 1998). If a worker must travel to a doctor’s office or hospital to receive a medical evaluation or re-evaluation, or a follow-up medical examination, OSHA preliminarily estimates that the employer would incur costs equal to 30 minutes of travel time, plus $5.00 in travel costs, for that worker. The total unit cost of this travel time in dollars would depend on the wage of the affected worker.

For this analysis, OSHA is preliminarily estimating two different types of unit costs associated with the medical re-evaluation requirement of the Respirator Protection standard. OSHA preliminarily believes that an employer would accrue the first type of unit cost when there is a change in work conditions, such as the introduction of a new hazard or a new process, or a switch to a different type of respirator. In this case, a medical re-evaluation will consist of the worker repeating the initial medical evaluation (i.e. filling out a questionnaire) and potentially undergoing the same type of medical examination as a worker who is newly required to wear a respirator. OSHA also preliminarily believes that an employer would accrue the second type of cost when a worker has been given an initial medical evaluation (and a possible follow-up medical examination), but a new or worsening health condition requires that worker to receive an additional follow-up medical examination with a PLHCP, and to potentially undergo additional tests or diagnostic procedures.

Based on the Respiratory Protection ICR, OSHA preliminarily estimates that: the questionnaire associated with the initial medical evaluation (or with the re-evaluation necessitated by a change in work conditions) requires 15 minutes of the worker's time to complete and five minutes for a PLHCP to review; and any follow-up medical examination associated with the initial medical evaluation (or with the re-evaluation necessitated by a change in work conditions) requires one hour of the worker's time, and costs, on average, $294.75 per worker, which includes the cost of any required tests, consultations, or diagnostic procedures, as well as the cost of the examination (OSHA, 2011).

The Agency also preliminarily estimates that a medical re-evaluation required by a new or worsening health condition will take 30 minutes of a worker's time, and that any associated follow-up medical examination that involves a visit with a PLHCP will cost $138 (FAIR Health, 2013; AMA, 2008; AHRQ, 2011a). OSHA preliminarily estimates that the follow-up medical examination associated with this type of re-evaluation is less burdensome than the initial follow-up medical examination (and less burdensome than the re-evaluation necessitated by a change in work conditions) because the medical examination is an evaluation of an already identified issue or (in the case of a potential issue not identified during the initial evaluation) a less serious issue that does not need extensive testing.

The Respiratory Protection standard requires that, before a worker is required to use a respirator with a negative or positive pressure tight-fitting facepiece, the employee must be fit tested with the same make, model, style, and size of respirator that will be used (OSHA, 1998). OSHA estimates, based on the Respiratory Protection ICR, that fit testing performed by an employer takes 30 minutes of the worker's time and 30 minutes of the fit tester's time, and that the process uses $1.15 worth of materials (OSHA, 2011). Some percentage of workplaces may be able to obtain fit testing services at no cost from the respirator manufacturer, and, in such cases, each worker would take 30 minutes to complete a fit test. Furthermore, some workplaces may opt to have fit testing performed by an outside contractor, and in such cases, OSHA estimates the fit testing would take 30 minutes of the worker's time and would cost $76.68 per worker who is fit tested (OSHA, 2011).

Table VI-4 below summarizes the potential costs, discussed above, that are associated with respiratory protection, including the estimated costs of the written respiratory protection plan, the medical evaluation and examination, and fit testing.

Table VI-4 Respiratory Protection			
Written Respiratory Protection Plan			
Facility Type	**Initial development**	**Annual review and update**	
High risk	8 hours	4 hours	
Low risk	4 hours	2 hours	
Medical Evaluation and Examination			
Activity	**Employee Time, in Hours**	**PLCHP Time, in Hours**	**Costs of Medical Exam**
Initial Medical Evaluation or Re-evaluation[1]	0.25	0.08	--
Follow-up Medical Exams if necessary [2]	1	--	$294.75
Additional Medical Re-evaluation[3]	0.5	--	$138
Fit Testing			
Provider	**Employee Time, in Hours**	**Fit Tester Time, in Hours**	**Additional Costs, per Employee**
Manufacturer	0.5	--	--
In-house	0.5	0.5	$1.15[4]
Contractor	0.5	--	$76.68[5]

[1] Cost for re-evaluation for changes in work conditions only.

[2] Cost of follow-up exams is for both follow-up exams necessary as a result of initial evaluations and re-evaluations due to changes in work conditions.

[3] Cost for medical re-evaluation resulting from new or worsening health conditions.

[4] Additional costs represent materials used for fit testing.

[5] Additional costs represent the estimated per-employee charge for an outside contractor to provide fit testing.

Source: OSHA, 2011, FAIR Health, 2013; AMA, 2008; AHRQ, 2011a.

Like other elements of a rule based on the regulatory framework, OSHA expects that the per-facility cost to develop and implement a respiratory protection program will vary greatly by setting and facility size. For example, a rule as outlined in the regulatory framework would add no respirator-related costs for establishments that do not normally see patients who are seeking treatment for the type of infectious diseases that would require respiratory protection (such as the majority of physical therapist or podiatrist offices).

Per the Draft Report on Current Compliance, and as shown in Table VI-10, OSHA preliminarily estimates that workers in laboratories have the highest estimated baseline use of respirators where airborne infection is possible, about 85 percent of the time, and workers in hospitals are estimated to be using respirators appropriately 64 percent of the time. Four settings have estimated compliance rates for respirator use below 40 percent. These include other "occupational settings," including morgues and mortuaries and waste handling and laundry services (26 percent), physicians' offices (29 percent), other ambulatory care settings (33 percent), and dentists' offices (38 percent).

Also, per the Draft Report on Current Compliance, and as shown in Table VI-10, OSHA preliminarily estimates that 86 percent of laboratories are providing initial fit testing and 57 percent are providing annual fit testing. Similarly, 84 percent of hospitals are estimated to be providing initial fit testing and 61 percent are estimated to be providing annual fit testing. Physicians' offices and establishments in "other occupational settings" are estimated to be the least compliant with these provisions of the Respiratory Protection standard, with baseline compliance rates for initial fit testing of 23 and 17 percent, respectively, and for annual fit testing of 14 and 15 percent, respectively. Establishments in the remaining settings are estimated to have baseline compliance rates of about 40 percent for initial fit testing, and between 15 and 30 percent for annual fit testing.

Finally, per the Draft Report on Current Compliance, and as shown in Table VI-10, OSHA preliminarily estimates the levels of current compliance with the Respiratory Protection standard's requirement to provide medical evaluations to employees prior to fit-testing. According to these estimates, 84 percent of hospitals, 71 percent of laboratories, and only 15 percent of establishments in "other occupational settings," are providing medical clearance to respirator-wearing employees. No other setting is estimated to have a baseline compliance rate of more than 38 percent (long term care and nursing homes), with most estimated to have a baseline compliance rate of between 20 and 27 percent.

OSHA welcomes any feedback the SERs may have on these preliminary estimates of current compliance.

Decontamination

Per the regulatory framework, OSHA would require implementation of procedures for routine and targeted decontamination of contaminated materials (i.e., contaminated items and/or surfaces) in the work setting that could be a source of occupational exposure. Decontamination encompasses cleaning, disinfection, and sterilization.

The regulatory framework does not prescribe any particular cleaning, disinfection, or sterilization methods that employers would be required to use, nor does OSHA intend to specify cleaning products or cleaning schedules. OSHA would require that employers generally be required to develop and implement decontamination procedures that are consistent with recognized and generally accepted good infection control practices. Employers would also need to follow EPA hazardous waste regulations (which are discussed in this SER Background Document in Section VII, "Description of Any Duplicative, Overlapping, or Conflicting Rules").

OSHA preliminarily concludes that appropriate decontamination procedures could be implemented through modifications in current practices and these modifications would not require additional time or materials over current practices. Studies have found no correlation

between the amount of time spent cleaning a room and the thoroughness of the cleaning (Rupp, 2013; Carling, 2008). This suggests that training workers to correctly disinfect rooms and equipment is an effective way to improve the thoroughness of decontamination procedures without devoting extra time to decontamination. Additional training (discussed later in this section of the SER Background Document) would provide workers with the background knowledge and procedures necessary for them to appropriately decontaminate contaminated items and surfaces.

OSHA believes that the flexibility of the approach presented in the regulatory framework would be key to keeping costs of complying with this provision at a minimum (or, as the Agency preliminarily estimates, no greater than current costs of cleaning and decontamination). Indeed, the flexibility of the regulatory framework would permit employers to reduce current costs, as less expensive decontamination products or methods are developed. Since the regulatory framework does not dictate what cleaning products must be used or how cleaning must be done, facilities could choose less costly disinfection products or methods so long as those products or methods are consistent with recognized and generally accepted good infection control practices.

Per the Draft Report on Current Compliance, and as shown in Table VI-10, OSHA preliminarily estimates that 71 percent of hospitals and 71 percent of laboratories properly clean and disinfect surfaces, giving these settings the highest baseline compliance rates for this provision of the regulatory framework. Only an estimated 25 percent of facilities in "other occupational settings," including morgues and mortuaries and waste handling and laundry services, properly clean and disinfect surfaces, giving these settings the lowest baseline compliance rates. Facilities in other ambulatory care settings and physicians' offices have estimated baseline compliance rates of 34 and 35 percent, respectively, and facilities in the remaining settings have estimated baseline compliance rates of between about 40 and 50 percent.

OSHA welcomes any feedback on these estimates. Do you agree with OSHA's preliminary finding that, with adequate training, facilities not currently cleaning and disinfecting surfaces properly could do so in the same amount of time and with the same materials they are currently using? And do you agree with OSHA's preliminary estimates of baseline compliance?

Handling, containerization, transport, or disposal of contaminated materials

Per the regulatory framework, OSHA would require employers to implement procedures to ensure that contaminated materials that could be a source of occupational exposure to infectious agents are properly containerized and labeled in order to prevent leaks and minimize worker contact with infectious materials during collection, handling, processing, storage, transport, shipping, or disposal.

OSHA's Bloodborne Pathogens standard (29 CFR 1910.1030) also contains requirements related to the safe handling, processing, storage, transport, shipping and disposal of contaminated materials. The Agency does not expect that most employers would incur additional costs related to handling, processing, storage, transport, shipping or disposal of contaminated materials above the costs attributed to the Bloodborne Pathogens standard. In addition, a number of establishments are already following the Department of Transportation's (DOT's) Hazardous Materials Regulations that involve requirements for the storage, transport and shipping of infectious or potentially infectious agents (these requirements are discussed in this SER Background Document in Section VII, "Description of Any Duplicative, Overlapping, or Conflicting Rules"), as well as applicable state-level requirements on transporting hazardous materials.

The Agency is interested in whether, in the opinion of the SERs, firms would incur additional costs in complying with this provision of the regulatory framework. Do the SERs agree with the Agency's preliminary determination that by following current rules, an employer would be in compliance with this provision? Are there additional potential costs that OSHA has failed to take into consideration?

Exposure incidents

Per the regulatory framework, OSHA would require establishments to investigate the circumstances surrounding each exposure incident, including a determination of the cause of the incident and whether existing policies, procedures, or training need to be revised to prevent future exposure incidents. OSHA preliminarily estimates that an exposure incident investigation would take, on average, 30 minutes. This average is meant to take into account both very simple investigations, which may take far less than 30 minutes (because, for example, the exposure incident involves an easily identified cause and existing policies, procedures, and training are readily determined to be adequate), and more complex investigations that require more than 30 minutes to fully investigate. OSHA has not made any determination as to the number of exposure incidents that facilities may need to investigate in a given year, but the Agency welcomes feedback from the SERs on the question.

Per the Draft Report on Current Compliance, and as shown in Table VI-10, OSHA preliminarily estimates that hospitals are currently investigating exposure incidents 82 percent of the time, while laboratories are estimated to be doing so 85 percent of the time. Dentists' offices, physicians' offices, and employers in "other occupational settings," including morgues and mortuaries and waste handling and laundry services, are estimated to be currently investigating exposure incidents about 30 percent of the time. OSHA welcomes any feedback the SERs may have to offer on these estimates of current levels of compliance.

Signage and Labeling/Color-coding

Per the regulatory framework, OSHA would require employers to implement procedures for the use of signage and labeling/color-coding to convey an appropriate hazard warning to workers throughout the employer's work settings. In addition, under the regulatory framework, OSHA would require employers to implement procedures for the use of signage and labeling/color-coding to convey an appropriate hazard warning to workers outside the employer's work settings in cases where the workers could come in contact with contaminated materials that originated in the employer's workplace (e.g., dirty linens) during collection, handling, processing, storage, transport, shipping, and disposal activities.

OSHA's Bloodborne Pathogens standard (29 CFR 1910.1030) also contains requirements related to signage and labeling/color-coding. The Agency does not expect that most employers would incur additional costs related to signage and labeling/color-coding above the costs attributed to the Bloodborne Pathogens standard. OSHA therefore preliminarily concludes that where employers comply with the Bloodborne Pathogens standard, the costs of this potential provision will be negligible. In addition, a number of establishments are already following signage and labeling procedures in accordance with DOT's hazardous materials requirements (these requirements are discussed in this SER Background Document in Section VII, "Description of Any Duplicative, Overlapping, or Conflicting Rules").

OSHA welcomes feedback from the SERs on the determination that compliance with this potential provision will not result in additional costs to employers. Do the SERs agree with this determination, or do the SERs feel that OSHA has failed to consider costs associated with this potential provision? If the SERs feel that the Agency is incorrect in this determination, how would current practices need to change for a firm to comply with this potential provision?

b. Implementation of Standard Operating Procedures for Direct Patient Care

In addition to the general SOPs discussed above, per the regulatory framework, OSHA would require the development and implementation of SOPs that are specific to direct patient care. This section discusses potential provisions that are specific to direct patient care. As always, OSHA welcomes any feedback the SERs have on the preliminary determinations presented in this section. Do you agree with OSHA's preliminary conclusions? Are there any procedures that OSHA has not considered that would need to be implemented as a result of the provisions in the regulatory framework that would result in costs – either time or materials?

Patient scheduling and intake/admittance

For employers that conduct patient scheduling and intake/admittance, OSHA would require implementation of SOPs to promptly identify individuals with suspected or confirmed infectious

diseases in order to initiate appropriate infection control practices. OSHA preliminarily concludes that these procedures could be achieved by modification of current work practices and therefore would not require any additional time for affected establishments to comply.

Procedures for implementing SOPs for standard, contact, droplet, and airborne precautions

OSHA would require implementation of SOPs for standard, contact, droplet, and airborne precautions. OSHA analyzed the major elements of these forms of precautions under the general SOP implementation discussed above. For example, the previous section details OSHA's estimated potential costs for the use of PPE (including respirators), hand hygiene, the maintenance of existing engineering controls, and work practice controls to minimize the generation of aerosols during certain procedures. The Agency has not identified any additional activities that potentially affected establishments would need to undertake to comply with these provisions of the regulatory framework, but OSHA welcomes any feedback from the SERs on this issue.

Procedures for patient transport

OSHA has preliminarily concluded that affected establishments would not incur costs associated with implementing SOPs for patient transport, which OSHA would require, per the regulatory framework. The Agency believes that facilities that would need to transfer patients under this potential requirement (mainly hospitals, nursing homes or long term care facilities, and embedded clinics in prisons) are already meeting this potential requirement. Any other facility where direct patient care is provided would not be caring for patients who would need this type of transport. As always, OSHA welcomes feedback on this preliminary determination. Do the SERs believe that this potential provision would require patient transport above what is currently standard practice?

Medical surge procedures

OSHA has not yet examined the costs of implementing medical surge procedures. For those employers who are not yet implementing adequate procedures, there would certainly be planning costs, as well as costs for the implementation of procedures for surge conditions that will depend on the nature of the surge situation. OSHA welcomes SER input on the costs associated with these activities.

c. Implementation of Standard Operating Procedures for Other Covered Tasks

In addition to the general SOPs discussed above, per the regulatory framework, OSHA would require SOPs that are specific to other covered tasks. This section discusses potential provisions

that are specific to other covered tasks. As always, OSHA welcomes any feedback the SERs have on the preliminary determinations presented in this section. Do you agree with OSHA's preliminary conclusions? Are there any procedures that OSHA has not considered that would need to be implemented as a result of these potential provisions that would result in costs – either time or materials?

Procedures for handling and intake of contaminated materials and procedures for the use of necessary control measures

Similar to the discussion in the section on general SOPs about handling contaminated materials, OSHA does not expect that most employers would incur additional costs in conjunction with this provision of the regulatory framework. OSHA anticipates that any establishments in the scope of a rule based on the regulatory framework would currently be familiar with, and have procedures for, handling and intake of contaminated materials, and for using necessary control measures.

Engineering controls

OSHA discussed the potential costs associated with upgrading and maintaining engineering controls in its discussion of potential costs for general SOPs, above.

Measures necessary to address uncontrolled releases of infectious agents, including mitigation of such releases and prompt reporting of such incidents to appropriate authorities

Per the regulatory framework, this provision would be specific to diagnostic, research, and production laboratory facilities. The Agency did not identify any additional potential costs associated with implementing measures to address uncontrolled releases of infectious agents, but welcomes any additional information the SERs can provide on the issue. In OSHA's preliminary estimation, these measures would rarely need to be implemented, but would involve (1) planning for such circumstances, which, the Agency preliminarily believes, affected firms are already doing, and (2) training workers on these measures. OSHA addresses any training costs associated with this potential requirement later in this section of the SER Background Document.

Do the SERs agree with OSHA's preliminary determination? Would the implementation of this draft provision of the regulatory framework result in additional costs that the Agency has not considered?

3. Medical screening, surveillance, and vaccination

The following sections address the implementation of occupational health services that could be required by OSHA, per the regulatory framework. These services could include vaccinations, medical screening and surveillance, medical evaluation and follow-up, maintenance of exposure incident records, and medical removal protection.

Vaccination

Per the regulatory framework, OSHA would require employers to make available to their employees vaccinations that are consistent with recognized and generally accepted good infection control practices relevant to the occupational exposures encountered during the job tasks of the employee. With the exception of employees in research and production laboratory facilities, employers could be required to make available to their employees, at a minimum, the following vaccinations:

- Influenza (Seasonal and Pandemic);
- Measles, Mumps and Rubella (MMR);
- Tetanus, Diphtheria, and Pertussis (Tdap);
- Varicella; and
- Any other vaccination(s) that is required by the employer's WICP, or determined by a PLHCP to be medically appropriate for a particular worker (e.g., the meningococcal vaccine.)

OSHA believes that making the specified vaccinations available would generally protect affected workers from the infectious agents to which they have occupational exposure. However, employers of employees in research and production laboratory facilities may be required to make available to those employees only those vaccinations that the employer determines are relevant to their work settings. For example, workers in a research laboratory handling one infectious agent only (e.g., *Neisseria meningitidis* bacteria) would be offered one vaccination only (in the example, the meningococcal vaccine) because they are not working with other infectious agents.

As outlined in the regulatory framework, OSHA could exempt an employer from offering a vaccination to a worker where the employer has documented that the worker has already received the vaccination, antibody testing reveals immunity, or the vaccine is contraindicated for medical reasons. OSHA preliminarily estimates the cost per vaccine as shown in Table VI-5 below.

Table VI-5		
Vaccinations		
Cost per Vaccine		
Influenza	$13.13	[1]
MMR	$54.07	[1]
Varicella	$181.10	[1]
Tdap	$39.31	[1]
Meningococcal	$111.83	[1]
Typhoid	$24.87	[2]
Inactivated Polio	$23.18	[3]

Source: [1] CDC, 2013d; CDC, 2012a. [2] VA, 2013; CDC, 2012a. [3] VA, 2013; CDC, 2011c.

In addition to the cost of the vaccine, OSHA preliminarily estimates that it would take 5 minutes of a worker's time to receive a vaccine on-site, plus 5 minutes of a PLHCP's time to administer each vaccine. Most workers potentially affected by a rule based on the regulatory framework would be able to receive a vaccine at their worksite, but if a worker must travel off-site to receive a vaccine, OSHA preliminarily estimates that it would take 30 minutes of his or her time plus $5.00 in travel costs.

Like many other elements of a rule based on the regulatory framework, the per-facility cost to make vaccinations available would vary based on the size and type of facility. OSHA delineated specific vaccines in the regulatory framework (influenza, MMR, Varicella, and Tdap) because OSHA preliminarily believes that employers in most settings would need to make these vaccines – and only these vaccines – available to the majority of their employees.

Per the regulatory framework, an employer would be required to ensure that an employee fill out a vaccine declination form when that employee declines a vaccination. The Agency preliminarily estimates that it would take two minutes of a worker's time to decline a vaccine and five minutes of an administrative assistant's time to process and file such a form.

Per the Draft Report on Current Compliance, and as shown in Table VI-10, OSHA preliminarily estimates that 85 percent of hospitals currently offer their workers the full complement of CDC/ACIP recommended vaccines and 72 percent of laboratories offer their workers the full complement of CDC/NIH BMBL recommended vaccines. About 30 percent of establishments in "other occupational settings," including morgues and mortuaries and waste handling and laundry services, dentists' offices, and physicians' offices, and about 40 percent of establishments in the remaining settings, currently offer their workers the full complement of recommended vaccines.

Also per the Draft Report on Current Compliance, and as shown in Table VI-10, OSHA preliminarily estimates that, for most settings except hospitals, a higher percentage of establishments make vaccines available in accord with state-level vaccine requirements that are less extensive (as opposed to the more extensive ACIP/CDC or CDC/NIH BMBL recommendations). OSHA preliminarily estimates that about 50 percent of physicians' offices and dentists' offices (the low end of baseline compliance), and about 60 to 80 percent of establishments in the remaining settings, offer workers vaccines in accord with state-level vaccine requirements.

OSHA welcomes feedback from the SERs on these preliminary estimates of current compliance.

Medical Screening and Surveillance

Per the regulatory framework, OSHA would require employers to provide medical screening and surveillance to their employees who have occupational exposure during the provision of direct patient care or the performance of other covered tasks. The costs of medical screening and surveillance for each establishment, like many other provisions in the regulatory framework, would depend largely on the size of the establishment. A small provider with few employees and low turnover would incur minimal costs, while a large provider with hundreds of employees and high turnover would incur higher total costs, to comply with this provision.

Furthermore, the flexibility inherent in the regulatory framework would allow each employer to comply with the provision in a manner appropriate for their individual facility. As such, employers could choose a less costly method of medical screening and surveillance so long as the chosen method is effective.

For example, medical screening could take the form of a pre-placement "health inventory" that determines immunization status and obtains histories of any conditions that might predispose personnel to acquiring or transmitting infectious diseases. Medical surveillance could also encompass initial and yearly TB testing. OSHA addresses the potential costs associated with employees who have a positive result on a TB screening test in the following section on medical follow-up and medical removal protection.

OSHA preliminarily estimates that medical screening that includes a questionnaire filled out by new employees would take 10 minutes of time to complete. And the Agency estimates that reviewing and verifying the information in the questionnaire with a PLHCP would take an additional 15 minutes of the employee's time plus 15 minutes of a PLHCP's time. Workers who need to travel to an off-site location to complete their medical screening would incur an estimated additional 30 minutes of travel time plus $5.00 in travel costs. The total unit cost of this screening in dollars would depend on the wage of the affected worker.

