



Office of Advocacy

March 5, 1998

Honorable Charles N. Jeffress
Assistant Secretary
for Occupational Safety and Health
Department of Labor
200 Constitution Avenue, N.W.
Washington, D.C. 20210

[Re: October 17, 1997 proposed rule on Occupational Exposure to Tuberculosis\[PDF File\]](#)

Dear Mr. Jeffress:

The Office of Advocacy submits the following comments on the Occupational Safety and Health Administration's (OSHA) October 17, 1997 proposed rule on Occupational Exposure to Tuberculosis. (1) Please include the comments in the public record.

The Office of Advocacy was established by Congress under Public Law No. 94-305 to represent the views of small businesses before Federal agencies and Congress. Advocacy also is required by §612 of the Regulatory Flexibility Act (RFA) (2) to monitor agencies' compliance with the RFA and report annually to the President and Congress.

INTRODUCTION

Overview

Tuberculosis (TB) afflicts the most vulnerable members of our society, the sick, the poor, the elderly and the homeless. It is the responsibility of the U.S. Public Health Service to address TB in the general population. OSHA is responsible for protecting workers from TB on the job. OSHA's proposal estimates that more than 5 million workers are exposed to TB in the workplace, a majority of these workers, almost 4 million, are employed in hospitals and nursing homes. (3) OSHA predicts that this rule would avert 21,000 to 26,000 work related TB infections per year; 1,500 to 1,750 active disease cases resulting from these infections; and 115 to 136 deaths directly related to the infections.

In order to control worker exposure to TB, OSHA's proposal includes specific workplace requirements that include, but are not limited to: the development and implementation of a written plan to control employee exposure to TB; the required use of respirators when administering certain job functions and patient care; provisions specifying the medical management and medical recordkeeping of employees who may be exposed to TB; and detailed requirements for work practice and engineering controls.

According to the U.S. Public Health Service's Centers for Disease Control and Prevention (CDC) the number of TB cases reported annually in the United States during 1992-1995 has declined substantially, 14.5%. (4) The reasons for this decline appears to be an open question that deserves exploration. Furthermore, in light of the decline in reported TB cases, the Office of Advocacy encourages OSHA to view this rulemaking as an opportunity to engage public and private sectors in a public health discussion as to the best approach for controlling this disease further. Questions to be addressed: Is OSHA's approach the best way to control this disease and protect the health of

workers? Are increased requirements for costly engineering controls and patient transfer the best allocation of very limited resources to manage TB exposure in hospices, substance abuse centers, and homeless shelters?

Small Business Advocacy Review Panel

Many of the concerns addressed in this letter were originally raised by small entities in discussions with the Small Business Advocacy Review Panel convened, as required by the RFA, for this rule and were also outlined in the November 12, 1996 panel report. (5) The Office of Advocacy appreciates that OSHA has responded to many of the issues raised by small entities during the panel process, including further clarification of key terms, definitions, and requirements. OSHA has also provided a matrix which lists the small business panel recommendations side by side with OSHA's response to the recommendation. (6) For many of the recommendations, OSHA has solicited additional comment.

Advocacy continues to urge OSHA to consider more fully the alternatives and recommendations presented by affected small entities in response to the proposal.

What follows is a discussion of 1) the public policy implications of this rule; 2) the various small entity sectors covered by this rule; and 3) certain provision of the rule that need clarification and/or modification. Additional comments on OSHA's regulatory impact analysis are attached as an addendum.

Public Policy Issues

Complex issues surround the spread of TB. They include, but are not limited to, conditions such as poor health care, malnutrition, Auto Immune Deficiency Syndrome, and drug abuse. The Office of Advocacy supports OSHA's mission to protect the health of American workers. But it is also of the view that measures taken to protect workers should not create possibly greater risks in the general population, especially if there are regulatory/programmatic alternatives that could address the risk to workers almost as effectively as this proposal.

Several public bodies (Federal, state and local) and a variety of caregiver services/entities have programs in place to control infectious diseases, such as TB, in high risk populations. OSHA's efforts need to be coordinated with these activities to ensure maximum impact for the entire mosaic of health programs. However, Advocacy believes that OSHA's efforts to do so thus far have been inadequate and that insufficient attention has been paid to creating partnerships with these entities to reduce incidents of TB. Without a meaningful discussion on how best to coordinate and assess alternatives that might have equal but possibly less costly and less adverse impact on small entities, the feasibility and effectiveness of controlling workplace TB through the proposed regulation cannot be assessed. OSHA's proposal provides an opportunity for this discussion and Advocacy's comments are directed at stimulating that discussion on the public record.

Federal Agency Coordination

Advocacy continues to encourage coordination among Federal agencies to ensure that the most effective approach for controlling the spread of TB in the workplace is developed and implemented. We recommend that OSHA reevaluate its proposal against the backdrop of the responsibilities it shares with CDC and the Health Care Financing Administration (HCFA) in controlling infectious disease. CDC, in addition to keeping track of TB in the general population, has published peer reviewed guidelines for the prevention of transmission of TB in homeless shelters, long-term care facilities for the elderly, and correctional institutions. HCFA already requires that facilities receiving Medicare and Medicaid funding implement an infection control program.