Under a rule as outlined in the regulatory framework, an employer whose WICP requires that it perform a TB test on its workers may choose to obtain a basic medical history and administer a

TB test at the same time. OSHA preliminarily estimates costs for these procedures based on the payment to a medical provider for conducting medical screening and performing testing services, as well as employee time needed to undergo these procedures (including employee time associated with having a test read by a PLHCP, if applicable). Based on analyses conducted in conjunction with OSHA's proposed rule addressing occupational exposure to TB, OSHA preliminarily estimates that the medical screening portion of these procedures would cost $27, and, factoring in this $27 cost, that performance of medical screening and administration of a TB test at the same time would: (1) require 1 hour of the employee's time and cost $70, if the employee is administered a single step TB test; or (2) require 1.5 hours of an employee's time and cost $113, if the employee is administered a two-step TB test; or (3) require 30 minutes of an employee's time and cost $326, if the employee is given an IGRA (Interferon Gamma Release Assay) test (OSHA, 1997, updated to 2012 dollars, FAIR Health, 2013). OSHA preliminarily estimates that an IGRA costs $298.94 versus $43 for a single step skin test and $86 for a two-step skin test – but some employers may opt for the IGRA due to convenience because the IGRA can be administered in one visit (FAIR Health, 2013). Workers who need to travel to an off-site location to complete their medical screening plus TB test would incur an estimated additional 30 minutes of travel time plus $5.00 in travel costs.

OSHA also preliminarily estimates costs associated with an employee undergoing a TB test alone (without medical screening at the same time). As above, OSHA preliminarily estimates costs for a TB test alone based on the payment to a medical provider for performing testing services, as well as employee time needed to undergo the test (including employee time associated with having the test read by a PLHCP, if applicable). OSHA preliminarily estimates that administration of a TB test alone would: (1) require 1 hour of the employee's time and cost $43, if the employee is administered a single step TB test; or (2) require 1.5 hours of an employee's time and cost $86, if the employee is administered a two-step TB test; or (3) require 30 minutes of an employee's time, and cost $298.94, if the employee is given an IGRA (FAIR Health, 2013). Workers who need to travel to an off-site location to complete their TB test would incur an estimated additional 30 minutes of travel time plus $5.00 in travel costs.

Although full-pre-placement physical examinations would not be required by a rule as outlined in the regulatory framework, OSHA preliminarily estimates that establishments who choose to provide full pre-placement physical examinations to their employees would incur costs equivalent to one hour of the employee's time plus an additional $175, representing payment to a medical provider for testing services (OSHA, 1997, updated to 2012 dollars). Workers who need to travel to an off-site location to complete their physical would incur an estimated additional 30 minutes of travel time plus $5.00 in travel costs.

OSHA summarizes the potential costs associated with the potential requirements for medical screening and surveillance in Table VI-6 below. All potential costs associated with recordkeeping are addressed in the recordkeeping discussion later in this section of the SER Background Document.

Table VI-6			
Medical Screening and Surveillance Estimated Compliance Burden per Employee			
Type of Screening/Surveillance	Employee Time, in Hours	PHLCP Time, in Hours	Additional Costs[1]
Health Inventory only	0.42	0.25	--
Health Inventory plus TB test			
Single Step Test	1		$70
Two Step Test	1.5		$113
IGRA	0.5		$326
TB Test only			
Single Step Test	1		$43
Two Step Test	1.5		$86
IGRA	0.5		$299
Full Physical	1		$175

[1]Additional costs represent payments to medical providers for testing or exam services.

Source: OSHA, 1997; FAIR Health, 2013.

Per the Draft Report on Current Compliance, and as shown in Table VI-10, OSHA preliminarily estimates that hospitals currently provide pre-placement screenings (either in the form of a health inventory questionnaire or a full physical exam) to 70 percent of workers, and diagnostic testing to 90 percent of workers receiving such screenings. Three settings (long term care and nursing homes, home healthcare agencies, and laboratories) are preliminarily estimated to provide pre-placement medical screenings to roughly 50 percent of workers. Laboratories are estimated to provide diagnostic testing to 71 percent of the workers being screened. And OSHA estimates that long term care facilities and nursing homes and home healthcare agencies provide diagnostic testing to about 45 percent of screened workers. OSHA preliminarily estimates that in the remaining settings employers provide pre-placement medical screenings to between 10 percent and 19 percent of workers, with diagnostic testing provided to between 17 percent and 41 percent of workers receiving screens. OSHA welcomes any feedback or additional information the SERs may have on these preliminary estimates of current compliance.

Medical Evaluation, Follow-up, and Medical Removal Protection

Per the regulatory framework, OSHA would require that the employer make available to a worker a confidential medical evaluation and appropriate follow-up, either after a referral from a medical screening or surveillance program (provided a PLHCP has determined that the medical evaluation and appropriate follow-up is necessitated by a workplace exposure, as opposed to a non-workplace exposure), or after a report of an exposure incident. OSHA would also require that a confidential medical evaluation and appropriate follow-up after an exposure incident include the following elements: the route(s) and circumstances of the exposure; documentation of the source of the exposure (unless the employer can establish that identification is not feasible or prohibited by law); baseline testing; post-exposure prophylaxis and treatment; appropriate counseling; evaluation of reported illnesses that may be attributable to exposure; and, as necessary, recommendations for job modifications or restrictions or for precautionary removal of the employee from the workplace. Finally, except for most cases of occupational exposure to the common cold or influenza, OSHA would require medical removal protection benefits, *i.e.*, that, an employer pay the total normal earnings and maintain the seniority, rights, and benefits of an employee removed from the job or otherwise medically limited as a result of an exposure incident.

For the purposes of this SER Background Document, OSHA preliminarily estimates the full unit costs of diagnosing and treating a select few workplace acquired infectious diseases, as well as the medical restriction times associated with the infectious diseases. This means that OSHA will be discussing the potential costs of any relevant drug therapies, recommended post-exposure vaccines, any doctor's visits or testing necessary to diagnose a suspected infectious disease, any treatments for the disease, and any recommended days of medical restriction.

Employers would only be required to provide medical removal protection for as long as an employee is infectious. In most cases of occupationally-acquired infections, the worker is treated as an outpatient, and, the duration of medical removal protection would generally vary, depending on the disease (see, for example, discussion of influenza, below). In cases where a worker is hospitalized as a result of a workplace-acquired MRSA infection, OSHA has preliminarily estimated that once that worker is released from the hospital, he or she is usually no longer infectious and therefore no longer subject to medical removal protection. Because of this assumption, days of hospitalization for MRSA (where relevant) are assumed to be equal to days of work restriction subject to medical removal protection coverage. Cases of TB will require that medical removal protection be provided for three to four weeks in addition to any time the worker would be hospitalized.

This section will not be deriving a single estimate for the cost of post-exposure prophylactic treatment or a total estimated cost for treating a given case of an infectious disease. It also does not estimate how many cases may be expected in a given year, or how many workers may

potentially need post exposure prophylaxis or medical evaluation, follow-up or medical removal protection.

The total, per-establishment costs of these potential provisions are largely dependent on the number of employees an establishment has and on the number and type of infectious diseases to which employees in that establishment have occupational exposure. Similar to many OSHA standards, it would not be uncommon for some facilities to have years in which no workers become ill as a result of a workplace exposure. Some facilities are unlikely to ever see a patient with many of the diseases that would be covered under a rule as specified in the regulatory framework (e.g., it would be unlikely that podiatrists and optometrists would see patients with active TB or an infection with *Clostridium difficile*). Finally, many infectious diseases are relatively uncommon in the United States, and only a handful of facilities would even see one case in a given year.

The estimates presented below also do not take into account health insurance or workers' compensation coverage, both of which may reduce the actual burden to the employer of treating a case of an occupationally acquired infectious disease. OSHA has addressed this issue in past rulemakings (in the ergonomic rulemaking, for example) by discounting the cost to employers to account for insurance or workers' compensation; thus, the Agency is aware of the issue but is still in the process of determining how to apply such a discount in this instance and what the appropriate discount would be for the purposes of a rule based on the regulatory framework. OSHA welcomes any feedback the SERs may have on how the costs of treating occupationally acquired infectious diseases are currently being borne and how that might change as a result of a rule based on the regulatory framework.

While the Agency usually uses a generalized estimate for medical removal protection, after examining the range of the most common infectious diseases and the infectious diseases specifically addressed by public health officials, OSHA has determined that the range of treatment requirements and medical removal recommendations are too varied for a generalized estimate to be reasonable. For this SER Background Document, OSHA will be examining the potential costs for medical evaluation, follow-up, post exposure prophylaxis and medical removal protection for three diseases: influenza, tuberculosis, and MRSA. The Agency believes that these diseases are representative of the types of infectious diseases that will be included in a full analysis. They were chosen to show how OSHA would undertake this analysis for what OSHA preliminarily considers a low-cost but common disease (influenza), a high-cost but low incidence disease (tuberculosis), and a disease with multiple possible manifestations from relatively low cost to very high cost (MRSA). If the Agency proceeds with proposing a rule based on the regulatory framework, OSHA anticipates expanding this analysis to account for potential costs related to medical evaluation, follow-up, post exposure prophylaxis and medical removal protection for additional diseases, including measles, mumps, rubella, pertussis, varicella, meningococcal disease, typhoid, SARS, norovirus, VRE, adenovirus, and Group A Streptococcus (GAS). These agents – those being evaluated for this SER Background Document

and those that would be evaluated for a proposal – are diseases covered by the CDC's guidelines for post-exposure treatment for healthcare workers (CDC, 2011d), plus those that the Agency has preliminarily concluded represent the most common infectious agents to which workers within the potential scope of a rule based on the regulatory framework are exposed. It is currently OSHA's intent to cover post-exposure treatment and medical removal for most occupationally acquired infectious diseases amongst the covered worker population. For the three diseases OSHA looked at for this SER Background Document, the treatment, treatment costs, and days of medical restriction for exposed workers – both those with a suspected case of the disease and those with a confirmed case of the disease – are presented below in Tables VI-7 and VI-8.

Per the Draft Report on Current Compliance, and as shown in Table VI-10, OSHA preliminarily concludes that hospitals and laboratories are already highly compliant with a potential requirement to provide post exposure prophylactic treatments, as recommended by the CDC/HICPAC guidelines. OSHA estimates that hospitals provide post exposure prophylactic treatment 91 percent of the time, while laboratories provide post exposure prophylactic treatment 86 percent of the time. Three settings are estimated to be providing post exposure prophylactic treatment more than 60 percent of the time: other ambulatory care settings (62 percent), home healthcare agencies (66 percent), and nursing homes and long-term care facilities (68 percent). Employers in "other occupational settings," including morgues and mortuaries and waste handling and laundry services, are estimated to provide post exposure prophylactic treatment just 32 percent of the time.

OSHA also preliminarily concludes that hospitals and laboratories are already highly compliant with a potential requirement to provide post exposure testing for workers exposed to suspected or confirmed sources of infectious diseases. OSHA estimates that employers in those settings provide such testing 88 and 86 percent of the time, respectively. Employers in other ambulatory care settings, home healthcare agencies, and nursing homes and long-term care facilities provide such post exposure testing an estimated 55 to 70 percent of the time, while employers in "other occupational settings" provide such post exposure testing just an estimated 34 percent of the time.

OSHA also preliminarily estimates baseline compliance rates with respect to: (1) the percentage of the time that employers restrict workers' normal duties and/or assign them alternative job duties when they have a known or suspected infectious disease; (2) the percentage of employers that direct workers not to come to work when they have a known or suspected infectious disease; and (3) the percentage of the time that employers provide normal pay and benefits during periods in which workers with a known or suspected infectious disease are directed not to come to work. OSHA preliminarily estimates that 77 percent of the time, hospitals already restrict or alter workers' duties when they have a known or suspected infectious disease, and that 59 percent of hospitals direct those workers not to come to work. With respect to long term care and nursing home facilities and laboratories, OSHA estimates that 60 and 66 percent of the time,

respectively, employers in those settings restrict the duties of workers who have a known or suspected infectious disease and that, for each of those settings, just under 50 percent of employers direct affected workers not to come to work. The Agency estimates that between 40 and 50 percent of the time, physicians' offices, dentists' offices and employers in other ambulatory care settings restrict the duties of affected workers, and that about 30 to 35 percent of employers in those settings direct affected workers not to come to work. Employers in "other occupational settings," including morgues and mortuaries and waste handling and laundry services, have the lowest estimated baseline compliance rates. Employers in those settings are estimated to restrict the duties of affected workers 23 percent of the time. And an estimated 27 percent of employers in those settings direct affected workers to not report to work.

While the percentage of employers estimated to be currently directing workers with a suspected or confirmed infectious disease to not report to work is relatively low for most settings (between 25 and 50 percent of employers in all settings except hospitals (59 percent)), the percentage of the time that employers are estimated to provide pay in the event workers are told not to report to work is relatively high. In all settings except two (home healthcare (45 percent) and "other occupational settings" (41 percent)), OSHA estimates that employers pay affected workers at least 60 percent of the time, with hospitals estimated to be providing pay most frequently (84 percent of the time). OSHA is interested in any feedback or additional information that the SERs could supply on these preliminary estimates of the levels of current compliance with these draft provisions.

The remainder of the discussion on medical evaluation, follow-up, and medical removal protection outlines the potential costs of post exposure prophylaxis, related testing and treatment, and the estimated number of days a worker would need to be excluded from the workplace based on current guidelines and the potential requirements of a rule as outlined in the regulatory framework. This information is also contained in Tables VI-7 and VI-8, at the end of the discussion.

Influenza

OSHA assumes, based on recommendations from the CDC (CDC, 2011d), that, as part of exposure incident-related post-exposure prophylaxis, a worker exposed to influenza should be offered a vaccine – estimated to cost $13.13 - if they have not already received the vaccine (CDC, 2013d). The same CDC source recommends that an exposed worker needs the following post-exposure prophylactic treatment: either Oseltamivir 75 mg once a day for 10 days, or Zanamivir 10 mg (inhalation) once a day for 10 days.[54] CDC guidance states that widespread or routine use of antiviral medications for chemoprophylaxis is not recommended but instead suggests close monitoring of exposed individuals with early initiation of antiviral treatment

[54] More recent CDC guidance advises a 7-day course of either drug, but OSHA has used the earlier recommendation of a 10-day course of treatment for costing purposes in this SER Background Document. OSHA will reexamine this preliminary decision if it decides to engage in rulemaking.

(CDC, 2011d). OSHA has not made any determination as to the percentage of workers exposed to influenza who may be offered post-exposure prophylactic treatment, but the Agency preliminarily calculates, based on the average of the total cost for Oseltamivir and Zanamivir, that the average post-exposure preventative chemoprophylaxis for influenza is $69.03 per exposed, vaccinated worker (including the average cost of medication only) and $82.16 per exposed, unvaccinated worker (including both the cost of vaccination and the average cost of medication) (VA, 2013; PDR, 2013).

If a worker becomes ill with a case of influenza, CDC recommends the following treatment: either Oseltamivir twice a day for 5 days; or Zanamivir twice a day for 5 days. OSHA preliminarily estimates that treatment would cost, on average, $69.03, based on the average of the total cost for Oseltamivir and Zanamivir. In addition, some workers may be given a rapid influenza diagnostic test, which OSHA estimates will cost $105. OSHA has made no determination about the number of workers with influenza who may receive diagnostic testing, but welcomes comments from the SERs on this issue. In sum, OSHA estimates a treatment cost of $69.03 per worker who is offered antiviral medication only, and $174.03 per worker who is offered both diagnostic testing and antiviral medication (CDC, 2011d; VA, 2013; PDR, 2013; AHRQ, 2011a). And OSHA estimates that any employer whose workers would need to travel to an off-site location to receive tests would incur costs equal to 30 minutes of the worker's time for the time spent in transit plus $5.00 in travel costs.

With respect to influenza, a rule based on the regulatory framework would require medical removal protection benefits for one type of worker only: a research or production laboratory worker removed from the job or otherwise medically limited as a result of an occupational exposure incident to an infectious agent (influenza) with which he or she is working. It is easier to identify that influenza has been occupationally acquired in laboratories where specific infectious agents are being handled on a daily basis, than it is in other settings. Current guidelines recommend that a worker with an active case of influenza be excluded from work until at least 24 hours after they no longer have a fever (without the use of fever-reducing medicines such as acetaminophen). Further, workers in certain settings may be temporarily reassigned or excluded from work for 7 days from symptom onset or until the resolution of all non-cough symptoms, whichever is longer (CDC, 2011d, CDC, 2013e).

Tuberculosis

OSHA addresses the potential costs of routine screening for TB in the previous section on medical screening and surveillance. A worker with a positive TB skin test or IGRA may be referred to a PLHCP for a chest x-ray and a determination regarding whether the worker has latent or active TB. OSHA preliminarily estimates that a chest x-ray will cost $44 and take approximately thirty minutes of worker time for the x-ray plus an additional thirty minutes to review the results with a PLHCP. The exam is estimated to cost $138 (FAIR Health, 2013; AMA, 2008). If a worker must travel to a doctor's office or hospital to receive a chest x-ray,

OSHA preliminarily estimates that the employer would incur costs equal to 30 minutes of travel time for that worker plus $5.00 in travel costs.

Cases of latent TB are treated with a six-to-nine month course of isoniazid, either daily or two times a week. OSHA preliminarily estimates that isoniazid costs $0.05 per dose, resulting in a cost of $2.70 for 52 doses (a six month, twice a week course of treatment), $9.36 for 180 doses (a six month, daily dose course of treatment), $3.95 for 76 doses (a nine month, twice a week course of treatment), and $14.04 for 270 doses (a nine month daily course of treatment). Cases of latent TB can also be treated with a four-month course of rifampin once a day, which, OSHA preliminarily estimates, costs $1.82 per dose, or $218.82 for 120 doses (CDC, 2013f, VA, 2013). OSHA has not, at this time, made any determination as to the percentage of workers treated for latent TB who are treated with rifampin versus isoniazid, but the Agency welcomes comments from the SERs on the issue.

In addition to medication, workers treated for latent TB need to be seen by a doctor monthly to be administered a liver injury test. OSHA preliminarily estimates that each office visit costs $138 and each hepatic function panel costs $46.12, for a total cost for doctor's visits and liver tests of $1,104.72 for a six month course of treatment, or $1,657.08 for a nine month course of treatment (AHRQ, 2011a).

OSHA preliminarily estimates that workers suspected of having an active case of TB, but who are eventually diagnosed with something other than TB, require a stay in a hospital isolation room for an average of 4 days. The total cost of this hospitalization, and any related tests and treatments, is preliminarily estimated to be $12,578 (AHRQ, 2011a). A worker who is confirmed to have an active case of TB will require, on average, an 8.3 day stay in a hospital isolation room, and the total cost of this hospitalization, and any related tests and treatments, is preliminarily estimated to be $42,327 (AHRQ, 2011a).

Treatment for an active case of TB would depend on the extent of disease and microbial antibiotic sensitivity, but it usually involves 6-9 months of a four drug regimen. The initial treatment phase from the CDC recommended treatment is eight weeks of daily doses (56 doses total) of four different medications: isoniazid, rifampin, ethambutol, and pyrazinamide, followed by 18 weeks of daily doses (126 doses) of isoniazid and rifampin, or 18 weeks of twice weekly doses (36 doses) of isoniazid and rifampin. OSHA preliminarily estimates that isoniazid costs $0.05 per dose, rifampin costs $1.82 per dose, ethambutol costs $1.77 per dose, and pyrazinamide costs $1.29 per dose. This results in a total cost for the initial phase of treatment of $276.29. For the daily dose option, the continuation phase of treatment is preliminarily estimated to cost $236.10. For the twice-weekly dose option, the continuation phase of treatment is preliminarily estimated to cost $67.46 (CDC, 2013g, OSHA, 1997, VA, 2013). In addition to treatment, a worker with an active case of TB that a PLHCP has determined was workplace acquired would need to be excluded from the workplace for three to four weeks (CDC, 2012b).

MRSA

Presently, no prophylactic treatment is recommended after an exposure to an active MRSA infection. An active MRSA infection may result in a skin or soft tissue infection, which can be treated with topical antibiotic ointments, or may result in a skin abscess, which must be incised and drained and requires clinic or emergency department visits. Some skin infections become severe and will need oral antibiotics (Liu et al. 2011).

OSHA preliminarily estimates that an average active case of a MRSA-related skin or soft tissue infection will be diagnosed with a wound culture screening only, which is preliminarily estimated to cost $48.88. If that culture is positive for MRSA, the worker will likely receive a second wound culture screening, this time with a colony count estimation (preliminarily estimated to cost an additional $32.01), and if that second culture is positive, the worker will likely receive a third wound culture screening, this time with molecular typing, either by nucleic acid probe (preliminarily estimated to cost an additional $100.80), or by pulsed-field gel electrophoresis (preliminarily estimated to cost an additional $46.20) (FAIR Health, 2013). Any employer whose workers would need to travel to an off-site location to receive these diagnostic tests would incur costs equal to 30 minutes of that worker's time for the time spent in transit plus $5.00 in travel costs. OSHA has not yet made a determination as to how many workers displaying a skin or soft tissue infection would be offered each type of diagnostic test and believes that some workers would be offered treatment without undergoing some or all of the testing described above. OSHA welcomes feedback from the SERs on this issue.

OSHA preliminarily estimates that, for less serious cases, which do not require hospitalization, some workers positively diagnosed with MRSA-related skin and soft tissue infection may, depending on the location of the infection and the worker's job duties, require one week of medical restriction and treatment with a course of a topical antibiotic (Liu et al. 2011). The topical treatment is preliminarily estimated to cost $0.94 per dose, and necessitate 10 doses, for a total cost of $9.43 (VA, 2013; PDR, 2013; Liu et al., 2011). In some cases, a worker with a MRSA-related skin or soft tissue infection will receive a course of oral antibiotics, either Bactrim or Clindamycin, in addition to topical treatment. OSHA preliminarily estimates that a course of Bactrim costs $33.60 (28 doses at $1.20 per dose) and a course of Clindamycin costs $47.04 (42 doses at $1.12 per dose) (PDR, 2013; VA, 2013) If the infection results in an abscess, OSHA preliminarily concludes that the worker will need the abscess incised and drained. This procedure can be done in a doctor's office or in an emergency department. The abscess will either be drained through needle aspiration or through manual aspiration. OSHA preliminarily estimates that the procedure costs between $329 and $650, depending on how complicated the procedure is (AHRQ, 2011a). OSHA also preliminarily estimates that the procedure takes between 60 and 90 minutes of an employee's time, plus an additional 30 minutes and $5.00 in travel costs if the worker needs to travel to an off-site location.

In rare cases, MRSA may cause serious infections, such as complicated soft tissue infections, endocarditis, pneumonia, meningitis and bone (osteomyelitis) or joint infections. These infections may require hospitalization, which may include surgical intervention, intensive medical therapy, and extended recovery time.

At this time, OSHA has not made any determination as to how many workplace-acquired MRSA infections there are in a given year, or any determination as to the percentage of those infections that are of the very serious type that are expensive to treat and require hospitalization. The Agency welcomes any information the SERs can provide on the issue.

OSHA has, however, made preliminary estimates of the time and costs associated with hospitalizations for serious MRSA infections and various complications that can result from serious MRSA infections. OSHA preliminarily estimates: (1) that a serious MRSA-related skin and soft tissue infection requiring hospitalization results in nine days in the hospital, and costs $64,447; (2) that MRSA-related pneumonia requires eight days in the hospital, and costs $45,212; (3) that, depending on the location of the infection, MRSA-related osteomyelitis requires between five and eight days (average of just over six) in the hospital and costs between $25,262 and $53,791 (average of $39,067); (4) that MRSA-related endocarditis requires nine days in the hospital, and costs $62,051; and (5) that MRSA-related meningitis requires eight days in the hospital, and costs $50,258 (AHRQ, 2011a; CMS, 2013b).

A worker with a MRSA skin or soft tissue infection may require medical restriction, depending on the extent of the infection and the worker's job duties. The Agency preliminarily concludes that workers will be non-infectious upon release from the hospital and would no longer be entitled to medical removal protection benefits under a rule as outlined in the regulatory framework.

Table VI-7

Post-Exposure Prophylaxis and Medical Follow-up by Worker Characteristic and Infectious Agent

Preventative Treatment or Treatment of Non-Active Cases Only

Disease	Worker Type	Diagnostic Testing and Treatment, type	Diagnostic Testing and Treatment Cost		Vaccine Recommended Post-exposure		Vaccine Cost per dose		Doses		Vaccine Cost		Medication Recommended		Medication cost per dose		Recommended Doses		Medication Total Cost
Influenza	Unvaccinated				Yes	[1]	$13.13	[3]	1	[4]	$13.13	[3][4	Oseltamivir	[1]	$8.05	[3]	10	[1][4]	$80.53
													Zanamivir	[1]	$5.75	[3]	10	[1][4]	$57.52
	Vaccinated				No	[1]							Oseltamivir	[1]	$8.05	[3]	10	[1][4]	$80.53
													Zanamivir	[1]	$5.75	[3]	10	[1][4]	$57.52
Tuberculosis	Workers with	Chest x-ray	$44	[5]	No	[6]	N/A		N/A		N/A		soniazide	[2]	$0.05	[3]	52[1]	[2]	$2.70
	Latent TB	Initial appointment with PLHCP	$138	[5]													180[2]	[2]	$9.36
		Appointment with PLHCP, monthly for 6 or 9 months	$828 or $1,242	[5]													76[3]	[2]	$3.95
		Liver Injury Test, monthly for 6 or 9 months	$276.72 or $415.08	[5]													270[4]	[2]	$14.04
													Rifampin	[2]	$1.82	[3]	120[5]	[2]	$218.62

1 - number of doses reflects a six month (26 week), twice weekly dose course of treatment
2 - number of doses reflects a six month, daily dose course of treatment assuming a thirty day month
3 - number of doses reflects a nine month (38 week), twice weekly dose course of treatment
4 - number of doses reflects a nine month, daily dose course of treatment assuming a thirty day month
5 - number of doses reflects a four month, daily dose course of treatment assuming a thirty day month

Note: Totals may not sum due to rounding.

Sources:	
[1]	CDC, 2011d
[2]	CDC, 2013e
[3]	VA, 2013
[4]	PDR, 2013
[5]	FAIR Health, 2013
[6]	Bolyard et al., 1998

Table VI-8

Treatment by Infectious Agent

Active Case Treatment

Disease	Worker Type	Diagnostic Testing, type	Diagnostic Testing and Treatment cost		Medication Recommended		Medication cost per dose		Recommended Doses		Medication Total Cost	Days of Hospitalization		Cost of Hospitlization	
Influenza	All workers	Rapid Influenza Diagnostic Test	$105	[2]	Oseltamivir (Tamiflu)	[1]	$8.05	[7]	10	[1][6]	$80.53				
					Zanamivir (Relenza)	[1]	$5.75	[7]	10	[1][6]	$57.52				
Tuberculosis	Workers with Active TB				Isoniazid (initial)	[3]	$0.05	[7]	56	[3]	$2.91	4 days[1]	[4] [5]	$12,578	[4] [5]
					Rifampin (initial)	[3]	$1.82	[7]	56	[3]	$102.02				
					Ethambutol (initial)	[3]	$1.77	[7]	56	[3]	$99.12				
					Pyrazinamide (initial)	[3]	$1.29	[7]	56	[3]	$72.24	8.3 days[2]	[4] [5]	$42,327	[4] [5]
					Total Cost (initial)						$276.29				
					Isoniazid + Rifampin (daily continuation)	[3]	$1.87	[7]	126	[3]	$236.10				
					Isoniazid + Rifampin (semiweekly continuation)	[3]	$1.87	[7]	36	[3]	$67.46				
MRSA	Workers with skin and soft tissue infection	Wound Culture Screening	$48.88	[2]	Topical antibiotic	[9]	$0.94	[7]	10	[6]	$9.43	9 days	[4] [5]	$64,447	[4] [5]
		Wound Culture Screening with Colony Estimation	$32.01	[2]	Bactrim	[10]	$1.20	[7]	28	[6]	$33.60				
		Wound Culture Typing - nucleic acid probe	$100.80	[2]	Clindamycin	[9]	$1.12	[7]	42	[6]	$47.04				
		Wound Culture Typing - pulse gel field	$46.20	[2]											
		Abscess draining[3]	$329 - $650	[2] [8]											
	Workers with MRSA related pneumonia											8 days	[4] [5]	$45,212	[4] [5]
	Workers with MRSA related osteomyelitis											6-8 days[4]	[4] [5]	$25,262 - $53,791	[4] [5]
	Workers with MRSA related endocarditis											9 days	[4] [5]	$62,051	[4] [5]
	Workers with MRSA related meningitis											8 days	[4] [5]	$50,258	[4] [5]

1 - Represents hospitalization for a worker who is suspected of having active TB but who is ultimately found to not have TB.
2 - Represents hospitalization for a worker who is confirmed to have an active case of TB.
3 - Cost of the procedure is estimated to vary based on complexity.
4 - Time and cost of hospitalization are estimated to vary based on where the osteomyelitis manifests.

Note: Totals may not equal the sum of the components due to rounding.

Sources:	
[1]	CDC, 2011d
[2]	FAIR Health, 2013
[3]	CDC, 2013g
[4]	AHRQ, 2011a
[5]	CMS, 2013b
[6]	PDR, 2013
[7]	VA, 2013
[8]	AHRQ, 2011b
[9]	Patel et al., 2013
[10]	Malebranche, 2005

4. Training

Per the regulatory framework, OSHA would require that employers institute a training program and ensure each worker who has occupational exposure during provision of direct patient care and/or performance of other covered tasks participates in the program. OSHA would also require that training be provided initially, prior to the time of assignment to tasks where occupational exposure may take place, and that the initial training contain, at a minimum:

- An accessible copy of a rule as outlined in the regulatory framework and an explanation of its contents;
- A general explanation of the epidemiology and symptoms of common infectious diseases, including the signs and symptoms of infectious diseases that require further medical evaluation;
- An explanation of the modes of transmission of infectious agents and applicable infection control procedures;
- Information on vaccine(s) that will be made available to the worker;
- An explanation of the employer's WICP and the means by which the worker can obtain a copy of the written plan;
- Training on all of the SOPs developed as part of the WICP that are applicable to the worker's duties;
- An explanation of the use and limitations of engineering, administrative and work practice controls; and
- Information on the types, proper use, limitations, location, handling, decontamination, removal, and disposal of PPE.

The annual refresher training program, as presented in the regulatory framework, would be required to address at least the following elements:

- Information on the types, proper use, limitations, location, handling, decontamination, removal, and disposal of PPE.
- All of the SOPs developed as part of the WICP that are applicable to the worker's duties, and;

- Information on vaccination(s) that will be made available to the worker in the year of training.

OSHA preliminarily estimates that it would take a total of 30 hours for the individual who would be training exposed workers to develop training materials. The initial training is preliminarily estimated to take either two or three hours, depending on the job tasks of the workers, and the annual refresher training is also preliminarily estimated to take two or three hours, again depending on the job tasks of the workers.

Per the Draft Report on Current Compliance, and as shown in Table VI-10, OSHA preliminarily estimates that laboratories provide 86 percent of workers with appropriate training and that hospitals provide 84 percent of workers with appropriate training. Moreover, laboratories provide an estimated 79 percent of workers with annual refresher training, and hospitals provide an estimated 75 percent of workers with annual refresher training. Home healthcare and long term care and nursing homes also are estimated to have relatively high levels of compliance with training requirements. Home healthcare agencies provide an estimated 68 percent of workers with appropriate training, and long term care and nursing home establishments provide an estimated 72 percent of workers with appropriate training. Further, home healthcare agencies provide an estimated 50 percent of workers with annual refresher training, and long term care and nursing home establishments provide an estimated 54 percent of workers with annual refresher training. Employers in "other occupational settings," including morgues and mortuaries and waste handling and laundry services, provide only an estimated 23 percent of workers with appropriate training, and physicians' offices provide only an estimated 25 percent of workers with appropriate training; baseline compliance rates for annual refresher training are estimated to be only 14 percent and 18 percent in those settings, respectively. OSHA welcomes any feedback the SERs may have to offer on these preliminary estimates of current compliance.

5. Recordkeeping

Per the regulatory framework, OSHA would require employers to maintain the following records: medical records generated in conjunction with medical screening and surveillance (including evaluations, examinations, testing, follow-up, and vaccinations); exposure incident records; and WICP review records. In addition, OSHA's Respiratory Protection Standard (29 CFR 1910.134), discussed earlier in this section of the SER Background document, requires the employer to maintain records regarding medical evaluations, fit testing, and the respiratory protection program (29 CFR 1910.134(m). OSHA anticipates that a final rule as outlined in the regulatory framework would have costs associated with all of these recordkeeping provisions.

OSHA preliminarily concludes that there would be no additional costs associated with a provision of the regulatory framework that would require maintenance of WICP review records. The costs associated with reviewing and updating the WICP were addressed previously in this section of the SER Background Document. Likewise, the Agency preliminarily estimates that

there would not be any additional recordkeeping costs associated with a respiratory protection program, above the cost of the time to develop the program, which costs OSHA also addressed previously in this section of the SER Background Document.

OSHA preliminarily estimates that it would take 25 minutes to create and file records for each medical screening performed in conjunction with the medical screening and surveillance provisions of the regulatory framework. This estimate is based on estimates of 10 minutes to create a file for each new employee, as estimated in OSHA's 2010 ICR for bloodborne pathogens (OSHA, 2010), and 15 minutes for recordkeeping associated with initial medical screenings, as estimated in OSHA's PEA for the Proposed Rule on Silica (OSHA, 2013a). In addition, based on the 2011 ICR for OSHA's Respiratory Protection standard, the Agency preliminarily estimates that any medical evaluation, done for the purposes of evaluating a worker's ability to use a respirator, or as a result of a worker having a medical evaluation per the regulatory framework, would generate a medical record, which would take five minutes for a record-keeper to maintain (OSHA, 2011). For vaccinations, the time requirement is estimated to be 15 minutes per employee for a record-keeper to create and file a vaccination record (OSHA, 1991), or five minutes for the record-keeper to create and file a signed declination form. OSHA also preliminarily estimates that an additional five minutes per year, per employee will be necessary to update vaccination records in settings where workers would be required to get annual vaccines, such as the flu vaccine. For respirator fit-testing, the Respiratory Protection ICR suggests a recordkeeping unit cost of five minutes annually per fit test (OSHA, 2011).

OSHA preliminarily estimates that employers would spend 15 minutes generating and filing exposure incident records in accordance with a rule as outlined in the regulatory framework. The Agency estimated costs related to the investigation of exposure incidents earlier in this section of the SER Background Document, and estimates that the information potentially required in the exposure incident records would be collected during those investigations. The additional 15 minutes accounted for here is the time OSHA estimates it would take for an employer to transfer the information to a formal record and to file that record. OSHA notes that, per the regulatory framework, OSHA would require that each exposure incident record include a description of any post-exposure evaluations and follow-ups that were performed, the results of those evaluations, and the dates on which they occurred. As noted above, OSHA preliminarily estimates that it would take a record-keeper five minutes to maintain records related to medical evaluations, and any post-exposure evaluations and follow-ups that result from an exposure incident and that take place after the exposure incident record is initially generated will, likewise, take an additional five minutes to document (over the 15 minutes that OSHA preliminarily estimates would be needed to generate and file the exposure incident record).

OSHA requests comments on the time required to create, file, and maintain records that would be required under a rule as outlined in the regulatory framework.

C. Summary of Preliminary Estimates of Unit Costs

Table VI-9, below, presents all of OSHA's preliminary estimates of the potential unit costs of compliance that would be associated with provisions of a rule as outlined in regulatory framework for infectious diseases. OSHA discussed how these unit costs were derived throughout this section of the SER Background Document. To the extent SERs seek clarification about the entries in Table VI-9, they should refer to this discussion.

Table VI-9 Unit Cost Summary Table

Cost Category	Cost	Frequency	Comments/Assumptions
Worker Infection Control Plan			
Developing Plan	20-40 hours	One Time	Time varies depending on complexity of setting
Annual Update of Plan	4-16 hours	Annually	Time varies depending on complexity of setting
Standard Operating Procedures			
Hazard Evaluation	No extra cost	Per patient	Can be achieved with adjustments to current practice (cost of training is below)
Hand Hygiene (soap and water)	50 seconds	See Comments and Assumptions column	Before/after patient contact, also for certain other activities (contact with contaminated surfaces,inserting catheter, etc.)
Hand Hygiene (alcohol hand-rub)	25 seconds	See Comments and Assumptions column	Before/after patient contact, also for certain other activities (contact with contaminated surfaces, inserting catheter, etc.)
Restricted areas for employee eating and related activities	No extra cost	One time	Estimated to already be in place
Setting up triage stations/Separate areas for suspected/confirmed cases	No extra cost	One time	Can be achieved with adjustments to current practice
Decontamination of materials/surfaces	No extra cost	As established by employer's SOPs	Can be achieved with adjustments to current practice (cost of training is below)
Handling, containerization, transport, or disposal of contaminated materials	No extra cost	Per Event	Can be achieved with adjustments to current practice (Often already covered by Bloodborne Pathogens Standard)
Exposure Incident Investigation	30 minutes	Per incident	
Signage and Labeling/Color Coding	No extra cost	Wherever needed to convey hazard warning	Can be achieved with adjustments to current practice (Often already covered by Bloodborne Pathogens Standard)
Patient Scheduling and Intake	No extra cost	As established by employer's SOPs	Can be achieved with adjustments to current practice (cost of training is below)
Patient Transport Procedures	No extra cost	Per patient requiring transport	Settings where applicable would already follow appropriate procedures, or need simple adjustment to current practice

Table VI-9 Unit Cost Summary Table, continued			
Cost Category	**Cost**	**Frequency**	**Comments/Assumptions**
Upgrade and Maintenance of Existing Engineering Controls			
Upgrade Airborne Infection Isolation Room (AIIR)	$7,217	One time	Only necessary for existing AIIRs that are being used for isolation purpose
Annual Maintenance AIIR	$866	Annually	
Upgrade Autopsy Suite	$14,435	One time	
Annual Maintenance Autopsy Suite	$1,732	Annually	
Upgrade Biological Safety Cabinet (BSC)	$809	One time	Only necessary for existing BSCs that are being used for containment purposes
Annual Maintenance BSC	$97	Annually	
Personal Protective Equipment			
Disposable Gloves	$0.16	When employee interacts with new patient and when gloves become visibly soiled. Also handling of contaminated items (e.g., linens, biohazard waste, used medical equipment)	
Face Mask (e.g., Surgical Mask)	$0.13	When encounter a suspected or confirmed case of droplet transmissible disease, and when facemask is visibly soiled	For all HCWs and for patients with suspected or confirmed droplet transmissible diseases who can tolerate a facemask
N95 Respirator	$0.33	When encounter a suspected or confirmed case of airborne transmissible disease, during aerosol generating procedures, and when N95 respirator is visibly soiled	
Disposable Gown	$2.42	When employee is at risk of skin or clothes becoming contaminated. Also when working in an Airborne Infection Isolation Room	
Disposable Face Shield	$4.55	Mainly when employee potentially exposed to droplet spray and during aerosol-generating activities	
Safety glasses, goggles	$2.05	When employee potentially exposed to splashes or sprays. Also during aerosol-generating activities	

Table VI-9 Unit Cost Summary Table, continued			
Cost Category	**Cost**	**Frequency**	**Comments/Assumptions**
Respiratory Protection			
Written Plan Development	4-8 hours	One time, all employers whose employees wear respirators	Time varies depending on complexity of setting
Written Plan Review and Update	2-4 hours	Annually	Time varies depending on complexity of setting
Initial Medical Questionnaire, or Re-evaluation for change in working conditions			
Employee's time	15 minutes	Per employee completing a questionnaire	Only necessary when the employee is required to wear a respirator. If must travel off site then another 30 minutes of employee time plus $5
PLHCP's time	5 minutes	Per employee completing a questionnaire	
Followup Medical Examination (if needed)	$294.75	Per employee	Plus one hour of employee time. As needed from initial examination, or change in work conditions. If must travel off site then another 30 minutes of employee time plus $5 travel costs
Additional Medical Re-evaluation	$138	Per employee	For new or worsening health condition. Plus 30 minutes employee time. If must travel off site then another 30 minutes of employee time plus $5 travel costs
Respirator Fit Testing			
Manufacturer	30 minutes	Per employee	Cost represents employee time
In-house	$1.15	Per employee	Plus 30 minutes employee time plus 30 minutes tester's time.
Third party testing	$76.68	Per employee	Plus half hour employee time
Vaccines			
Influenza	$13.13	Annually	Also 5 minutes of employee time and 5 minutes of PLHCP time. If must travel off site then another 30 minutes of employee time plus $5 travel
MMR	$54.07	One time, if born after 1957 with no serologic immunity.	Also 5 minutes of employee time and 5 minutes of PLHCP time. If must travel off site then another 30 minutes of employee time plus $5 travel
Varicella	$181.10	One time, if no previous history of disease and no serologic immunity.	Also 5 minutes of employee time and 5 minutes of PLHCP time. If must travel off site then another 30 minutes of employee time plus $5 travel
Tdap	$39.31	One time if never vaccinated/ booster every 10 years	Also 5 minutes of employee time and 5 minutes of PLHCP time. If must travel off site then another 30 minutes of employee time plus $5 travel
Meningococcal	$111.83	One time, as needed	Also 5 minutes of employee time and 5 minutes of PLHCP time. If must travel off site then another 30 minutes of employee time plus $5 travel
Typhoid	$24.87	One time, as needed/ then booster every 5 years if vaccine Ty21a, booster every 2 years if vaccine ViCPS	Also 5 minutes of employee time and 5 minutes of PLHCP time. If must travel off site then another 30 minutes of employee time plus $5 travel costs
Inactivated Polio	$23.18	One time, as needed	Also 5 minutes of employee time and 5 minutes of PLHCP time. If must travel off site then another 30 minutes of employee time plus $5 travel

Table VI-9 Unit Cost Summary Table, continued			
Cost Category	**Cost**	**Frequency**	**Comments/Assumptions**
Medical Screening and Surveillance			
Pre-placement Health Inventory			
Employee's time	25 minutes	Per new employee	If must travel off site then another 30 minutes of employee time plus $5 travel costs
PLHCP's time	15 minutes	Per new employee	
TB Test (if required)	$43-$299	Per employee	Also 0.5 – 1.5 hours of employee time. Either one-step, two step, or IGRA test. If must travel off site then another 30 minutes of employee time plus $5 travel costs
Full Pre-placement Physical (not required)	$175	Per employee	At employer's discretion. Also one hour employee time. If must travel off site then another 30 minutes of employee time plus $5 travel costs
Medical Evaluation, Follow-up, and Medical Removal Protection			
Influenza			
Vaccination	$13.13	Per infected worker	If previously without vaccination
Zanamivir or Oseltamivir Medication	$57.52/$80.53	Per infected worker	Either medication can be recommended
Rapid Influenza Diagnostic Test	$105	Per infected worker	If needed
Latent Tuberculosis			
Chest X-ray	$44	Per infected worker	If indicated. Add 30 minutes of employee time to cost. If must travel off site then another 30 minutes of employee time plus $5 travel costs
Initial PLHCP Examination	$138	Per infected worker	If needed. Add 30 minutes of employee time. If must travel off site then another 30 minutes of employee time plus $5 travel costs
Isoniazid or Rifampin Drug Treatment	$2.70-$218.62	Per infected worker	Either medication can be recommended. 4-9 month period
Liver Injury Test	$1,105/$1,657	Per infected worker	Monthly Test. Either 6 or 9 months
Active Tuberculosis			
Initial Drug Treatment	$276.29	Per infected worker	8 weeks of all 4: isoniazid, rifampin, ethambutol, and pyrazinamide
Followup Drug Treatment- Isoniazid and Rifampin	$67.46/$236.10	Per infected worker	18 weeks: either daily or twice weekly doses
Hospitalization	$12,578/$42,237	Per suspected/confirmed case	4 to 8.3 days, including hospital tests/treatment. Also Medical Removal Protection Benefits during this time period plus an additional 3-4 weeks

Table VI-9 Unit Cost Summary Table, continued

Cost Category	Cost	Frequency	Comments/Assumptions
Medical Evaluation, Follow-up, and Medical Removal Protection			
MRSA			
Wound Culture Screening	$48.88-$181.69	Per infected worker	Up to 3 rounds of screening tests. If must travel off site then another 30 minutes of employee time plus $5 travel costs
Abscess Draining	$329-$650	Per infected worker	Depending on complication of procedure. Also 60 to 90 minutes of employee time. If must travel off site then another 30 minutes of employee time plus $5 travel costs
Hospitalization (for serious cases)	$25,262-$62,051	Per infected worker	6 to 9 days of hospitalization, depending on complications. Also Medical Removal Protection Benefits during this time period
Drug Treatment	$9.43-47.04	Per infected worker	Various possible treatments, see text
Training			
Developing Training Materials	30 hours	One time	
Employee Training Time	2-3 hours	Annually	Both for initial training and annual refresher training
Record Keeping			
Medical Screening Record Keeping	25 minutes	Per employee	10 minutes to create employee file, 15 minutes for recording screening
Medical Record	5 minutes	Per medical record generated	Record of any medical evaluation
Vaccination Record	15 minutes	Per employee	Or 5 minutes if need to file employee declination form. Also 5 minutes each year for any annual vaccines
Respirator Fit Test Record	5 minutes	Per employee	
Exposure Incident Record	15 minutes	Per incident	In connection with exposure incident investigation

OSHA, Office of Regulatory Analysis. See text for sources.

D. Preliminary Estimates of Baseline Compliance Rates

Table VI-10, below, presents OSHA's preliminary estimates of current compliance with selected provisions of the regulatory framework for infectious diseases. OSHA described how it generated these preliminary estimates in the Introduction to this section of the SER Background Document.

Table VI-10

Preliminary Estimates of Current Compliance with Selected Provisions of the Conceptual Framework on Infectious Diseases

Question	Hospitals	Physicians' Offices	Dentists' Offices	Other Ambulatory Care Settings	Long Term Care & Nursing Homes	Home Healthcare Agencies	Laboratories	Other Occupational Settings
What percentage of establishments have a written infection control plan (WICP)?	94%	42%	54%	49%	90%	62%	90%	39%
What percentage of establishments review their ICP on an annual basis?	77%	16%	18%	34%	63%	49%	70%	12%
What percentage of establishments have implemented procedures to promptly identify patients with a range of suspected or confirmed infectious diseases?	81%	51%	28%	56%	79%	43%	62%	20%
What percentage of the time do workers practice proper hand hygiene?	58%	51%	66%	57%	56%	63%	80%	34%
What percentage of establishments with AIIRs maintain them so that they meet industry standards?	83%	--	--	--	--	--	--	--
What percentage of establishments that have biological safety cabinets have them certified at least annually?	91%	--	--	--	--	--	94%	--
What percentage of establishments that perform autopsies maintain autopsy suites to a level that meets industry standards?	83%	--	--	--	--	--	--	58%
What percentage of the time do workers with exposure to infectious patients or materials use appropriate PPE?	76%	46%	76%	54%	56%	58%	86%	35%
What percentage of the time do workers who are exposed to potential airborne transmissible infectious agents wear the appropriate respirators?	64%	29%	38%	33%	51%	57%	85%	26%
In settings where some or all workers are required to wear a respirator, what percentage of establishments provide fit testing to those workers prior to their initial use of a respirator?	84%	23%	36%	39%	41%	43%	86%	17%

Table VI-10, continued

Preliminary Estimates of Current Compliance with Selected Provisions of the Conceptual Framework on Infectious Diseases

Question	Hospitals	Physicians' Offices	Dentists' Offices	Other Ambulatory Care Settings	Long Term Care & Nursing Homes	Home Healthcare Agencies	Laboratories	Other Occupational Settings
What percentage of establishments provide annual fit testing to workers who wear respirators?	61%	14%	16%	30%	29%	21%	57%	15%
What percentage of establishments provide medical clearance to affected workers before they are fit tested for or required to use a respirator in the workplace?	84%	20%	26%	26%	38%	27%	71%	15%
What percentage of facilities properly clean and disinfect surfaces in accordance with their ICP or other applicable guidelines?	71%	35%	51%	34%	47%	44%	71%	25%
What percentage of the time do employers document recognized occupational exposure incidents involving infectious agents not covered by OSHA's BBP standard?	82%	34%	30%	47%	64%	49%	85%	29%
What percentage of the time do employers generate medical records for workers with occupational exposure to infectious agents not covered by OSHA's BBP standard?	71%	21%	17%	31%	33%	31%	66%	30%
What percentage of establishments offer their workers the full complement of CDC/ACIP or CDC/NIH BMBL recommended vaccines?	85%	33%	30%	37%	42%	42%	72%	29%
What percentage of establishments make only the vaccines required by their applicable state level health department available to their workers?	60%	52%	51%	67%	77%	72%	72%	69%
What percentage of workers are provided a full physical and/or a verbal or written questionnaire as part of their medical screening prior to their placement?	70%	19%	13%	16%	51%	46%	47%	10%

Table VI-10, continued

Preliminary Estimates of Current Compliance with Selected Provisions of the Conceptual Framework on Infectious Diseases

Question	Hospitals	Physicians' Offices	Dentists' Offices	Other Ambulatory Care Settings	Long Term Care & Nursing Homes	Home Healthcare Agencies	Laboratories	Other Occupational Settings
What percentage of workers are provided pre-placement diagnostic testing as part of their medical screening prior to placement?	90%	28%	26%	41%	46%	45%	71%	17%
Where CDC/HICPAC guidelines recommend PEP such as medications, vaccines or immune globulins, please estimate what percentage of time employers provide the recommended PEP.	91%	48%	44%	62%	68%	66%	86%	32%
What percent of time do employers provide post-exposure testing?	88%	44%	45%	58%	68%	64%	86%	34%
When a worker has a known or suspected infectious disease, what percentage of the time dp employers restrict the worker's normal duties and assign alternative job duties?	77%	44%	45%	49%	60%	46%	66%	23%
When a worker has a known or suspected infectious disease, what percentage of employers direct the worker not to come to work?	59%	29%	35%	30%	48%	50%	49%	27%
Where establishments or employers direct employees with known or suspected infectious diseases not to come to work, what percentage of the time are those workers provided with their normal pay and benefits during the restricted time	84%	60%	65%	67%	63%	45%	72%	41%
What percentage of workers are provided with appropriate training?	84%	25%	33%	41%	72%	68%	87%	23%
What percentage of workers are currently being provided refresher training on infection control practices at least annually?	75%	18%	16%	24%	54%	50%	79%	14%

Source: ERG, 2013

Section VII. Description of Any Duplicative, Overlapping, or Conflicting Rules

The Regulatory Flexibility Act (RFA) requires that the Agency's "initial regulatory flexibility analysis . . . identif[y], to the extent practicable, [] all relevant Federal rules which may duplicate, overlap or conflict with the proposed rule." 5 U.S.C. 603(b)(5). (Separately, the OSH Act does not apply to "working conditions" of workers with respect to which another federal agency has "exercise[d] statutory authority to prescribe or enforce standards or regulations affecting occupational safety or health." 29 U.S.C. 653(b)(1).)

OSHA has not yet developed a proposed rule addressing occupational exposure to infectious diseases. However, as discussed in prior sections of the SER Background Document, OSHA has developed a regulatory framework showing its preliminary thinking on what a proposed rule would encompass. OSHA has identified several federal rules and guidelines that address infection control. Below, the Agency discusses whether these rules and guidelines would duplicate, overlap, or conflict with a rule as outlined in the regulatory framework.

The first set of federal rules or guidelines that OSHA identified are guidelines promulgated by CDC/HICPAC (CDC, 1998). The CDC/HICPAC guidelines include provisions for: identification and isolation of infectious cases; immunizations for vaccine-preventable diseases; standard and transmission-based precautions; training; PPE; management of healthcare workers' risk of exposure to infected persons, including post-exposure prophylaxis; and work restrictions for exposed or infected healthcare personnel (Bolyard et al., 1998; *see also, e.g.*, Siegel et al., 2007).

While the CDC/HICPAC guidelines present recommended practices for reducing the risk of infectious disease transmission to patients and workers, the guidelines are non-mandatory. Such non-mandatory guidelines do not constitute rules that would duplicate, overlap, or conflict with a rule as outlined in the regulatory framework. *Cf. Ensign-Bickford Co. v. OSHRC*, 717 F.2d 1419, 1421 (D.C. Cir. 1983) (agency regulates working conditions only if it "implements [a] regulatory apparatus"); *Marshall v. Northwest Orient Airlines, Inc.*, 574 F.2d 119 (2d Cir 1978) ("sister agency must actually be exercising a power to regulate safety conditions").

There also would be no conflict between a rule as outlined in the regulatory framework and the CDC/HICPAC guidelines because a rule as outlined in the regulatory framework would be performance-based and is, in fact, intended to assure that employers adopt and implement infection control practices consistent with the CDC/HICPAC guidelines. Such a rule would require employers having workers covered by the rule to develop, implement, and update SOPs that are consistent with recognized and generally accepted good infection control practices

relevant to their work setting. To determine whether SOPs are consistent with recognized and generally accepted good infection control practices, the employer would have to consider applicable regulations, such as state and local regulations, and current guidelines, such as the CDC/HICPAC guidelines. Moreover, in the absence of such regulations and guidelines, the employer would need to consider current guidance issued by professional organizations and accrediting bodies. As such, a rule as outlined in the regulatory framework would allow employers to incorporate appropriate CDC/HICPAC guidelines into their infection control programs. Therefore, OSHA concludes that the CDC/HICPAC guidelines would not duplicate, overlap, or conflict with such a rule.

The second set of federal rules or guidelines that OSHA identified are Centers for Medicare and Medicaid Services (CMS) regulations that condition a provider's participation in Medicare or Medicaid on the provider's implementation of an infection control program.[55] CMS interpretive guidelines say that, to meet this condition, providers should ensure that their infection control programs conform to nationally-recognized infection control practices and guidelines, such as the CDC/HICPAC guidelines.[56] CMS regulations do not cover providers that do not accept or collect payment through Medicare or Medicaid. However, they do cover health care providers that accept or collect payment through Medicare or Medicaid (which requires a certification, that involves an inspection covering infection control procedures as they affect patient safety in order to participate), including hospitals, nursing homes, home health care (of kinds covered by Medicare), hospices and ambulatory care facilities providing hospital-like services, such as ambulatory surgical centers and specialty clinics. The CMS regulations do not cover employers engaged in some other covered tasks that take place in facilities where direct patient care is not also provided, such as those that occur in research or production laboratories and death care facilities

A rule as outlined in the regulatory framework would not conflict with the CMS regulations. To the contrary, the joint effect of the CMS regulations and a new OSHA rule would improve the quality and implementation of infection control programs in a manner that the CMS regulations cannot do, and have not done, alone. The Joint Commission (a CMS-approved accreditation organization) recognizes the need to improve the quality and implementation of infection control programs. (See for example http://www.centerfortransforminghealthcare.org/assets/4/6/hand_hygiene_storyboard.pdf). Moreover, other evidence OSHA has examined thus far (some of which is discussed in Section III, above) indicates that, notwithstanding the CMS regulations, many employers receiving

[55]See, e.g., 42 CFR 482.42 (hospitals), 483.65 (long term care facilities), 483.470(l) (intermediate care facilities for individuals with intellectual disabilities), 485.62(b) (outpatient rehabilitation facilities).
[56]See, e.g., CMS State Operations Manual App. A – Survey Protocol, Regulations and Interpretive Guidelines for Hospitals, App. PP - Guidance to Surveyors for Long Term Care Facilities, App. J - Guidance to Surveyors: Intermediate Care Facilities for Persons With Mental Retardation (CMS, 2013a).

Medicare and Medicaid funding are not fully conforming to nationally recognized infection control practices and guidelines.

OSHA has, at its disposal, enforcement mechanisms that CMS does not have. For example, OSHA can respond to complaints and conduct random unannounced inspections. On the other hand, the CMS regulations establish the terms of a contractual or quasi-contractual agreement between CMS and a provider. A provider agrees to implement an infection control program in exchange for the right to participate in Medicare and Medicaid. *Cf. Ensign-Bickford Co.*, 717 F.2d at 1421 n.3 (noting that the repercussions of violating a contractual agreement "stand[] in sharp contrast to the civil and criminal penalties provided for in the [OSH] Act"). Compliance with the CMS regulations is generally validated through periodic accreditation surveys of the employer's facility by CMS-approved accreditation organizations, including the Joint Commission, state survey agencies, and other organizations that specialize in accrediting various types of healthcare facilities (e.g., Accreditation Association for Ambulatory Health Care (AAAHC)).

The joint effect of OSHA and CMS enforcement can reasonably be expected to result in better compliance than either one alone. This conclusion is borne out by the joint effect of CMS's enforcement of its infection control regulations alongside OSHA's enforcement of its existing Bloodborne Pathogens standard – a regime that has been in place for over twenty years. As noted in Section III, the Bloodborne Pathogens standard, which has existed alongside the CMS regulations since its promulgation, led to significant declines in bloodborne diseases among healthcare workers.

A rule as outlined in the regulatory framework would also not conflict with the CMS regulations because such a rule, like the CMS regulations, would allow employers to incorporate into their infection control programs appropriate nationally-recognized infection control practices and guidelines, such as the CDC/HICPAC guidelines. Thus, such a rule would complement the CMS regulations and would be likely to improve overall compliance with infection control practices.

The third set of federal rules or guidelines that OSHA identified are a group of identical regulations for research that require the protection of human subjects and that were jointly promulgated by fifteen federal agencies, including HHS,[57] the Department of Veterans Affairs,[58] and the Environmental Protection Agency (EPA).[59] 56 FR 28003 (June 18, 1991). Pursuant to those regulations, when research involving human subjects is conducted, supported, or otherwise subject to regulation by a federal department or agency, an Institutional Review Board (IRB)

[57]45 CFR Pt. 46.
[58]38 CFR Pt. 16.
[59]40 CFR Pt. 26.

must review and approve the research and determine that the risks to the subjects are minimized.[60]

Unlike a rule as outlined in the regulatory framework, the regulations requiring the protection of human subjects do not necessarily require the protection of workers. That an individual protocol reviewed and approved by an IRB may address worker protection does not mean the regulations themselves address working conditions. Due to these factors, OSHA concludes that the regulations requiring the protection of human subjects would not duplicate, overlap, or conflict with a rule as outlined in the regulatory framework.

A rule as outlined in the regulatory framework would also not conflict with the regulations requiring the protection of human subjects because such a rule would permit employers conducting research on infection control practices to consider research protocols that are not consistent with recognized and generally accepted good infection control practices, provided those protocols have been approved by an IRB and adequately address worker protection as a component of the overall protection of the human subjects. A rule as outlined in the regulatory framework would therefore complement the regulations requiring the protection of human subjects.

The fourth set of federal rules or guidelines that OSHA identified are Department of Transportation (DOT) regulations that address the safe transport of hazardous materials, including infectious agents.[61] These requirements contain provisions regulating, among other things, the containerization, packaging, marking, labeling, and placarding of these materials.

The fifth set of federal rules or guidelines that OSHA identified are EPA regulations, promulgated pursuant to the Clean Air Act (42 U.S.C. 7401 *et seq.*), governing emissions from hospital/medical/infectious waste incinerators.[62] The regulations require that the training of incinerator operators cover, among other things, "work safety procedures."[63]

The sixth set of federal rules or guidelines that OSHA identified are EPA guidelines contained in its Guide for Infectious Waste Management. These guidelines address primarily decontamination, but also address several other areas, including packaging, storage, and transport of infectious waste, as well as disposal of treated waste (EPA, 1986).

OSHA concludes that there may be some duplication or overlap between the DOT regulations, and the EPA regulations and guidelines, and a rule as outlined in the regulatory framework. However, OSHA believes that, unlike these regulations and guidelines, an OSHA rule would

[60]*See*, *e.g.*, 45 CFR 46.101(a), 46.103(b), 46.109, 46.111(a).
[61]49 CFR Parts 171 through 180.
[62]40 CFR Pt. 60 Subpts. Ce, Ec; Pt. 62 Subpt. HHH
[63]40 CFR 60.53c

protect workers in a comprehensive manner. A rule as outlined in the regulatory framework would address, not only the training of workers, or the decontamination, transport, containerization, packaging, marking, labeling, and placarding of infectious agents, but myriad other means of protecting workers against the hazards associated with exposure to infectious agents (such as, the provision in the regulatory framework addressing the development and implementation of a written worker infection control plan designed to prevent or minimize the transmission of infectious agents to each worker).[64] The DOT regulations, and the EPA regulations and guidelines, also would not conflict with a rule as outlined in the regulatory framework because, again, such a rule would be performance-based.[65]

The final set of federal rules or guidelines that OSHA identified are existing OSHA standards, including: the Bloodborne Pathogens standard (29 CFR 1910.1030); the Respiratory Protection standard (29 CFR 1910.134); the Personal Protective Equipment standard (29 CFR 1910.132); and the Specifications for Accident Prevention Signs and Tags standard (29 CFR 1910.145). All of these existing standards would remain in place unless otherwise stated in a rule as outlined in the regulatory framework.[66]

The Agency believes that the Bloodborne Pathogens standard would not be duplicative, overlapping, or conflicting with a rule as outlined in the regulatory framework for the following reason: a rule as outlined in the regulatory framework addresses occupational exposure to infectious agents transmitted by contact, droplet and airborne routes other than occupational exposure as defined by the Bloodborne Pathogens standard. OSHA notes that an employer's implementation of a rule as outlined in the regulatory framework may be streamlined in light of the infection control procedures already required by the Bloodborne Pathogens standard.

OSHA believes that an Infectious Diseases rule would help assure that all employers comply with these diverse requirements as part of a comprehensive duty to protect workers from the hazards associated with exposure to infectious agents. If OSHA finds, through the rulemaking process, that some provisions of existing standards become duplicative, unclear, or confusing, it

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[64]While OSHA's authority to regulate working conditions is generally restricted by §4(b)(1) of the OSH Act, which states that "[n]othing in this Act shall apply to working conditions of employees with respect to which other Federal agencies . . . exercise statutory authority to prescribe or enforce standards or regulations affecting occupational safety or health," 29 U.S.C. 653(b)(1), the statutes authorizing the EPA regulations and the DOT regulations each contain a reverse-preemption provision. 42 U.S.C. 7610(a); 49 U.S.C. 5107(g)(2).

[65]OSHA notes, moreover, that the EPA guidelines are non-mandatory. As stated above, non-mandatory guidelines, such as the EPA guidelines, do not constitute rules that would duplicate, overlap, or conflict with a rule as outlined in the regulatory framework.

[66]For example, in OSHA's regulatory framework it is noted that:

> Infection control practices normally rely upon a multi-layered and overlapping strategy of employing engineering, work practice, administrative controls, and PPE. Therefore, OSHA would permit adherence to the required hierarchy of controls, such as that required in 29 CFR 1910.134(a)(1), to be modified in accordance with recognized and generally accepted good infection control practice.

may choose to modify the requirements of some existing standards or to modify a proposed Infectious Diseases standard. OSHA will seek comment during the SBAR process and throughout the rulemaking on provisions that may need to be modified.

Section VIII. Description of Regulatory Alternatives and Options

I. Introduction

Per Section 603(c) of the RFA, if OSHA proposes a rule based on its regulatory framework, it must, in its Initial Regulatory Flexibility Analysis, describe any significant alternatives to the proposed rule that accomplish the stated objective of the OSH Act to "assure so far as possible every working man and woman in the Nation safe and healthful working conditions, 29 USC 651(b), and, at the same time, minimize any significant economic impact of the proposed rule on small entities. To this end, in Part II of this section, and pursuant to Section 609(b) of the RFA, OSHA asks SERs to suggest to the Panel alternatives to the regulatory framework that they believe would accomplish the OSH Act's protective purpose and minimize any significant economic impact on small entities. In Part II, OSHA also asks SERs to suggest to the Panel regulatory options associated with promulgating an infectious diseases standard. While these options are not alternatives for purposes of the RFA, OSHA believes that discussing these options at this stage will aid the rulemaking process.

Part III of this section describes regulatory alternatives to the regulatory framework that the Panel developed that would minimize the significant economic impact on small entities. To allow the SERs to fully understand these alternatives, OSHA provides the SERs with any preliminary determinations the Agency has made about whether the alternatives would accomplish the stated objective of the Act. OSHA asks SERs to comment on these alternatives and OSHA's preliminary determinations to help the Agency make an informed judgment about whether these alternatives would sufficiently protect employee health.

Part IV of this section examines regulatory options that OSHA is considering. OSHA asks SERs to comment on these options and OSHA's preliminary determinations about these options to help the Agency make an informed judgment about whether these options would sufficiently protect employee health.

II. OSHA Asks SERs to Suggest Alternatives and Options

As discussed in the issues paper attached to the SER Background Document, SERs are invited to suggest alternatives and options of their own choice, based on their view of what works and is needed in their kind of facility and what does not work or is unnecessary. The Panel is particularly interested in comments on whether portions of the regulatory framework would have significant costs, but little or no benefit, in a particular kind of facility. The Panel is also interested in comments from SERs indicating those provisions of the regulatory framework they do not already follow, why they do not follow those provisions, and the anticipated costs of

implementing those provisions.[67]

In addition, OSHA is interested in feedback from the SERs on the necessity and usefulness of individual provisions in the regulatory framework. To this end, OSHA asks SERs to respond to the following question:

- What provisions, if any, do you believe you would have to implement as a result of this potential rule that, in your opinion, would not improve worker safety?

Finally, the Agency is interested in the SERs' views on whether there are additional provisions, not contained in the regulatory framework, that are necessary in order to improve worker safety. To this end, OSHA asks SERs to respond to the following question:

- What, if any, additional provisions do you think should be added to the framework, and why?

In commenting on the rule's specific provisions, OSHA asks SERs to keep in mind that elimination of provisions in the regulatory framework would not impact requirements contained in existing standards. For example, as explained in Section IV, Description of the Important Components in the Regulatory framework, the Respiratory Protection standard (29 CFR 1910.134) generally applies to the use of respirators by workers performing tasks that would be covered by a rule as outlined in the regulatory framework. The applicability of, and costs associated with complying with, the Respiratory Protection standard do not depend on the inclusion in the regulatory framework of respiratory protection provisions. Moreover, OSHA's Bloodborne Pathogens standard (29 CFR 1910.1030) contains requirements related to the safe handling, processing, storage, transport, shipping and disposal of contaminated materials. The applicability of, and costs associated with complying with, the Bloodborne Pathogens standard do not depend on the inclusion of such provisions in the regulatory framework.

III. Alternatives to the Regulatory framework That Would Minimize Any Significant Economic Impact of the Proposed Rule on Small Entities

Alternative 1 would develop an infectious diseases rule that is specification-oriented rather than performance-oriented.

The regulatory framework is a flexible, performance-oriented approach that reflects what OSHA believes conscientious employers are already doing. Under this alternative, OSHA would

[67] Many employers who have provided comment to the Agency thus far have objected to the promulgation of a rule on the grounds that they already follow most of what OSHA would require. If this is the case, the costs of a rule for these particular employers would be minimal.

promulgate a specification-oriented standard (i.e., an approach that spells out exactly what employers must do to comply with the standard). Such a specification-oriented approach would provide less flexibility, but greater clarity, than a performance-oriented approach.

A rule as outlined in the regulatory framework would require affected employers to assess the infectious disease hazards present in their facilities, and develop and implement appropriate infection control plans that are relevant to those hazards. Infection control plans would also need to be consistent with recognized and generally accepted control practices, which OSHA recognizes, are generally contained in regulations and guidelines, such as the 2007 CDC/HICPAC guidelines (Siegel et al., 2007) and the BMBL guidelines (CDC/NIH, 2009). Therefore, under this possible approach, OSHA would require employers to consider applicable regulations and guidelines in developing their infection control plans. OSHA believes this possible approach offers employers a significant amount of flexibility, since development and implementation of an infection control plan would be dependent on the hazards present. For instance, the Agency believes it is unlikely that a podiatrist's office would need to develop and implement a respiratory protection program under the regulatory framework.

OSHA believes that, in promulgating a specification-oriented infectious diseases rule, the Agency would likely fail to anticipate all of the potential hazards, and, therefore, all of the necessary controls, for every type and every size of facility. As such, such a rule would under-protect workers to the extent the rule did not include specifications to address particular hazards. Similarly, a specification-oriented approach would likely result in requiring employers to implement some protective measures that are not applicable to their facilities.

While structuring an OSHA standard using performance-based language, such as the language presented in the regulatory framework, has distinct advantages, such a rule also is not without some drawbacks. Because the rule does not lay out explicit requirements for each type of affected firm, employers must develop and implement their own infection control plans. OSHA believes that the affected firms have sufficient familiarity with infection control practices to meet these requirements, but the Agency is interested in the views of the SERs.

Specifically, OSHA is interested in whether SERs would find it difficult to determine how a rule based on the regulatory framework would apply in their facilities, or how OSHA would enforce the performance-oriented provisions in the regulatory framework. OSHA is also interested if SERs think that OSHA should promulgate a specification-oriented standard that spells out exactly what employers must do to comply with each provision. OSHA also asks SERS to respond to the following questions:

- Do SERS find the performance-based approach outlined in the regulatory framework to be flexible?

- How could OSHA structure a potential rule in order to provide additional flexibility?
- Do you feel confident that you could interpret the potential requirements included in the regulatory framework well enough to be in compliance with an infectious diseases rule?
- Do you understand what needs to be done at your facility when a provision is not applicable to your setting?
- Are there any specific provisions that you believe are unclear that OSHA should clarify or eliminate?
- Are there areas where greater specification would be useful (i.e., for certain types of facilities or for certain provisions)?
- What compliance assistance could OSHA provide if a rule as outlined in the regulatory framework were promulgated to best help small entities comply in the least burdensome manner?

Alternative 2 would rely on enforcement under the General Duty Clause.

OSHA would decide not to promulgate a new rule addressing occupational exposure to infectious diseases. Instead, OSHA would issue guidance on workplace exposures to infectious diseases recommending that employers follow current guidelines, such as those issued by the CDC, CDC/HICPAC, and NIH, and then attempt to protect workers exposed to infectious agents through enforcement of the OSH Act's General Duty Clause (29 USC 654(a)(1)). The General Duty Clause requires "[e]ach employer" to "furnish to each of his employees employment and a place of employment which are free from recognized hazards that are causing or are likely to cause death or serious physical harm to his employees" (*id.*). To establish that an employer exposed its employees to infectious disease hazards in violation of the General Duty Clause, OSHA would need to establish, in part, that the hazard was recognized and that a feasible and useful method exists to correct the hazard. For example, OSHA would show that an employer had knowledge of, and would have followed, applicable federal, state and local regulations, and current guidelines.[68]

OSHA does not believe that this approach would adequately protect workers with occupational exposure to infectious diseases. A rule based on the regulatory framework would require employers to, among other things, develop and follow worker infection control plans, conduct medical surveillance, and provide medical removal protection benefits. Some elements of the regulatory framework go beyond what is addressed in current regulations and guidelines. OSHA believes that all of the provisions of the regulatory framework would work in concert to minimize the spread of infectious disease to workers; the use of enforcement actions under the

[68] *See, e.g., Kelly Springfield Tire Co. v. Donovan*, 729 F.2d 317, 320-21 (5th Cir. 1984); *Georgia Elec. Co. v. Marshall*, 595 F.2d 309, 320-21 (5th Cir. 1979).

General Duty Clause would be a much less comprehensive approach to addressing workplace exposures to infectious diseases. Thus, the promulgation of a rule based on the regulatory framework would be more protective of employee health than enforcement based on the General Duty Clause. In addition, federal enforcement of the General Duty Clause would not necessarily protect employees in the 25 states and 2 U.S. Territories that operate their own OSHA-approved occupational safety and health plans; even though all state plan states have adopted statutory provisions that are comparable to the OSH Act's General Duty Clause, they were not required to do so, and need not enforce such statutory provisions to the same extent as federal OSHA. (State plans *do* need to promulgate standards that are at least as effective as standards promulgated by federal OSHA.) And finally, enforcement solely through the General Duty Clause is disfavored because it can impose heavy litigation burdens on both OSHA and employers.

Given the limitations associated with enforcement under the General Duty Clause, choosing this non-regulatory alternative would not do as much to accomplish the goals of the OSH Act as the promulgation of a comprehensive standard on workplace exposures to infectious diseases. Thus, OSHA does not believe this would be a desirable approach as long as there is a viable rulemaking alternative (see Section II, Legal Basis for an OSHA Standard Addressing Occupational Exposure to Infectious Diseases). OSHA welcomes comments from SERs on non-regulatory alternatives. In commenting on this issue, OSHA asks SERs to examine the preliminary conclusions OSHA made in Section III of this SER Background Document, Reasons Why Action by the Agency is Being Considered. For example, SERs may examine and comment on the evidence on which OSHA based its preliminary conclusions that: (1) there is a well-recognized risk to workers associated with exposure to infectious agents during the provision of direct patient care and/or performance of other covered tasks; (2) current infection control guidelines are non-mandatory, are not consistently and rigorously followed, and therefore are not sufficient to adequately reduce the risk of transmission of infectious agents to workers who provide direct patient care and/or perform other covered tasks; and (3) following recognized and generally accepted good infection control practices considerably reduces the risk of transmission of infectious agents to workers providing direct patient care and/or performing other covered tasks.

Alternative 3 would exempt very small entities (those with fewer than 20 workers) from all requirements of an infectious diseases rule.

Under this alternative, very small entities (i.e., entities with fewer than 20 workers) would be exempted from all requirements of an infectious diseases rule. Approximately 87 percent of the 637,000 entities that OSHA has preliminarily determined to be affected by a rule as outlined in the regulatory framework are very small establishments with fewer than 20 workers. Approximately 1.5 million of the estimated 9 million workers affected by a rule as outlined in the regulatory framework work in very small entities. Thus, exempting very small entities from

all requirements of an infectious diseases rule would result in only about 82,000 entities and 7.5 million workers remaining in the scope.

OSHA believes strongly that exempting workers based solely on the size of their employer's firm is inconsistent with the objectives of the OSH Act. Congress emphasized in the OSH Act, without reference to the size of individual firms, "every working man and woman" has a right to "safe and healthful working conditions." 29 USC 651(b). OSHA believes that exempting workplaces solely on the basis of size (number of workers) would not provide adequate protection to workers at very small establishments, as workers providing direct patient care and performing other covered tasks in very small establishments also face an elevated risk of occupational exposure to infectious diseases. Additionally, because of the overall shift in the delivery of healthcare services away from larger institutional settings to smaller settings or home healthcare, the Agency is concerned that exempting establishments solely on the basis of size would, over time, have an adverse effect on an increasing proportion of workers.

Alternative 4 would apply an infectious diseases rule to workers providing direct patient care, but not to workers performing other covered tasks.

Under this alternative, OSHA would restrict an infectious diseases rule to workers who have occupational exposure during the provision of direct patient care and not cover those workers with occupational exposure during performance of other covered tasks (as those terms are used in the regulatory framework). Based on the figures in the industry profile presented in Section V of this SER Background Document, OSHA calculates that this alternative would reduce the number of workers affected by such a rule by from about 9 to about 8 million workers: a reduction of approximately 1 million workers. About 500,000 of these one million workers would be employed at SBA defined small businesses. This alternative would reduce the number of affected workers employed at SBA defined small businesses from about 5.8 to about 5.3 million workers, which includes, among other employees described in the industry profile, a reduction of approximately: 69,000 employees at approximately 4,000 diagnostic laboratories, 19,000 medical waste and laundry handlers at approximately 6,000 establishments, and more than 54,000 morticians, medical examiners, and other health care service providers employed at approximately 11,000 morgues/mortuaries.

While the majority of workers with occupational exposure are engaged in direct patient care, there is also occupational exposure in workers performing other covered tasks, including, but not limited to: providing patient support services (e.g., triage, reception, housekeeping, food services, facility maintenance); handling, transporting, receiving or processing contaminated materials (e.g., laundering healthcare linens, transporting medical specimens, disposing of medical waste, reprocessing medical equipment); maintaining, servicing or repairing contaminated medical equipment; conducting autopsies (e.g., in medical examiners' offices);

performing mortuary services; manipulating and analyzing cultures, specimens, and/or human remains containing infectious agents in diagnostic, research and production facilities; and dispensing medications and/or medical supplies in settings where direct patient care is provided. While employers would face a cost burden in complying with a rule as outlined in the regulatory framework, OSHA believes, based on the evidence – particularly a number of studies it has thus far analyzed – that workers performing other covered tasks face a risk of infection because of their occupational exposure. For example, Henkel et al. (2012) reported that 11 laboratory-acquired infections with select agents[69] occurred in the U.S. between 2004 and 2011. In addition, at least ten laboratory-acquired Vaccinia infections were reported following occupational exposure to the virus (Byers, 2005, Lewis et al., 2006). And in another example, laundry workers who had contact with contaminated linen in a nursing home in Tennessee suffered the highest attack rate[70] of salmonellosis among the nursing home's workers despite having had no direct contact with infected patients (Standaert et al., 1994). Therefore, the Agency chose to include these workers in the regulatory framework.

Alternative 5 would exempt very small employers (those with fewer than 20 workers) from written documentation requirements.

Under this alternative, employers with fewer than 20 workers would not be subject to written documentation requirements. Per the regulatory framework, OSHA would require covered employers to have a written worker infection control plan (WICP), WICP review records, medical records, and exposure incident records. Therefore, this alternative would decrease the paperwork burden on very small employers. However, OSHA believes it would be virtually impossible to adequately train workers and assure they are routinely and rigorously implementing the employer's infection control plan without a written plan, as the written plan would contain all the Standard Operating Procedures (SOPs) that workers would need to follow to protect themselves.

Inadequate training would, in turn, lead to a higher degree of risk for these workers. It is also important for workers to have access to a written WICP so that workers can review SOPs for newly assigned procedures or review SOPs for their current activities. Finally, it is crucial to document exposure incidents to allow for adequate medical follow-up and contact tracing (i.e., tracing the line of exposure to other workers or patients who also may have had exposure or who may have been a source of exposure), and to update the WICP to account for new or emerging infectious agents or changes in community patterns of infectious diseases (e.g., emergence of an antibiotic resistant infectious agent, an outbreak, or a change in prevalence of an infectious disease).

[69] Pursuant to 42 USC 262a and 7 USC 8401, select agents and toxins are a subset of biological agents and toxins that HHS and the United States Department of Agriculture (USDA) have determined to have the potential to pose a severe threat to public health and safety, to animal or plant health, or to animal or plant products. The current list of select agents and toxins can be found at 42 CFR §§ 73.3, 73.4; 9 CFR §§ 121.3, 121.4; and 7 CFR § 331.3.

[70] Attack rate is the number of workers infected with the infectious agent out of the total number of workers exposed to the infectious agent.

Moreover, OSHA believes that many employers of workers with occupational exposure have already developed and implemented infection control plans in their workplaces, as these actions are required for accreditation by the Joint Commission and other CMS approved accrediting agencies in order to receive funding through CMS. In addition, OSHA believes that many employers of workers that would be covered by a rule as outlined in the regulatory framework have already developed and implemented infection control plans in their workplaces to meet the requirements of the Bloodborne Pathogens standard, the recommendations of CDC/NIH's *Biosafety in Microbiological and Biomedical Laboratories*, and/or the recommendations of the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules*. These existing infection control plans would only need to be expanded to include additional elements relevant to a rule as outlined in the regulatory framework. The amount of additional documentation that would be required under a rule as outlined in the regulatory framework would therefore be minimal for these workplaces.

Alternative 6 would exclude from an infectious diseases rule any requirement that employers that have workers that provide direct patient care include contact precautions in their SOPs.

Under this alternative, employers would not be required to develop, implement, and update SOPs for contact precautions. The regulatory framework uses the term contact precautions to mean infection control practices designed to prevent or minimize transmission of infectious agents spread by direct contact (i.e., infectious agent transmission from one infected individual to another individual without a contaminated intermediate item or surface, or individual) or indirect contact (i.e., infectious agent transmission through a contaminated intermediate item or surface, or individual). If the Agency adopted this alternative, its approach would more closely align with that taken by the California Division of Occupational Safety and Health (Cal-OSHA), when it promulgated its Aerosol Transmissible Diseases standard in 2009 (California OSHA, 2009). The Cal-OSHA standard was promulgated to protect workers from exposure to droplet- and airborne-transmissible diseases, but not to contact-transmissible diseases. OSHA believes that Cal-OSHA's approach does not adequately protect workers because, based on the evidence the Agency has thus far analyzed, there are a number of contact-transmissible diseases that pose an elevated risk to workers who provide direct patient care and/or perform other covered tasks. Occupational exposure of workers to contact-transmissible infectious agents such as methicillin-resistant *Staphylococcus aureus* (MRSA) and vancomycin resistant *Enterococcus* (VRE), is quite common in healthcare settings and is of concern to OSHA. In a recent publication on MRSA that reviewed 127 studies, for example, it was estimated that approximately 5 percent of healthcare workers are colonized with MRSA and 5 percent of these develop infections (Albrich & Harbarth, 2008). Based upon this and other peer-reviewed studies, it is OSHA's position that failing to cover contact-transmissible infectious agents in an infectious disease rule would not protect workers adequately.

Alternative 7 would exclude from an infectious diseases rule any requirement that employers make vaccinations available.

Under this alternative, employers would not be required to make vaccinations available to workers. The alternative would also eliminate the paperwork burden associated with recordkeeping requirements for vaccine administration and signed vaccine declination statements, and eliminate vaccination-related training that would be required by a rule as outlined in the regulatory framework. However, vaccination is generally considered an important component of an effective infection control program, as it protects inoculated workers from infections, lessens chances of outbreaks by minimizing transmission of infections from workers to other workers and patients, and may also lessen the duration and severity of infections, depending on the efficacy of the vaccine. The recommendations of CDC's Advisory Committee on Immunization Practices (ACIP) assert that "optimal use of recommended vaccines helps maintain immunity and safeguard [healthcare workers] from infection" (Shefer et al., 2011). Therefore, as in OSHA's Bloodborne Pathogens standard (§1910.1030), OSHA thinks it is important to require employers to make vaccinations available to workers.

Alternative 8 would exclude from an infectious diseases rule any requirement that employers provide medical removal protection benefits.

Under this alternative, employers would not be required to provide medical removal protection (MRP) benefits. Not incorporating such a provision in an infectious diseases rule would decrease employers' compliance costs, specifically, the cost of paying a worker's total normal earnings, and maintaining the worker's seniority, rights, and benefits, when the worker has been removed from his or her job or otherwise medically limited as a result of occupational exposure.

While OSHA has not calculated the total costs related to medical removal protection, the Agency believes that the costs will be minimal for most employers, especially because full implementation of the provisions in a rule as outlined in the regulatory framework would reduce the need for medical removal protection. The provisions of the regulatory framework are aimed at preventing or minimizing worker contact with potentially infectious agents and, if fully implemented, a rule as outlined in the regulatory framework would greatly reduce the number of occupationally-acquired infections in the workers covered. In addition, if OSHA required employers to provide MRP benefits, this would encourage worker participation in (and therefore increases the effectiveness of) any medical surveillance program that would be required, by ensuring that reporting symptoms or health conditions will not result in loss of job or pay. Without a requirement for MRP benefits, workers might be deterred from reporting signs and symptoms that could be indicative of infection and might work while sick (due to concerns about loss of pay or other such punitive consequences), potentially resulting in further infections to co-

workers and/or patients. Most occupationally acquired infectious diseases that would require extensive leave under a medical removal provision are seen relatively infrequently - especially since, under the regulatory framework, OSHA would not require MRP benefits for most workers who are removed from their jobs or otherwise medically limited as a result of occupational exposure to the common cold or influenza. Many employers would have no cases in any given year. However, OSHA seeks input on whether the MRP provision would have significant economic impacts on small or very small firms in the relatively uncommon circumstance of an employee being removed from the workplace because of a long-term serious illness.

Alternative 9 would only include initial training and training-as-needed in an infectious diseases rule.

Under this alternative, OSHA would not require employers to conduct annual training for workers. Under the regulatory framework, annual training would, at a minimum, include: information on the types, proper use, limitations, location, handling, decontamination, removal, and disposal of PPE; all of the SOPs developed as part of the WICP that are applicable to the worker's duties; and information on vaccine(s) that will be made available to the worker in the year of the training (including their efficacy, contraindications, likelihood and severity of possible adverse health effects, method of administration, the benefits of being vaccinated, and that the vaccines and vaccinations will be offered at no cost and at reasonable times and places). Not including these provisions in an infectious diseases rule would decrease the burden for all employers. Research, however, shows that an effective training program, which includes annual training, is essential to ensuring that workers understand the hazards to which they are exposed and how employers must protect them from these hazards (Bolyard et al., 1998). Effective training can result in fewer injuries and illnesses, better morale, and lower insurance premiums, among other benefits. Inclusion of an annual training requirement reflects OSHA's belief that training is an essential part of every employer's safety and health program for protecting workers from injuries and illnesses (Bolyard et al., 1998), and that workers will not be adequately protected unless they regularly receive information about the safety and health aspects of their jobs. In its review of current scientific literature related to occupational exposure to infectious agents, OSHA found nearly 100 studies that supported the need for such training programs to ensure worker familiarity with general infection control practices, proper use of PPE, effective hand hygiene, and other methods for reducing occupational exposure (see, e.g., Aboumatar et al., 2012; Nichol et al., 2013; Chen et al., 2011).

Moreover, even if OSHA does not require annual training in an infectious diseases rule, this would not affect a requirement that employers conduct supplemental training that is tied to the employer's WICP. Under the regulatory framework, OSHA would require the employer to conduct supplemental training to address changes in the WICP. And, per the regulatory framework, OSHA would require the WICP to be reviewed and updated at least annually, and

whenever necessary to reflect various changes in occupational exposure. So given the regulatory framework's provisions for supplemental training, the alternative of not requiring annual training would not significantly limit the overall training burden on employers.

Alternative 10 would add additional time for small employers to phase-in compliance with an infectious diseases rule.

A phase-in of an infectious diseases rule would have several advantages in regards to potential impacts on small businesses. First, it would reduce the one-time initial costs of such a rule by spreading these costs out over time. A differential phase-in for smaller firms would also assist very small firms in developing and implementing a WICP specific to their workplace based upon the experience of larger firms. However a phase-in would also postpone the benefits of an infectious diseases rule.

IV. Regulatory Options Under Consideration

Option 1 would include in the scope of an infectious diseases rule workers who perform first aid only.

Under this option, workers who perform first aid only would be considered to provide direct patient care for the purposes of an infectious diseases rule. Inclusion of these workers would substantially increase the number of covered workers. However, OSHA believes the resulting increased burden on employers is unnecessary for reducing the health hazards posed by infectious diseases. First aid primarily involves attention to persons with conditions such as cardiac or respiratory arrest, small lacerations (cuts), insect stings and bites, poisonings, and burns, not attention to persons with infectious diseases. Moreover, OSHA believes that general public health measures are adequate to protect first aid workers from the types of infectious agents covered by a rule as outlined in the regulatory framework, and thus that it is not necessary to impose the burden of implementing and maintaining a comprehensive infection control plan for such workplace exposures.

Option 2 would define other covered tasks to include a greater range of tasks (e.g., tasks done by teachers and prison guards) and to cover tasks performed by flight attendants while on airplanes.

Under this option, in addition to tasks that would be covered by a rule as outlined in the regulatory framework, other tasks, such as tasks performed by teachers and prison guards would fall within the scope, even when these workers are not performing other covered tasks, as that

term is used in the regulatory framework. In addition, the scope would be expanded to include the tasks performed by flight attendants when they are working on airplanes.

Per the regulatory framework, OSHA would cover healthcare-related and certain other limited tasks, such as mortuary services and laboratory activities. Expanding the scope of an infectious diseases rule beyond the regulatory framework would greatly increase the number of employers that would be required to comply. Including prison guards, child daycare teachers, and elementary and secondary school teachers would add an additional 5 million workers to the scope of an infectious diseases rule and affect approximately 99,000 additional establishments. Adding flight attendants would result in coverage for approximately 88,000 more workers and 467 additional establishments.

The tasks that would be covered by a rule as outlined in the regulatory framework – unlike the typical duties of workers such as prison guards, teachers and flight attendants – would generally be subject to the standard and transmission-based precautions laid out in the CDC/HICPAC guidelines. Many of the programmatic elements contained in the regulatory framework are already in place for the tasks that would be covered by a rule as outlined in the regulatory framework, but that is not the case for tasks in this option. Development and implementation of these programmatic elements could be expensive for the employers affected by the option. Moreover, OSHA believes, based on the evidence it has thus far analyzed, that general public health measures are adequate to protect workers performing the tasks outlined in this option, and that it is not necessary to impose the burden of implementing and maintaining a comprehensive infection control plan for such workplace exposures.

Option 3 would define direct patient care to include all tasks performed by pharmacists that involve face-to-face contact.

In this option, the direct patient care definition would include all the tasks of pharmacists that involve face-to-face contact. Covering these additional tasks of pharmacists would increase the number of employers that would be required to comply with an infectious diseases rule, adding approximately 172,000 more workers to the scope of this rule and affecting approximately 72,000 additional establishments.

The regulatory framework defines direct patient care, in part, as job duties involving hands-on or face-to-face contact with patients. An exception for pharmacists in the regulatory framework states that pharmacists who provide hands-on care (e.g., administer vaccinations) provide direct patient care, while those who perform duties that involve face-to-face contact only (e.g., dispense medications) do not provide direct patient care. This option would eliminate this exception to the direct patient care definition.

OSHA believes, based on the evidence it has thus far analyzed, that general public health measures are adequate to protect pharmacists who neither provide direct patient care nor perform other covered tasks, as those terms are used in the regulatory framework, and that the cost of implementing and maintaining a comprehensive infection control plan for the tasks of all pharmacists would impose an unreasonable burden on employers. However, OSHA will continue to examine these job tasks carefully, and may explore ways to specifically address the infectious disease hazards that may be associated with the tasks of this job classification in the future. The Agency is seeking input on whether it should cover these tasks.

Option 4 would add increased specificity to the exposure determination that could be required.

This option would require the exposure determination to contain a list of all job classifications *and job tasks* in which all or some of the workers have occupational exposure. Under the regulatory framework, the employer would provide a list of job classifications for the exposure determination, but would not need to prepare a list of job tasks. OSHA believes that including a list of tasks workers perform where occupational exposure occurs would impose an unnecessary paperwork burden on employers.

Moreover, while the Agency expects that some employers may choose to add an additional list of tasks and procedures for the job classifications identified, at this time OSHA does not believe that it should require this increased specificity. Such specificity may lead to over-reliance on a list of specific tasks that may be incomplete when developing training programs, selecting PPE, and implementing other requirements of an infectious diseases rule, particularly considering the difficulty associated with anticipating all tasks that may be required as part of workers providing direct patient care and/or performing other covered tasks. OSHA recognizes that the nature of treating patients and completing tasks related to healthcare is dynamic, and that developing lists of specific job tasks associated with job classifications may be counterproductive and may result in a lower level of protection for workers.

The Agency is seeking input on the amount of time employers anticipate it would take to develop lists of all job classifications and specific job tasks with occupational exposure, as well as the utility of such an undertaking.

Option 5 would require written documentation for infectious agent hazard evaluations.

Under this option, employers would be required to document infectious agent hazard evaluations. Per the regulatory framework, OSHA would require employers to conduct, but not necessarily document, these evaluations (which the regulatory framework defines as assessments to determine the presence of suspected or confirmed sources of infectious agents to which workers

have occupational exposure during provision of direct patient care and/or performance of other covered tasks). Under the regulatory framework, OSHA would require employers to develop, implement, and update procedures to promptly identify suspected or confirmed sources of infectious agents that are present in the work setting by conducting timely infectious agent hazard evaluations. In the regulatory framework, OSHA thus envisions an ongoing process meant to ensure that workers are continually protected from hazards that may change frequently due to the variety of infectious agents circulating in the community, the types of patients a facility receives, and other factors. The regulatory framework provides further that infectious agent hazard evaluations may be incorporated into routine activities, such as triage.

OSHA believes that requiring employers to document infectious agent hazard evaluations would increase both the paperwork burden, through additional requirements for written documentation and recordkeeping, and the cost, through time required to achieve compliance for employers. Further, the Agency believes that a documentation requirement would not advance (and might even detract from) OSHA's goal in the regulatory framework that occupational exposure to infectious agent hazards be continually evaluated in an ongoing fashion. Finally, OSHA believes that the recordkeeping provisions that are currently in the regulatory framework would sufficiently protect workers. For example, per the regulatory framework, OSHA would require employers to keep exposure incident records, which would allow the employer to document elements such as the work setting and work task(s) being performed when the exposure incident(s) occurred, which would, in turn, allow the employer to focus efforts on decreasing or eliminating specific circumstances or routes of exposures that caused the incident(s).

OSHA believes that requiring employers to keep infectious agent hazard evaluations in written form would not greatly improve protection of workers beyond what would be achieved with the recordkeeping provisions that are currently in the regulatory framework.

Option 6 would require hospitals to follow the hierarchy of controls as required in OSHA's Respiratory Protection Standard (29 CFR 1910.134(a)(1)), and to have in their workplaces an appropriate number of airborne infection isolation rooms (AIIRs).

Under this option, adherence by hospitals to the required hierarchy of controls as required in 29 CFR 1910.134(a)(1), would not be modified in accordance with recognized and generally accepted good infection control practices. This option, therefore, would require hospital employers to prevent or minimize airborne transmission of infectious agents in their work settings by first installing and employing effective engineering controls, i.e., an appropriate numbers of AIIRs, based on expected demand for airborne isolation.

OSHA recognizes that infection control practices normally rely upon a multi-layered and overlapping strategy of employing engineering, work practice and administrative controls, and

PPE. Therefore, in the regulatory framework, OSHA notes that the Agency would permit adherence to the required hierarchy of controls, such as that required by 29 CFR 1910.134(a)(1), to be modified in accordance with recognized and generally accepted good infection control practices.

OSHA's review of the scientific literature suggests that, when maintained and used properly, using AIIRs is an effective method for controlling the spread of airborne infectious agents (see, e.g., Parvez et al., 2010; Roberts et al., 2006; Saravia et al., 2007; Stroud et al., 1995). On the other hand, OSHA believes that workers will be adequately protected through compliance with a requirement that employers must develop, implement, and update airborne precautions that are consistent with recognized and generally accepted good infection control practices relevant to their work settings. Moreover, per section IV of the regulatory framework (Standard Operating Procedures Development and Implementation), OSHA would require employers that provide services in medical surge conditions to develop, implement, and update procedures for the implementation of temporary control measures, including the use of temporary engineering controls used to establish temporary airborne infection isolation areas, or AIIAs[71], where appropriate. This provision, if promulgated, would provide additional protection.

Option 7 would require all employers to provide medical removal protection benefits for common cold and influenza.

This option would apply medical removal protection (MRP) benefits to all infectious diseases, including influenza and the common cold. Per the regulatory framework, OSHA would require employers to pay a worker's total normal earnings, and maintain the worker's seniority, rights, and benefits, when the worker has been removed from his or her job or otherwise medically limited as a result of occupational exposure, but would not generally require employers to provide these benefits when a worker is removed from his or her job or otherwise medically limited as a result of occupational exposure to the common cold or influenza.

Requiring employers to provide MRP benefits encourages worker participation in (and therefore increases the effectiveness of) the medical surveillance program that would be required by an infectious diseases rule by ensuring that reporting symptoms or health conditions will not result in loss of job or pay. The expansion of MRP benefits to cover influenza and the common cold would likely reduce additional infections in coworkers and/or patients. Moreover, exclusion of the common cold and influenza, frequent occupational exposure to both of which is supported by scientific evidence, could deter workers from reporting signs and symptoms consistent with cold

[71] An AIIA is an area (e.g., room, booth, tent, or other enclosure), other than a dedicated airborne infection isolation room (AIIR), that is maintained at negative pressure to adjacent areas in order to control the spread of an airborne-transmissible infectious agent(s) outside of the AIIA.

or influenza (e.g., cough, runny nose, sneezing, sore throat, muscle aches, tiredness) that may also be indicative of infection with other, potentially more serious, agents.

Option 8 would require employers whose workplace settings have workers that provide direct patient care to develop and display signage in patient rooms encouraging patients to request that workers use proper hand hygiene before any direct patient care is provided.

Under this option, employers would be required to develop and display signage in patient rooms encouraging patients to request that workers use proper hand hygiene before any direct patient care is provided. CDC encourages patients to ask or remind HCWs to wash their hands (CDC, 2010b). Wu et al. (2013) found that patients were willing to participate in such initiatives to improve hand hygiene among HCWs; and McGuckin et al. (2004) found that, when patients asked HCWs to use soap or hand sanitizer products, HCWs washed or sanitized their hands about 4.7 times more per day compared with HCWs not asked about hand hygiene by patients in the study. This option would not only ensure placement of visual reminders to HCWs and workers performing other covered tasks to use proper hand hygiene, but would also help to promote a general culture of good hand hygiene for organizations by incorporating patient awareness and possible resulting action(s). However, printed signs would create additional compliance costs for employers, and represent an increased paperwork burden. OSHA invites stakeholder comment about the efficacy and cost of this option.

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Appendix A – SBA Definitions of Small Entities for all Affected Industries at the Six-Digit NAICS Level

Table A-1. SBA Definitions of Small Entities for all Affected Industries at the Six-Digit NAICS Level

NAICS code	NAICS industry	SBA Definition - Revenue	SBA Definition - Employees	SBA Definition - Other	SBA Definition Converted To Employees
	Local Government Entities			Population <50,000	
	Non-Profits			Not dominant in their field	
221100	Electric Power Generation, Transmission and Distribution			4 million megawatt hours	500
221200	Natural Gas Distribution		500		500
221310	Water Supply and Irrigation Systems	$25,500,000			500
221320	Sewage Treatment Facilities	$19,000,000			100
221330	Steam and Air-Conditioning Supply	$14,000,000			20
311100	Animal Food Manufacturing		500		500
311200	Grain and Oilseed Milling		500		500
311300	Sugar and Confectionery Product Manufacturing		500		500
311400	Fruit and Vegetable Preserving and Specialty Food		500		500
311500	Dairy Product Manufacturing		500		500
311600	Animal Slaughtering and Processing		500		500
311700	Seafood Product Preparation and Packaging		500		500
311800	Bakeries and Tortilla Manufacturing		500		500
311900	Other Food Manufacturing		500		500
312100	Beverage Manufacturing		500		500
312200	Tobacco Manufacturing		500		500
313100	Fiber, Yarn, and Thread Mills		500		500
313200	Fabric Mills		1,000		1,000
313300	Textile and Fabric Finishing and Fabric Coating		1,000		1,000
314100	Textile Furnishings Mills		500		500
314900	Other Textile Product Mills		500		500
315100	Apparel Knitting Mills		500		500
315200	Cut and Sew Apparel Manufacturing		500		500
315900	Apparel Accessories and Other Apparel		500		500
316100	Leather and Hide Tanning and Finishing		500		500
316200	Footwear Manufacturing		1,000		1,000
316900	Other Leather and Allied Product Manufacturing		500		500
321100	Sawmills and Wood Preservation		500		500
321200	Veneer, Plywood, and Engineered Wood Product Manufacturing		500		500
321900	Other Wood Product Manufacturing		500		500
322100	Pulp, Paper, and Paperboard Mills		750		750
322200	Converted Paper Product Manufacturing		500		500
323100	Printing and Related Support Activities		500		500
324100	Petroleum and Coal Products Manufacturing		1,500		1,500
325100	Basic Chemical Manufacturing		1,000		1,000
325200	Resin, Synthetic Rubber, and Artificial Synthetic Fibers and Filaments Manufacturing		750		750

Table A-1. SBA Definitions of Small Entities for all Affected Indiustries at the Six-Digit NAICS Level, continued					
NAICS code	NAICS industry	SBA Definition - Revenue	SBA Definition - Employees	SBA Definition - Other	SBA Definition Converted To Employees
325300	Pesticide, Fertilizer, and Other Agricultural Chemical Manufacturing		1,000		1,000
325400	Pharmaceutical and Medicine Manufacturing		750		750
325500	Paint, Coating, and Adhesive Manufacturing		500		500
325600	Soap, Cleaning Compound, and Toilet Preparation Manufacturing		750		750
325900	Other Chemical Product and Preparation Manufacturing		500		500
326100	Plastics Product Manufacturing		500		500
326200	Rubber Product Manufacturing		1,000		1,000
327100	Clay Product and Refractory Manufacturing		750		750
327200	Glass and Glass Product Manufacturing		1,000		1,000
327300	Cement and Concrete Product Manufacturing		750		750
327400	Lime and Gypsum Product Manufacturing		500		500
327900	Other Nonmetallic Mineral Product Manufacturing		500		500
331100	Iron and Steel Mills and Ferroalloy Manufacturing		1,000		1,000
331200	Steel Product Manufacturing from Purchased Steel		1,000		1,000
331300	Alumina and Aluminum Production and Processing		1,000		1,000
331400	Nonferrous Metal (except Aluminum) Production and Processing		1,000		1,000
331500	Foundries		500		500
332100	Forging and Stamping		500		500
332200	Cutlery and Handtool Manufacturing		500		500
332300	Architectural and Structural Metals Manufacturing		500		500
332400	Boiler, Tank, and Shipping Container Manufacturing		500		500
332500	Hardware Manufacturing		500		500
332600	Spring and Wire Product Manufacturing		500		500
332700	Machine Shops; Turned Product; and Screw, Nut, and Bolt Manufacturing		500		500
332800	Coating, Engraving, Heat Treating, and Allied		750		750
332900	Other Fabricated Metal Product Manufacturing		500		500
333100	Agriculture, Construction, and Mining Machinery Manufacturing		500		500
333200	Industrial Machinery Manufacturing		500		500
333300	Commercial and Service Industry Machinery		500		500
333400	Ventilation, Heating, Air-Conditioning, and		500		500
333500	Metalworking Machinery Manufacturing		500		500
333600	Engine, Turbine, and Power Transmission Equipment Manufacturing		1,000		1,000
333900	Other General Purpose Machinery Manufacturing		500		500
334100	Computer and Peripheral Equipment Manufacturing		1,000		1,000
334200	Communications Equipment Manufacturing		1,000		1,000
334300	Audio and Video Equipment Manufacturing		750		750

Table A-1. SBA Definitions of Small Entities for all Affected Indiustries at the Six-Digit NAICS Level, continued					
NAICS code	NAICS industry	SBA Definition - Revenue	SBA Definition - Employees	SBA Definition - Other	SBA Definition Converted To Employees
334400	Semiconductor and Other Electronic Component Manufacturing		750		750
334500	Navigational, Measuring, Electromedical, and Control Instruments Manufacturing		500		500
334600	Manufacturing and Reproducing Magnetic and Optical Media		500		500
335100	Electric Lighting Equipment Manufacturing		1,000		1,000
335200	Household Appliance Manufacturing		750		750
335300	Electrical Equipment Manufacturing		750		750
335900	Other Electrical Equipment and Component Manufacturing		500		500
336100	Motor Vehicle Manufacturing		1,000		1,000
336200	Motor Vehicle Body and Trailer Manufacturing		1,000		1,000
336300	Motor Vehicle Parts Manufacturing		500		500
336400	Aerospace Product and Parts Manufacturing		1,500		1,500
336500	Railroad Rolling Stock Manufacturing		1,000		1,000
336600	Ship and Boat Building		1,000		1,000
336900	Other Transportation Equipment Manufacturing		500		500
337100	Household and Institutional Furniture and Kitchen Cabinet Manufacturing		500		500
337200	Office Furniture (including Fixtures) Manufacturing		500		500
337900	Other Furniture Related Product Manufacturing		500		500
339100	Medical Equipment and Supplies Manufacturing		500		500
339900	Other Miscellaneous Manufacturing		500		500
423400	Professional and Commercial Equipment and Supplies Merchant Wholesalers		100		100
446110	Pharmacies and Drug Stores	$25,500,000			100
452900	Other General Merchandise Stores	$27,000,000			500
454111	Electronic Shopping	$30,000,000			100
454113	Mail-Order Houses	$35,500,000			500
485991	Special Needs Transportation	$7,000,000			100
485999	All Other Transit and Ground Passenger Transportation				500
511200	Software Publishers	$25,000,000			100
523110	Investment Banking and Securities Dealing	$7,000,000			20
523120	Securities Brokerage	$7,000,000			20
523130	Commodity Contracts Dealing	$7,000,000			10
523140	Commodity Contracts Brokerage	$7,000,000			20
524113	Direct Life Insurance Carriers	$7,000,000			10
524114	Direct Health and Medical Insurance Carriers	$7,000,000			20
524126	Direct Property and Casualty Insurance Carriers		1,500		1,500
524127	Direct Title Insurance Carriers	$7,000,000			100

Table A-1. SBA Definitions of Small Entities for all Affected Indiustries at the Six-Digit NAICS Level, continued					
NAICS code	NAICS industry	SBA Definition - Revenue	SBA Definition - Employees	SBA Definition - Other	SBA Definition Converted To Employees
524128	Other Direct Insurance (except Life, Health, and Medical) Carriers	$7,000,000			20
524130	Reinsurance Carriers	$7,000,000			20
524200	Agencies, Brokerages, and Other Insurance Related Activities	$7,000,000			100
525910	Open-End Investment Funds	$7,000,000			500
525930	Real Estate Investment Trusts	$7,000,000			10
525990	Other Financial Vehicles	$7,000,000			20
531110	Lessors of Residential Buildings and Dwellings	$7,000,000			100
531120	Lessors of Nonresidential Buildings (except Miniwarehouses)	$7,000,000			20
531130	Lessors of Miniwarehouses and Self-Storage Units	$25,500,000			500
531190	Lessors of Other Real Estate Property	$7,000,000			100
531311	Residential Property Managers	$2,000,000			20
531312	Nonresidential Property Managers	$2,000,000			20
531320	Offices of Real Estate Appraisers	$2,000,000			20
531390	Other Activities Related to Real Estate	$2,000,000			10
532291	Home Health Equipment Rental	$7,000,000			100
532490	Other Commercial and Industrial Machinery and Equipment Rental and Leasing	$7,000,000			100
541380	Testing Laboratories	$12,000,000			100
541710	Research & Development in Physical Engineering and Life Sciences		500		500
551111	Offices of Bank Holding Companies	$7,000,000			100
551112	Offices of Other Holding Companies	$7,000,000			100
551114	Offices	$7,000,000			500
561100	Office Administrative Services	$7,000,000			100
561200	Facilities Support Services	$35,500,000			500
561310	Employment Placement Agencies	$7,000,000			100
561320	Temporary Help Services	$13,500,000			500
561330	Professional Employer Organizations	$13,500,000			500
561611	Investigation Services	$12,500,000			500
561612	Security Guards and Patrol Services	$18,500,000			500
561900	Other Support Services	$7,000,000			100
562100	Waste Collection	$12,500,000			100
562211	Hazardous Waste Treatment and Disposal	$12,500,000			100
562212	Solid Waste Landfill	$12,500,000			100
562213	Solid Waste Combustors and Incinerators	$12,500,000			500
562219	Other Nonhazardous Waste Treatment and Disposal	$12,500,000			100
562910	Remediation Services	$14,000,000			100
562920	Materials Recovery Facilities	$12,500,000			100
562991	Septic Tank and Related Services	$7,000,000			100
562998	Services	$7,000,000			100

Table A-1. SBA Definitions of Small Entities for all Affected Indiustries at the Six-Digit NAICS Level, continued					
NAICS code	NAICS industry	SBA Definition - Revenue	SBA Definition - Employees	SBA Definition - Other	SBA Definition Converted To Employees
611100	Elementary and Secondary Embedded clinics in schools, Privately owned	$7,000,000			100
611200	Junior colleges, Privately owned	$7,000,000			100
611300	Colleges, universities, and professional Embedded clinics in schools, Privately owned	$7,000,000			100
611400	Business Embedded clinics in schools and computer and management training, Privately owned	$7,000,000			100
611511	Cosmetology and Barber Schools Embedded clinics in schools, Privately owned	$7,000,000			100
611512	Flight Training Embedded clinics in schools, Privately owned	$25,500,000			500
611513	Apprenticeship Training Embedded clinics in schools, Privately owned	$7,000,000			100
611519	Other Technical and Trade Schools Embedded clinics in schools, Privately owned	$7,000,000			100
611610	Fine Arts Schools Embedded clinics in schools, Privately owned	$7,000,000			500
611620	Sports and Recreation Instruction Embedded clinics in schools, Privately owned	$7,000,000			500
611699	All Other Miscellaneous Schools and Instruction Embedded clinics in schools, Privately owned	$7,000,000			100
611700	Educational Support Services, Privately owned	$7,000,000			100
621111	Offices of Physicians (except Mental Health Specialists)	$10,000,000			100
621112	Offices of Physicians, Mental Health Specialists	$10,000,000			500
621200	Offices of Dentists	$7,000,000			100
621310	Offices of Chiropractors	$7,000,000			500
621320	Offices of Optometrists	$7,000,000			100
621390	Offices of All Other Health Practitioners	$7,000,000			500
621500	Medical and Diagnostic Laboratories	$13,500,000			100
621600	Home Health Care Services	$13,500,000			500
621910	Ambulance Services	$7,000,000			100
621990	All Other Ambulatory Health Care Services	$10,000,000			100
622100	General Medical and Surgical Hospitals, Privately owned	$34,500,000			500
622200	Psychiatric and Substance Abuse Hospitals, Privately owned	$34,500,000			500
622300	Specialty hospitals, Privately owned	$34,500,000			500
623100	Nursing Care Facilities	$13,500,000			500
623210	Residential Mental Retardation Facilities	$10,000,000			500
623220	Residential Mental Health and Substance Abuse Facilities	$7,000,000			500

Table A-1. SBA Definitions of Small Entities for all Affected Indiustries at the Six-Digit NAICS Level, continued					
NAICS code	NAICS industry	SBA Definition - Revenue	SBA Definition - Employees	SBA Definition - Other	SBA Definition Converted To Employees
623311	Continuing Care Retirement Communities	$13,500,000			500
623312	Homes for the Elderly	$7,000,000			500
623900	Other Residential Care Facilities	$7,000,000			500
624110	Child and Youth Services	$7,000,000			500
624120	Services for the Elderly and Persons with Disabilities	$7,000,000			500
624190	Other Individual and Family Services	$7,000,000			100
624230	Emergency and Other Relief Services	$7,000,000			20
624300	Vocational Rehabilitation Services	$7,000,000			500
624400	Child Day Care Services	$7,000,000			500
711200	Spectator Sports	$7,000,000			100
711300	Promoters of Performing Arts, Sports, and Similar Events	$7,000,000			100
713110	Amusement and Theme Parks	$7,000,000			100
713120	Amusement Arcades	$7,000,000			500
713200	Gambling Industries	$7,000,000			100
713910	Golf Courses and Country Clubs	$7,000,000			100
713920	Skiing Facilities	$7,000,000			500
713930	Marinas	$7,000,000			100
713940	Fitness and Recreational Sports Centers	$7,000,000			500
713950	Bowling Centers	$7,000,000			500
713990	All Other Amusement and Recreation Industries	$7,000,000			500
721199	All Other Traveler Accommodation	$7,000,000			500
721300	Rooming and Boarding Houses	$7,000,000			500
812191	Diet and Weight Reducing Centers	$19,000,000			500
812199	Other Personal Care Services	$7,000,000			500
812210	Funeral Homes and Funeral Services	$7,000,000			100
812220	Cemeteries and Crematories	$19,000,000			500
813100	Religious Organizations	$7,000,000			100

Notes: For those industries with a revenue criterion OSHA calculated the average revenue for each employment size class in the Census data, and found the largest size class where average revenue is less than the SBA definition. All non-profits were considered SBA entities for purposes OSHA's analysis. All governmental entities were considered not to be SBA entities.
Source: SBA, 2010.

Appendix B – Regulatory framework Crosswalk with Published Infection Control Guidelines/Regulations

Although OSHA's Bloodborne Pathogens standard (29 CFR 1910.1030) protects workers from occupational exposure to bloodborne pathogens, there are no other mandatory federal standards that protect workers from occupational exposure to the various infectious agents to which they may be exposed. However, infection prevention and control is a recognized and generally accepted practice in the healthcare industry, and, to this end, numerous non-mandatory guidelines on infection prevention and control provide recommendations for the protection of patients and workers from infectious agents.

Despite these recommendations, the focus of infection control practices, in general, has been on the protection of patients, with the common understanding that by reducing the transmission of infectious agents from healthcare workers to patients and between patients, the overall risk of exposure to healthcare workers would likely be reduced as well. Thus, the Centers for Medicare and Medicaid (CMS), as well as non-governmental organizations (e.g., CMS-approved accreditation organizations such as the Joint Commission), rely on recognized and generally accepted good infection prevention and control guidelines in developing their own programs

The Agency has been developing an extensive crosswalk comparing the provisions of the regulatory framework with existing guidelines and regulations for infectious disease prevention and control in workplaces where workers provide direct patient care and/or perform other covered tasks (as those terms are defined in the regulatory framework). The crosswalk currently contains 39 documents, and OSHA is working to analyze additional guidelines and regulations for inclusion. See List of Guidelines and Regulations OSHA Has Thus Far Analyzed, directly below this discussion.

OSHA concludes, based on the comparison it has thus far done, that many provisions in the regulatory framework are consistent with recommended infection control practices described in the crosswalk documents. For example, both the regulatory framework and infection control practices described in the 2007 *CDC/HICPAC Guidelines for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings* (Item 29 in the crosswalk), emphasize standard and transmission-based precautions to reduce the risk of transmission of infectious agents. Moreover, the 2007 guidelines contain infection control practices applicable to healthcare facilities (e.g., acute care hospitals, home care settings, and ambulatory care settings), which are addressed by the regulatory framework. The documents in the crosswalk also cover such diverse settings as behavioral health settings, dentists' offices, laboratories and funeral homes (Items 7, 12, 14, 22, 24, 25, 30, 32, 36, 37), which are also addressed by the regulatory framework.

The CDC guidelines have been widely accepted and incorporated into healthcare facilities' infection prevention and control programs. For example, the majority of employers that would be subject to a rule as outlined in the regulatory framework are also subject to CMS regulations (Items 16 thru 23 in crosswalk). These regulations condition a provider's participation in Medicare or Medicaid on the provider's implementation of an infection control program. Pursuant to CMS interpretive guidelines, to meet this condition, providers should ensure that their infection control programs conform to recognized and generally accepted infectious control practices and guidelines, such as the CDC/HICPAC guidelines. See, e.g., CMS State Operations Manual App. A – Survey Protocol, Regulations and Interpretive Guidelines for Hospitals, App. PP - Guidance to Surveyors for Long Term Care Facilities, App. J - Guidance to Surveyors: Intermediate Care Facilities for Persons With Mental Retardation. Furthermore, compliance with the CMS regulations is generally validated through periodic accreditation surveys of facilities by CMS-approved accreditation organizations, including The Joint Commission (TJC), a private not-for-profit organization that evaluates and accredits more than 20,000 healthcare organizations and programs in the United States. Consistent with these interpretive guidelines, many of the infection prevention and control practices TJC requires to be adopted for accreditation (Items 31 thru 36 of the crosswalk) vary based on healthcare setting, but those practices closely follow the 2007 CDC/HICPAC guidelines.

Finally, OSHA believes that many employers not directly subject to the CMS regulations are familiar with, and may have adopted, infection control programs that are consistent with the regulations and guidelines in the crosswalk, again, because these guidelines and regulations are widely accepted means of addressing infectious agent hazards. Moreover, OSHA believes that a large number of employers of workers performing other covered tasks, as that term is defined in the regulatory framework (for example, employers of workers performing maintenance and housekeeping in health care settings), work in facilities that are subject to the CMS regulations.

OSHA emphasizes that the crosswalk in this SER Background Document does not represent the universe of relevant guidelines and regulations addressing infection prevention and control. OSHA is in the process of compiling and analyzing other relevant guidelines and regulations issued by entities such as state licensing boards, trade associations, and credentialing agencies. However, because OSHA wants to ensure that it examines a representative number of relevant documents, OSHA requests that any guidelines or regulations addressing infection prevention and control that are not listed in the crosswalk be submitted by the regulated community to OSHA for analysis.

List of Guidelines and Regulations OSHA Has Thus Far Analyzed

1. American Academy of Pediatrics Committee on Infectious Diseases. 2007. Infection prevention and control in pediatric ambulatory settings. *Pediatrics. 120*: 650-665.
2. Bolyard, EA, et al. (CDC/HICPAC). 1998. Guideline for Infection Control in Healthcare Personnel, 1998. *Infect Control Hosp Epidemiol. 19*(6): 407-463. Available at http://www.cdc.gov/hicpac/pdf/infectcontrol98.pdf (Accessed November 18, 2013).
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OSHA's Infectious Diseases Regulatory Framework

Section 1: Scope

This section delineates the worker tasks being considered for coverage.

Occupational exposure of workers to contact, droplet, or airborne transmissible infectious agents during provision of direct patient care or performance of other covered tasks, as defined below, would be covered. Occupational exposure as defined in OSHA's Bloodborne Pathogens standard, 29 CFR 1910.1030, would not be covered.

Section 2: Definitions

This section explains the Agency's intended meaning of terms used in the body of this document. Examples given within a particular definition are intended to clarify the Agency's intent and do not represent an all-inclusive list.

- ***Accredited laboratory*** – A laboratory that has successfully participated in a quality assurance program leading to a certification of competence administered by a governmental or private organization that tests and certifies laboratories.

- ***Accrediting body*** - An entity, separate and distinct from an organization that provides direct patient care and/or performs other covered tasks, that assesses whether organizations that provide direct patient care and/or perform other covered tasks meet a set of requirements deemed necessary to ensure the organization's quality of services.

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- ***Administrative controls*** - Managerial measures that reduce the risk of transmission of, or infection by, infectious agents. Examples of administrative controls would include, but would not be limited to: promoting and providing vaccination; enforcing exclusion of ill employees from the workplace; setting up triage stations and separate areas for patients with suspected or confirmed infectious disease when they enter a healthcare facility; and assigning dedicated staff to minimize the number of employees exposed to those with a particular suspected or confirmed infectious disease.

- ***Airborne infection isolation area*** **(AIIA)** - An area (e.g., room, booth, tent, or other enclosure), other than a dedicated airborne infection isolation room (AIIR), that is maintained at negative pressure to adjacent areas in order to control the spread of an airborne-transmissible infectious agent(s) outside of the AIIA.

- ***Airborne infection isolation room*** **(AIIR)** - A negative pressure patient-care room, with special air handling capability that is used to isolate persons with a suspected or confirmed airborne-transmissible infectious disease.

- ***Airborne precautions*** - Infection control measures designed to prevent or minimize transmission of infectious agents that remain infectious over time and distance (e.g., between or across rooms; through ventilation systems) when suspended in the air.

- ***Assistant Secretary*** - The Assistant Secretary of Labor for Occupational Safety and Health, or designated representative.

- ***Contact precautions*** - Infection control practices designed to prevent or minimize transmission of infectious agents spread by direct contact (i.e., infectious agent

transmission from one infected individual to another individual without a contaminated intermediate item, surface, or individual) or indirect contact (i.e., infectious agent transmission through a contaminated intermediate item, surface, or individual) with an item, surface, or individual contaminated with, such an agent(s).

- ***Contaminated*** - The presence or reasonably anticipated presence of an infectious agent(s) in or on an item, surface, or individual.

- ***Contaminated material*** - An item (e.g., specimen, tissue, culture, biomedical waste, laundry, instruments, equipment) or surface (e.g., countertop, bed frame, examination table, laboratory bench, floor) contaminated with an infectious agent(s).

- ***Decontamination*** - The use of physical, radiological, and/or chemical means to remove, inactivate, or destroy an infectious agent(s) on an item or surface to the point where the infectious agent(s) is no longer capable of transmitting infectious particles and the item or surface is rendered safe for handling, use, or disposal. Decontamination can encompass cleaning, disinfection, and sterilization.

- ***Direct patient care*** - Job duties that involve the provision of healthcare services with hands-on or face-to-face contact with patients. An employee provides direct patient care only if she or he acts under a license, certification, or registration to provide healthcare services within a legally permitted scope of practice, or if she or he acts under the supervision of a licensed/certified/registered employee. Employees who provide direct patient care would include, but would not be limited to, nurses, physicians, physical and occupational therapists, and other healthcare employees who care for patients, as well as employees such as paramedics or emergency responders. An employee who provides first

aid only is not considered to provide direct patient care. Pharmacists who are licensed/certified/registered to perform hands-on care are considered to be providing direct patient care only when they perform duties that involve hands-on contact with patients (e.g., administering vaccinations), and not when they perform duties that involve face-to-face contact only (e.g., dispensing medications). A pharmacist(s) would still fall under the scope of this regulatory framework if the pharmacist(s) has occupational exposure during the performance of other covered tasks.

- ***Droplet precautions*** - Infection control measures designed to prevent or minimize transmission of infectious agents spread through direct contact of droplets containing the infectious agent with an individual's respiratory or mucous membranes.

- ***Engineering controls*** - Measures that reduce, isolate, or remove the infectious agents' hazard from the workplace. Examples of engineering controls would include, but would not be limited to, AIIRs and physical barriers, such as sneeze guards.

- ***Exposure incident*** – A specific event in which an employee has been exposed to a suspected or confirmed source of an infectious agent(s), either without the benefit of the infection control practices employers would be required to implement, or where the infection control practices have not adequately protected the employee from the exposure. For example, during an exposure incident investigation, a PLHCP may conclude that an employee has been exposed to a suspected or confirmed source of an infectious agent and that proper implementation of the employer's infection control practices have not adequately protected the employee from the exposure.

- ***Facemask*** - A U.S. Food and Drug Administration (FDA) cleared facemask (e.g., an FDA cleared surgical, medical procedure, dental, laser, or isolation mask). Facemasks are not tight-fitting. They are used as a physical barrier to protect from hazards such as splashes, splatters, or sprays of large droplets of blood or body fluids.

- ***Host employer*** - An employer that controls the operation of a work setting (e.g., hospital, doctor's office, laboratory) in which (a) the employer's employees have occupational exposure during provision of direct patient care and/or performance of other covered tasks, and (b) contractors, vendors, and/or licensed independent practitioners with privileges perform work.

- ***Infectious agent*** – A biological agent (including viruses, bacteria, fungi, protozoa, parasites, and aberrant proteins known as prions) that can be transmitted by the contact, droplet or airborne routes and that is capable of causing adverse health effects in infected individuals.

- ***Infectious agent hazard evaluation*** - An assessment to determine the presence of suspected or confirmed sources of infectious agents to which employees have occupational exposure during provision of direct patient care and/or performance of other covered tasks. An effective hazard evaluation would anticipate a range of infectious agent hazards and be appropriately linked with standard and transmission-based precautions. Such an evaluation would need to be consistent with recognized and generally accepted good infection control practices (e.g., Centers for Disease Control and Prevention (CDC) guidelines). In a healthcare setting, such an evaluation would include an assessment of a patient's infectious status based upon symptoms reported at scheduling and intake/admittance, and/or a

healthcare provider's index of suspicion based upon the provider's interactions with the patient.

- ***Institutional review board*** - A body established within a public or private entity or agency that is registered with an appropriate federal agency and operates in accordance with applicable federal regulations on the protection of human subjects (e.g., see the Department of Health and Human Services regulations on the Protection of Human Subjects, 45 CFR Part 46).

- ***Medical surge*** - An increase in the number or types of patients that severely challenges or exceeds the normal medical infrastructure of an affected community and its ability to provide adequate medical evaluation and care. Events that could lead to a medical surge include: pandemics, epidemics, other public health emergencies, natural or man-made disasters, or mass casualty incidents.

- ***Occupational exposure*** - Exposure, which is or should be reasonably anticipated, to sources of infectious agents resulting from an employee's execution of job duties that involve the provision of direct patient care or the performance of other covered tasks.

- ***Other covered tasks*** - Job duties that do not involve direct patient care but still involve occupational exposure in settings where direct patient care is provided, or occupational exposure to contaminated materials originating from settings where direct patient care is provided or to human remains. ***Other covered tasks*** also include job duties that involve occupational exposure to contaminated materials in diagnostic, research or production facilities. Examples of ***other covered tasks*** would include, but would not be limited to: providing patient support services (e.g., triage reception, housekeeping, food services,

facility maintenance); handling, transporting, receiving or processing contaminated materials (e.g., laundering healthcare linens, transporting medical specimens, disposing of medical waste, reprocessing medical equipment); maintaining, servicing or repairing contaminated medical equipment; conducting autopsies (e.g., in medical examiners' offices); performing mortuary services; manipulating and analyzing cultures, specimens, and human remains containing infectious agents in diagnostic, research and production facilities; and dispensing medications and/or medical supplies in settings where direct patient care is provided.

- ***Patient transport*** - The movement of a patient within a facility, as well as, inter-facility transfer, or movement during pre-hospital emergency medical care.

- ***Personal protective equipment*** **(PPE)** - Specialized clothing or equipment worn by an employee for protection against a hazard. General work clothing (e.g., uniforms, pants, shirts or blouses) not intended to function as protection against a hazard would not be considered PPE.

- ***Physician or other licensed healthcare professional*** **(PLHCP)** - An individual whose legally permitted scope of practice (e.g., a license, certification, or registration) allows her or him to provide a particular healthcare service that would be required by a provision in a rule as outlined in this regulatory framework. A PLHCP could delegate performance of some of these services to other healthcare professionals, provided their legally permitted scope of practice allows them to perform the tasks assigned under the supervision of the PLHCP. For example, although certain healthcare services, such as those that require a definitive diagnosis or post-exposure management, would necessitate a PLHCP with a

particular level of licensure (e.g., a physician, physician's assistant, or nurse practitioner), that PLHCP may delegate to a nurse, such tasks as, obtaining a medical history and exposure incident details.

- ***Standard operating procedures* (SOPs) -** An organizational directive that establishes a standard course of action to accomplish a task or goal.

- ***Standard precautions*** – The minimum infection control practices that apply to all direct patient care, regardless of suspected or confirmed infection status of the patient, in any setting where healthcare is provided.

- ***Transmission-based precautions* -** Infection control measures, used in addition to standard precautions that are designed to prevent or minimize transmission of infectious agents, based on the way the agent is transmitted. Categories include contact, droplet, and airborne precautions, or a combination of these precautions for infectious agents that can be transmitted by more than one route.

- ***Work practice controls* -** Measures designed to reduce the likelihood of transmission of infectious agents by specifying the manner of performing particular work tasks. Examples of work practice controls would include, but would not be limited to: performing tasks in a manner that minimizes generation of droplets or aerosols of infectious agents and practicing appropriate hand hygiene and respiratory hygiene/cough etiquette.

Section 3: Worker Infection Control Plan (WICP)

This section provides the overall framework for an infection control plan that all affected employers would be required to develop to protect their covered workers.

- Each employer having an employee(s) with occupational exposure during provision of direct patient care and/or performance of other covered tasks would be required to develop and implement a written WICP designed to prevent or minimize the transmission of infectious agents to each employee.

- **Exposure determination.** Each employer who has an employee(s) with occupational exposure during provision of direct patient care and/or performance of other covered tasks would be required to prepare an exposure determination. The exposure determination would be required to be made without regard to the use of PPE and would be required to contain a list of all job classifications in which all or some of the employees in those job classifications have occupational exposure.

- **WICP elements.** The WICP would be required to contain at least the following elements:

  - The name and title of, and contact information for, the plan administrator responsible for WICP implementation and oversight (e.g., infection preventionist, occupational health professional, biosafety officer). If the designated plan administrator does not have the knowledge, skills, or training necessary to implement and oversee the plan effectively, then she or he would be required to consult with appropriate personnel who have such knowledge, skills or training to ensure that the WICP is implemented and overseen effectively;

- The name of the person(s) responsible for the daily management of the WICP;
- The exposure determination that would be required; and
- The SOPs that would be required.

- Each employer would be required to ensure that a copy of the WICP is provided and accessible to all of its workers. The WICP could be part of a larger document, such as one addressing overall infection control in the workplace (e.g., a plan that also addresses patient safety, or a Biosafety Plan for laboratories) provided that the larger plan addresses all elements of the WICP. If the WICP is incorporated into a larger document, it would have to be a cohesive entity by itself or there would have to be a guiding document which states the overall program goals and references the elements of the larger document that comprise the WICP.
- The WICP would be required to be reviewed and updated at least annually, and whenever necessary to reflect changes in occupational exposure resulting from:
  - New or modified job tasks and procedures;
  - New or revised job classifications;
  - Changes in technology, updated federal, state, local, and other infection control guidelines, updated vaccination recommendations, or other medical advances that prevent or minimize transmission of infectious agents; and
  - New or emerging infectious agents, or changes in community patterns of infectious diseases (e.g., emergence of an antibiotic resistant infectious agent, an outbreak or a change in prevalence of an infectious disease).

- During development and reviews of the WICP, the employer would be required to:
  - Solicit input from non-managerial workers with occupational exposure regarding the WICP's implementation and possible improvements; and
  - Establish and maintain records for each review and/or update of the WICP that include:
    - The name(s) of the person conducting the review;
    - The dates the review was conducted and completed;
    - The name(s) and work area(s) of workers involved; and
    - A summary of the conclusions of the review and a timeline for completion of action items.
- **Host employer potential duties with respect to contractors, vendors, and licensed independent practitioners with privileges.** Where occupational exposure exists, the host employer would be required to:
  - Ensure that contractors, vendors, and licensed independent practitioners with privileges, at a minimum, adhere to infection control practices consistent with the host employer's WICP. Contractors, vendors, and licensed practitioners with privileges may adhere to infection control practices that are more protective than those contained in the host employer's WICP.
  - Ensure that its WICP is followed by each of its employees, even when instructions from a contractor, vendor or licensed independent practitioner with privileges (as described above) are contrary to the host employer's WICP. However, the host employer would

be permitted to allow its employees to follow contrary instructions from a contractor, vendor or licensed independent practitioner with privileges (as described above) if the host employer is able to show that not following the contrary instructions would be a greater hazard to a patient(s) or an employee(s), or that following the contrary instructions is consistent with recognized and generally accepted good infection control practices; and

- Ensure that a copy of its WICP is provided and accessible to all contractors, vendors, and licensed independent practitioners with privileges.

- **Contractors, vendors, and licensed independent practitioners with privileges.** Notwithstanding the host employer potential duties with respect to contractors, vendors, and licensed independent practitioners with privileges, employers that are contractors, vendors, and licensed practitioners with privileges would be obligated to comply with all components of a rule as outlined in the regulatory framework, including development and implementation of a written WICP.

- The WICP would be required to be made available to the Assistant Secretary, upon request, for examination and copying.

Section 4: Standard Operating Procedures Development and Implementation

This section describes the general considerations for, and sources that employers would be required to consider, in developing their SOPs. In addition, this section provides a list of SOPs that employers in all affected work settings would be required to develop as part of their WICPs,

and specific SOPs that employers with workers that provide direct patient or workers that perform other covered tasks would be required to develop.

- **General Considerations.** The employer would generally (unless otherwise stated in this regulatory framework) be required to develop, implement, and update written SOPs that are consistent with recognized and generally accepted good infection control practices relevant to the occupational exposures encountered by employees during their job tasks.
    - In developing and updating SOPs, the employer would be required to consider applicable regulations (e.g., federal, state and local regulations) and current guidelines (e.g., those issued by the CDC and its Federal Advisory Committees, such as the Healthcare Infection Control Practices Advisory Committee (HICPAC) and the Advisory Committee on Immunization Practices, CDC/National Institutes of Health (NIH) Biosafety in Microbiological and Biomedical Laboratories guidance, and the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules); and
    - In the absence of such regulations and guidelines, the employer would be required to consider current guidance issued by professional organizations and accrediting bodies.
    - In the situation where the employer is conducting research on infection control practices, the employer would be allowed to consider research protocols not consistent with recognized and generally accepted good infection control practices, provided those protocols have been approved by an institutional review board and adequately address employee protection as a component of the overall protection of the human subjects.

- The employer would be required to develop, implement, and update written SOPs that are consistent with applicable requirements in Part 1910 (e.g., requirements contained in 29 CFR 1910.134, and 29 CFR 1910 Subpart I); and, if a recognized and generally accepted good infection control practice conflicts with an applicable requirement in Part 1910, the employer would be required to incorporate into its SOPs, and implement, the Part 1910 requirement.

- **All Affected Work Settings.** All employers' SOPs would be required to contain at least the following procedures:

  - **Infectious agent hazard evaluations.** Procedures to promptly identify suspected or confirmed sources of infectious agents that are present in the work setting by conducting timely infectious agent hazard evaluations.

    Note: OSHA would not require infectious agent hazard evaluations to be written documents; OSHA would permit the evaluations to be incorporated into routine activities, such as triage;

  - **Communication of hazard evaluation results.** Procedures to communicate the results of the infectious agent hazard evaluation and the status of any suspected or confirmed sources of infectious agents to the person(s) responsible for implementing worker protection precautions;

  - **Hand hygiene.** Procedures to ensure that handwashing facilities are available and accessible, and for following recognized and generally accepted good infection control practices for hand hygiene.

- **Food and cosmetics.** Procedures for restricting eating, drinking, smoking, applying cosmetics or lip balm, handling contact lenses, and storage of food and drink to areas where there is no occupational exposure during provision of direct patient care and/or performance of other covered tasks. The procedures would be required to prohibit storage of food and drink in refrigerators or freezers that contain contaminated materials.

- **Engineering, administrative and work practice controls, and personal protective equipment (PPE).**

  - Procedures for the use of engineering, administrative and work practice controls in accordance with recognized and generally accepted good infection control practices;

  - Procedures to provide, make readily accessible, and ensure that each employee uses PPE (such as, but not limited to, gloves, gowns, laboratory coats, face shields, facemasks, and respirators) in accordance with recognized and generally accepted good infection control practices;

    Note: Infection control practices normally rely upon a multi-layered and overlapping strategy of employing engineering, work practice, administrative controls, and PPE. Therefore, OSHA would permit adherence to the required hierarchy of controls, such as that required by 29 CFR 1910.134(a)(1), to be modified in accordance with recognized and generally accepted good infection control practices.

- Procedures for examining engineering controls on a regular schedule, and maintaining or replacing them to ensure their effectiveness; and
- Procedures involving occupational exposure that are performed in a manner that prevents or minimizes generation of infectious agents. Where generation of droplets or aerosols is necessary (e.g., sputum induction), OSHA would require the procedures to prevent or minimize transmission of infectious agents;

- **Decontamination.**
  - Procedures for the routine and targeted decontamination of all contaminated materials (i.e., contaminated items and/or surfaces) in the work setting that could be a source of occupational exposure; and
  - Procedures to ensure that contaminated equipment is inspected and decontaminated prior to servicing or shipping. If decontamination of such equipment or portions of such equipment is not feasible, OSHA would require that the procedures ensure that the equipment be labeled/color-coded;

- **Handling, containerization, transport, or disposal of contaminated materials.**
  - Procedures to ensure that contaminated materials that could be a source of occupational exposure are placed in a container that is labeled/color-coded and that prevents leakage, and that employee contact with the contaminated materials during collection, handling, processing, storage, transport, shipping or disposal is minimized or prevented; and

- Procedures to ensure that, if the contaminated materials could puncture the primary container, the primary container is placed within a secondary container that is puncture-resistant and prevents leakage. In such cases, OSHA would require that the procedures provide that the secondary container also be labeled/color-coded;

- **Occupational health services.** Procedures for the employer to provide occupational health services, including screening, surveillance, vaccinations and vaccination regimens (e.g., doses, intervals), post-exposure treatment and follow-up, and medical removal protection, that are consistent with recognized and generally accepted good infection control practices relevant to the occupational exposures encountered by employees during their job tasks, as would be required under section 5 (Medical screening, surveillance and vaccination);

- **Exposure incidents.** Procedures to investigate the circumstances surrounding each exposure incident, including determination of the cause of the incident, and whether existing policies, procedures, or training need to be revised to prevent future exposure incidents;

- **Signage and labeling/color-coding.** Procedures for the use of signage and labeling/color-coding to convey an appropriate hazard warning to employees throughout the employer's work settings. The procedures would also require the use of signage and labeling/color-coding to convey an appropriate hazard warning to employees outside the employer's work setting, when such employees may be exposed to contaminated materials originating from the employer's work setting (e.g.,

specimens, equipment, laundry) during collection, handling, processing, storage, transport, shipping, and disposal activities; and

- **Notification of occupational exposure during transfer, transport, shipping, or receipt of sources of infectious agents.** Employers that transfer, transport, ship, or receive sources of infectious agents (e.g., suspected or confirmed infectious individuals and/or contaminated materials) would be required to include procedures in their SOPs for notifying other employers whose employees have or had occupational exposure to such sources;

- **Direct patient care.** In addition to the SOPs that would be required for all affected work settings, employers whose employees provide direct patient care would be required to develop, implement, and update SOPs that contain at least the following procedures for those employees:
  - **Patient scheduling and intake/admittance.** For employers that conduct patient scheduling and intake/admittance, procedures to promptly identify individuals with suspected or confirmed infectious diseases in order to initiate appropriate infection control practices (e.g., precautionary isolation or segregation; and patient placement and/or transfer, including procedures guiding patient treatment or transfer outside of the facility);
  - Procedures for standard precautions;
  - Procedures for contact precautions;
  - Procedures for droplet precautions;

- Procedures for airborne precautions, including:
  - If the employer's healthcare setting does not have an available AIIR, the procedures for the temporary isolation and inter-facility transfer of an individual with a suspected or confirmed airborne-transmissible infectious disease. OSHA would require that these procedures include the methods the employer will use to: isolate the individual, to the extent feasible, until transfer or AIIR placement; limit occupational exposure to the individual; and transfer the individual, as soon as feasible after identification, to a facility with an available AIIR;

    Note: OSHA would not require transfer of the individual if: a transfer would be medically detrimental to the individual's health; it is not medically necessary for the individual to remain in the healthcare facility (e.g., it is appropriate to send the individual home); or an AIIR becomes available for isolation of the individual.
  - If the employer's healthcare setting has an AIIR, the procedures for ensuring proper AIIR operation. These would include procedures for ensuring that each AIIR, associated ducting, and filtration are constructed, operated, and maintained so that they maintain negative pressure, achieve sufficient air changes per hour, properly exhaust contaminated air, and function to prevent or minimize transmission of infectious agents, and for ensuring that, when in use, each AIIR is monitored daily for maintenance of negative pressure; and
  - The procedures for use of respiratory protection. These would include, but would not be limited to, procedures for use: when entering areas, rooms, or homes where individuals have been isolated; when transporting individuals with suspected or

confirmed infectious disease in an enclosed vehicle; during aerosol-generating procedures; during maintenance of air systems or equipment reasonably likely to contain airborne-transmissible infectious agents; and in any situations where the infectious agent hazard evaluation indicates that respiratory protection is necessary for employee protection. These would also include procedures to ensure that a facemask is not used to provide respiratory protection if the use of a respirator is required under 29 CFR 1910.134;

- Procedures for patient transport;
- **Medical surge procedures.** For employers that provide services in medical surge conditions, procedures for the implementation of temporary control measures for medical surge conditions. OSHA would require that these control measures include: work practices; decontamination; set-up, performance testing, and use of temporary engineering controls used to establish AIIAs (where appropriate); and preparation for the appropriate use of PPE during such situations, including procedures for stockpiling necessary supplies and PPE; and
- Any other employee protection precautions necessary to address specific infectious diseases or circumstances.

- **Other covered tasks.** In addition to the SOPs that would be required for all affected work settings, employers whose employees perform other covered tasks would be required to develop, implement, and update SOPs that contain at least the following procedures for those employees:
  - Procedures for the handling and intake of contaminated materials;

- Procedures for the use of control measures necessary to prevent or minimize transmission of infectious agents;
- For diagnostic, research and production facilities, in addition to the other procedures that would be required for other covered tasks, procedures to implement standard microbiological practices and any special practices for handling infectious agent(s) of a specific biosafety level, including, as appropriate:
  - Engineering controls, such as biosafety cabinets, laboratory hoods, and other laboratory design and containment measures, which would need to be appropriately constructed, operated, and maintained (e.g., proper air flow, exhaust air filtration, double access doors, special design requirements for Biosafety Level 3 and 4 facilities); and
  - Measures necessary to address uncontrolled releases of infectious agents, including mitigation of such releases and prompt reporting of such incidents to appropriate authorities (e.g., federal, state, and local authorities); and
- Procedures covering any other employee protection precautions necessary to address specific infectious diseases or circumstances.

- The employer would be required to ensure that each employee follows the SOPs applicable to that employee's job duties.

Section 5: Medical screening, surveillance and vaccination

This section specifies, among other things, the medical screening, surveillance and vaccinations that would be required to be provided to workers who have occupational exposure, and the procedures that would be required to be followed after an exposure incident occurs.

- **General.**
  - The employer would be required to make available medical screening, surveillance, and vaccinations to each employee who has occupational exposure during provision of direct patient care and/or performance of other covered tasks, and post-exposure evaluation and follow-up to each employee who has had an exposure incident.
  - The employer would be required to ensure that each medical evaluation and procedure is performed by, or under the supervision of, a PLHCP and that each laboratory test is conducted by an accredited laboratory.
- **Vaccinations.**
  - The types of vaccinations made available, and associated vaccination regimens (e.g., doses, intervals), would be required to be consistent with recognized and generally accepted good infection control practices relevant to the occupational exposures encountered during the job tasks of the employee.
    - The employer of an employee(s) in a research or production facility would be required to make available to that employee(s) any vaccination(s) specified in the employer's WICP, or determined by a PLHCP to be medically appropriate for a particular employee.

- The employer of an employee(s) in a work setting other than a research or production facility would be required to make available to that employee(s), at a minimum, the following vaccinations:
  - Influenza (Seasonal and Pandemic);
  - Measles, Mumps and Rubella (MMR);
  - Tetanus, Diphtheria, and Pertussis (Tdap);
  - Varicella; and
  - Any other vaccination(s) that is specified in the employer's WICP, or determined by a PLHCP to be medically appropriate for a particular employee (e.g., the meningococcal vaccine).

- The employer would be required to review and update the vaccination(s) specified in its WICP at least annually, and whenever necessary to reflect changes in occupational exposure.

- **Exception.** The employer would not need to make available a vaccination(s) to an employee with occupational exposure if the employer has documented that the employee's vaccination(s) is up-to-date, antibody testing has revealed that the employee is immune, or a vaccine(s) is contraindicated for medical reasons.

- The employer would be responsible for monitoring administration of a vaccination series until completion. Upon completion of the series, any further testing, (e.g., antibody titer) would be required to be made available in accordance with recognized and generally accepted good infection control practices.

- Vaccinations would be required to be made available after the employee has received the training that would be required, as appropriate, and prior to the initial assignment to a job with occupational exposure. Vaccinations that require a series of inoculations would be required to be started prior to initial assignment to a job with occupational exposure.

- If, after completing the training that would be required, the employee declines a vaccination(s) or decides not to complete a vaccination that requires a series of inoculations, the employer would be required to ensure that the employee signs a declination statement (see Attachment B of this regulatory framework).

- If the employee initially declines a vaccination(s) but, at a later date, decides to accept the vaccination(s), the employer would be required to make the vaccination(s) available at that time.

- Revaccination or booster dose(s) of a vaccine would be required to be made available for each employee with occupational exposure in accordance with recognized and generally accepted good infection control practices.

- **Medical Screening and Surveillance.** The employer would be required to ensure that a PLHCP determines the necessity and frequency of medical screening and surveillance of the employer's employees who have occupational exposure during provision of direct patient care and/or performance of other covered tasks. Based upon this determination, the employer would be required to make available confidential medical surveillance (e.g., tuberculosis testing) for each employee with occupational exposure. Where medical surveillance tests indicate the need for further medical evaluation and follow-up (e.g., to

determine the need for precautionary removal of an employee), the employee would be referred to a PLHCP for such services.

- **Medical Evaluation and Follow-up.**
  - Following a referral from a medical screening or surveillance program, the employer would be required to promptly make available to the employee(s) a confidential medical evaluation and appropriate follow-up.
  - Following a report of an exposure incident, the employer would be required to investigate the incident and would be required to promptly make available to the exposed employee(s) a confidential post-exposure medical evaluation and appropriate follow-up, including at least the following elements:
    - Documentation of the route(s) of exposure and the circumstances under which the exposure incident occurred;
    - Identification and documentation of the source, unless the employer could establish that identification is not feasible or is prohibited by federal, state or local law;
    - Appropriate baseline testing of the exposed employee(s), after consent is obtained, for use in determining future seroconversion or infection;
    - Post-exposure prophylaxis and treatment appropriate to the infectious agent(s) of concern;
    - Counseling, as necessary;
    - Evaluation of reported illnesses that may be attributable to the exposure; and

- Recommendations, if any, for modifications or restrictions to the employee's job duties or for precautionary removal of the employee from the workplace.

- **Exposure incident records.** The employer would be required to establish and maintain records of exposure incident(s). The employer would not be obligated to establish and maintain records of exposure incident(s) that involve occupational exposure to the common cold or influenza, with one exception. In research and production facilities, the employer would be required to establish and maintain records of an exposure incident(s) involving infectious agents, including those that cause the common cold and influenza. Records would be required to include:

  - The date of the exposure incident(s), where feasible;
  - The work setting and the work task(s) being performed when the exposure incident(s) occurred;
  - The name(s) or any other identifier(s) (e.g., employee ID number(s)) of the employee(s) to which post-exposure evaluation and follow-up was made available;
  - The infectious agent(s) to which the employee(s) was exposed;
  - A description of any post-exposure evaluations and follow-ups that were performed, the results of those evaluations, and the dates on which they occurred; and
  - The date of contact and contact information for any other party who either notified the employer, or was notified by the employer, regarding the exposure incident(s).

- **Information Provided to the PLHCP.**

- The employer would be required to ensure that the PLHCP providing the employee's vaccination(s) is given a copy of a rule as outlined in the regulatory framework.
- The employer would be required to ensure that the PLHCP evaluating an employee after an exposure incident is provided the following information:
  - A copy of a rule as outlined in the regulatory framework;
  - A description of the exposed employee's duties as they relate to the exposure incident;
  - Documentation of the route(s) of exposure and circumstances under which exposure occurred; and
  - Other medical records regarding the exposure incident that are relevant to the appropriate treatment of the employee, including, but not limited to, the employee's vaccination status (for which the employer would be required to establish and maintain an accurate record).

- **PLHCP's Written Opinions.** The employer would be required to obtain and provide the employee with a copy of the evaluating PLHCP's written opinion(s) within 15 days of the completion of the evaluation.
  - All findings or diagnoses would be required to remain confidential between the PLHCP and the employee and not be included in the written report to the employer.
  - The written opinion for vaccination(s) that is provided to the employer would be required to be limited to whether a vaccination(s) is (are) indicated for an employee, and if the employee has received or refused such vaccination(s).

- The written opinion for the evaluation and follow-up for medical screening and surveillance that is provided to the employer would be required to be limited to the following information:
  - That the employee has been informed of the results of the evaluation; and
  - Recommendations, if any, for modifications or restrictions to the employee's job duties or for precautionary removal of the employee from the workplace.
- The written opinion for post-exposure evaluation and follow-up that is provided to the employer would be required to be limited to the following information:
  - That the employee has been informed of the results of the evaluation;
  - That the employee has been told about any medical conditions resulting from exposure to infectious agents that require further evaluation or treatment; and
  - Recommendations, if any, for modifications or restrictions to the employee's job duties or for precautionary removal of the employee from the workplace.

- **Medical Removal Protection.**
  - **Employee Restrictions or Removal.** The employer would be required to follow the PLHCP's recommendations concerning modifications or restrictions to an employee's job duties or precautionary removal of an employee from the workplace (e.g., to protect patients or co-workers).
  - **Medical Removal Protection Benefits.** When an employee has been removed from his or her job or otherwise medically limited as a result of an exposure incident, the employer would be required to pay the employee her or his total normal earnings, and

maintain the employee's seniority and all other employee rights and benefits, including the employee's right to his or her former job status.

- The employer would not be obligated to provide medical removal protection benefits to employees removed from their jobs or otherwise medically limited as a result of occupational exposure to the common cold or influenza, with one exception. In research and production facilities, if an employee is removed from her or his job or otherwise medically limited as a result of an exposure incident to any infectious agent with which she or he is working (including the common cold or influenza viruses), the employer would be required to provide medical removal protection benefits to the employee.

- The employer would be required to provide medical removal benefits until the employee is determined to be noninfectious or is otherwise able to return to normal duties, but provision of benefits would not need to exceed a period of 18 months.

- The employer's obligation to provide medical removal protection benefits to a removed or restricted employee would be required to be reduced to the extent that the employee receives compensation for earnings lost during the period of removal either from a publicly- or employer-funded compensation program, or from employment with another employer made possible by virtue of the employee's removal.

  Note: OSHA's regulatory framework in no way is intended to preclude the employer from offering administrative or sick leave for medical removal of an

employee even when a rule as outlined in the regulatory framework would not require medical removal protection benefits.

- **Medical Records.**
  - The employer would be required to establish and maintain an accurate record for each employee who has occupational exposure during provision of direct patient care and/or performance of other covered tasks, in accordance with 29 CFR 1910.1020.
  - This record would be required to include:
    - The employee's name or any other employee identifier (e.g., employee ID number);
    - A copy of the employee's vaccination status for all vaccines that the employer would be required to offer, including the dates of all vaccinations, any medical records relative to the employee's ability to receive a vaccination(s) that would be required, and any vaccination declination statements signed by the employee;
    - A copy of all results of examinations, medical testing, and follow-up procedures that would be required;
    - A copy of the information provided to the PLHCP; and
    - The employer's copy of the PLHCP's written opinion.
- **Confidentiality.** The employer would be required to ensure that employee medical records are kept confidential and not disclosed or reported, without the employee's express written consent, to any person within or outside the workplace, except as would be required by OSHA or as may be required by law.

Section 6: Training

This section specifies the types and periods of training that employers would be required to provide to workers with occupational exposure to infectious agents.

Training.

- The employer would be required to institute a training program and ensure each employee who has occupational exposure during provision of direct patient care and/or performance of other covered tasks participates in the program, and is provided training as follows:
    - Initially, prior to the time of assignment to tasks where occupational exposure may take place;
    - Annually thereafter, not to exceed 12 months from the previous training. If an employee(s) has received infectious diseases training in the 12 months preceding the effective date of the standard, OSHA would require the employer to provide training only to the extent that the previous training was deficient; and
    - Supplemental training to address specific deficiencies would be required to be provided when:
        - Changes, such as modification of tasks or procedures or institution of new tasks or procedures or control measures, affect the employee's occupational exposure. This training would be limited to addressing the changes;
        - Inadequacies in the employee's knowledge or work practices indicate that the employee has not retained the requisite understanding or skill; or

        - Any other situation arises in which retraining is necessary to ensure employee protection from occupational exposure.

    - The training program would be required to:
        - Be overseen or conducted by a person knowledgeable in the program's subject matter as it relates to the employees' workplace;
        - Consist of material appropriate in content and vocabulary to educational level, literacy, and language of employees; and
        - Provide an opportunity for interactive questions and answers with a person knowledgeable in the program's subject matter as it relates to the workplace.

- The initial training program would be required to contain, at a minimum, the following elements:
    - An accessible copy of a rule as outlined in the regulatory framework and an explanation of its contents;
    - A general explanation of the epidemiology and symptoms of common infectious diseases, including the signs and symptoms of infectious diseases that require further medical evaluation;
    - An explanation of the modes of transmission of infectious agents and applicable infection control procedures (e.g., standard and transmission-based precautions) so that the employee can recognize tasks and other activities that may involve occupational exposure and take precautionary measures;

- Information on vaccine(s) that would be required to be made available to the employee, including their efficacy, contraindications, likelihood and severity of possible adverse health effects, method of administration, the benefits of being vaccinated, and that the vaccines and vaccinations will be offered at no cost to the employee and at reasonable times and places;
- An explanation of the employer's WICP and the means by which the employee can obtain a copy of the written plan;
- Training on all of the SOPs developed as part of the WICP that are applicable to the employee's duties;
- An explanation of the use and limitations of engineering, work practice, and administrative controls; and
- Information on the types, proper use, limitations, location, handling, decontamination, removal, and disposal of personal protective equipment.

- The annual training program would be required to address, at a minimum, the following elements:
  - Information on the types, proper use, limitations, location, handling, decontamination, removal, and disposal of personal protective equipment;
  - All of the SOPs developed as part of the WICP that are applicable to the employee's duties; and
  - Information on vaccine(s) that would be required to be made available to the employee in the year of the training, including their efficacy, contraindications, likelihood and

severity of possible adverse health effects, method of administration, the benefits of being vaccinated, and that the vaccines and vaccinations would be required to be offered at no cost and at reasonable times and places.

Section 7: Recordkeeping

This section specifies the types of records that would be required to be retained by the employer, the retention period that would be required for each record, and the employer's potential obligation to make certain records available to the worker and OSHA upon request.

- **Record maintenance**. The employer would be required to maintain the following records for the time periods specified:
  - Medical records for at least the duration of employment plus 30 years;
  - Exposure incident records for at least the duration of employment plus 30 years; and
  - WICP review records for three years.
- **Availability.**
  - Exposure incident records, the WICP, and the WICP review records would be required to be made available for examination and copying to workers and/or their representatives;
  - Medical records of each employee would be required to be provided, upon request, for examination and copying to the employee and to anyone having written consent of the employee; and

- The employer would be required to ensure that all records that would be required to be maintained be made available to the Assistant Secretary, upon request, for examination and copying.

Section 8: Cost and Availability

This section specifies that costs incurred by employee(s) would be compensable and that any activities that would be required of employees be conducted at a reasonable time and place.

- **Cost.** OSHA would require that the implementation of all provisions outlined in this regulatory framework be at no cost to the employee(s) and that all employee time that would be spent complying with the provisions outlined in this regulatory framework, including time for training, medical evaluations/procedures, and reasonable travel time (as appropriate) be considered compensable time.

- **Availability.** OSHA would require that all medical evaluations and procedures (including vaccinations and post-exposure evaluation and follow-up) and any training be made available to the employee at reasonable times and places.

Attachment A – Common Infectious Agents and Their Modes of Transmission in Healthcare Settings (An appendix of this nature would be non-mandatory).

An appendix to a rule as outlined in the regulatory framework could contain a list of common diseases and infectious agents categorized by whether occupational exposure to the disease or agent typically requires contact, droplet or airborne precautions, as indicated below. This list represents scientific knowledge at the time this regulatory framework was written. However, there may be less common or new/emerging infectious diseases not reflected in this appendix. Additionally, continuing research on infectious diseases may impact how standard and transmission-based precautions are applied to the control of a particular disease.

To obtain current scientific information, employers should consult authoritative sources (e.g., CDC guidelines, state and local health department guidelines, medical journals, professional societies) on infectious diseases.

Infectious Agents/Diseases Requiring Contact Precautions
Clostridium difficile
Diphtheria cutaneous
Hepatitis A
Human metapneumovirus
Norovirus
Parainfluenza virus, in infants and young children
Respiratory syncytial virus (RSV), in infants, young children or immunocompromised adults
Rotavirus
Staphylococcal disease (including diseases caused by methicillin-resistant *Staphylococcus aureus* [MRSA])
- Major skin, wound or burn
- Scalded skin syndrome

Vancomycin-resistant *Enterococcu*s (VRE)
Any other disease for which public health guidelines recommend contact precautions

Infectious Agents/Diseases Requiring Droplet Precautions
Diphtheria pharyngeal
Epiglottitis, due to *Haemophilus influenzae* type b
Haemophilus influenzae Serotype b (Hib) disease/*Haemophilus influenzae* serotype b -- Infants and children
Influenza, human (typical seasonal variations)/influenza viruses
Meningitis
- *Haemophilus influenzae*, type b known or suspected
- *Neisseria meningitidis* (meningococcal) known or suspected

Meningococcal disease sepsis, pneumonia (see also meningitis)
Mumps (infectious parotitis)/Mumps virus
Mycoplasmal pneumonia
Parvovirus B19 infection (erythema infectiosum)
Pertussis (whooping cough)

Pharyngitis in infants and young children/Adenovirus, Orthomyxoviridae, Epstein-Barr virus, Herpes simplex virus,
Pneumonia
- Adenovirus
- Haemophilus influenzae Serotype b, infants and children
- Meningococcal
- *Mycoplasma*, primary atypical
- *Streptococcus* Group A

Pneumonic plague/*Yersinia pestis*
Rubella virus infection (German measles)/Rubella virus
Severe acute respiratory syndrome (SARS)
Streptococcal disease (group A streptococcus)
- Skin, wound or burn, Major
- Pharyngitis in infants and young children
- Pneumonia
- Scarlet fever in infants and young children
- Serious invasive disease

Viral hemorrhagic fevers due to Lassa, Ebola, Marburg, Crimean-Congo fever viruses (airborne precautions may be required for aerosol-generating procedures)
Any other disease for which public health guidelines recommend droplet precautions

Infectious Agents/Diseases Requiring Airborne Precautions
Aerosolizable spore-containing powder or other substance that is capable of causing serious human disease, e.g. Anthrax/*Bacillus anthracis*
Varicella disease (chickenpox, shingles)/Varicella zoster and Herpes zoster viruses, disseminated disease in any patient. Localized disease in immunocompromised patient until disseminated infection ruled out
Measles (rubeola)/Measles virus
Monkeypox/Monkeypox virus
Novel or unknown infectious agents
Severe acute respiratory syndrome (SARS)
Smallpox (variola)/Variola virus
Tuberculosis (TB)/*Mycobacterium tuberculosis* -- Extrapulmonary, draining lesion; Pulmonary or laryngeal disease, confirmed; Pulmonary or laryngeal disease, suspected
Any other disease for which public health guidelines recommend airborne precautions.

Attachment B – Vaccine Declination (An appendix of this nature would be mandatory)

OSHA would require employers to use a vaccination declination statement, like the one below, for workers who decline vaccination(s).

VACCINE DECLINATION

I understand that in the course of doing my work, I am at risk of exposure to infectious agents that cause diseases. There are vaccines to protect against some of these diseases. My employer has given me the opportunity to be vaccinated against some/all of the infectious agents listed in the table below. These vaccines have been offered to me at no cost to myself.

However, as I have indicated in the table below, I have decided not to receive some or all of the offered vaccination(s) at this time. I understand that by not receiving the vaccination(s), I continue to be at risk of being infected, and that some of these infections may be very serious.

I can change my mind at any time and ask to be vaccinated at no cost to myself if in the future I continue be at risk of exposure to the infectious agents at work.

Infectious Agent(s) To Which I Am At Risk of Exposure At Work, and Vaccines that Have Been Offered to Me for Protection Against Infection From The Agent(s)

Infectious agent	Worker at risk of occupational exposure to agent (Employer initials in boxes that apply)		Vaccine	Worker offered vaccine (Worker initials in boxes that apply)		Worker declined vaccine (Worker initials in boxes that apply)
	Yes	No		Yes	No	
Influenza virus			Influenza			
Mumps virus, Measles virus, and/or Rubella virus			MMR			
Chickenpox virus			Varicella			
Clostridium tetani, Corynebacterium diphtheriae, and/or *Bordetella pertussis*			Tetanus, Diphtheria, and Pertussis (Tdap)			
Other (specify)						

_____
Worker's Name (Printed)

_____ _____
Worker signature Date