Data Collection and Analysis

CDC data on the incidents of TB cases is the best data available. But it needs to be acknowledged that this data does not make a casual link between the workplace and the incidents of TB in health

care workers. This is not to say that it is unreasonable to make such an inference. However, from a public policy perspective it would be valuable to know if the incidents among workers are fewer in entities where either CDC guidelines have been implemented or where provisions of this rule are already in place than in entities where no such preventative programs exist. This would be evidence of the effectiveness of the preventive measures and possibly provide persuasive substantiation for regulatory action - whether at the federal or the state level.

Information and Education

We also recommend a coordinated effort of combining the resources of CDC and OSHA to perform outreach to sectors (e.g., small non-profits and homeless shelters) where education might be equally effective as regulatory oversight. OSHA should anticipate that certain sectors will be unable to implement this regulation. If the agency is to limit the spread of TB, it must provide guidance and assistance in controlling TB while recognizing the limited resources of these organizations. How will employees benefit if OSHA finalizes a rule which cannot and will not be implemented?

In addition, consideration should be given to developing a legal Memorandum of Understanding (MOU) with HCFA. HCFA has special expertise in infection control programs. An MOU between OSHA and HCFA could include special performance-based provisions for TB controls to address incidents of employee TB cases. TB controls could be incorporated as part of the larger infectious control program within any facility which receives Medicare and Medicaid reimbursements.

Other Federal agencies concerned with public health should be involved as partners in this effort, agencies such as the Health Resources and Services Administration, the Department of Housing and Urban Development and the Federal Emergency Management Administration - agencies that manage programs servicing high risk populations.

State and Local Health Care Programs

Cooperation is necessary among Federal, state and local governments to educate the regulated sectors on occupational exposure to TB. OSHA has determined that 18 states require TB screening of employees in medical facilities and 23 have testing requirements for nursing home employees. [\(7\)](#) What research exists on the effectiveness of these requirements? In addition, has OSHA considered that other states such as rural states, may not have implemented regulations because there was no prevalent TB problem? A better public policy decision will result with more information on the overlap, effectiveness or conflict with these state rules.

Local and state officials will have to address another problem. As a result of this rulemaking to protect workers, over 17,000 inmates per year are expected to be transferred for medical evaluation from correctional facilities, managed both publicly and privately. OSHA anticipates that each of the 2,000 facilities will have transfers. Questions obviously arise concerning the resources allocated for this purpose. In addition to the cost of transferring, local and state officials will have to assure that isolation-equipped medical facilities are available to handle the inmate population.

Private Sector

One mechanism available to regulate an industry is self-imposed requirements associated with certifications. OSHA is disregarding this option as insufficient to substitute for Federal regulations. Is this appropriate or justified? Specifically, Advocacy recommends that OSHA fully explore this alternative by engaging in discussion with the certifying bodies (e.g., Joint Commission for Accreditation of Healthcare Organizations). Recommendations from OSHA to certifying bodies could include: 1) a change in the certification requirements for hospitals and other medical facilities and 2) data collection on employee exposures to TB, TB conversions, infections and active cases.

Small Entities Subject to the Rule

OSHA has concluded that the rulemaking is expected to have a significant impact on a substantial

number of small entities. These entities, which include homeless shelters and hospices, provide services to the members of our society who are most in need of assistance. The question which OSHA needs to answer is how to structure a program which protects employee health while enabling public and private service organizations to continue to serve high TB risk populations. Will there be greater risk to the general population if social service providers are forced to close or limit care to the homeless, the poor, the sick and the aged? This question, which admittedly raises issues beyond OSHA's statutory mission of protecting employees, must nonetheless be answered before this rule is finalized. Advocacy is of the view that Federal health policy must be an integrated whole and not fragmented. To illustrate this point, Advocacy provides the following overview of the impact this rule is expected to have on key service sectors.

Homeless Shelters

OSHA estimates that two to three deaths of workers in homeless shelters per year will be prevented by application of this rule to this sector. It is unclear how this estimate was determined and no data source was identified. The shelter organizations consulted during the Small Business Advocacy Review Panel process (e.g. Salvation Army and Central Union Mission) were hard pressed to identify any conversions or active cases of TB in the shelter sector.

OSHA estimates that 10,000 homeless shelters will identify, isolate and transfer suspected TB cases. To illustrate the rule's potential impact on homeless shelters, the Office of Advocacy has provided an overview of the costs to homeless shelters. Under this rule:

- o the average cost for a homeless shelter would be \$1000 per year; [\(8\)](#)
- o the cost for a homeless shelter with an active case of TB would be a total cost of \$41,000; [\(9\)](#)
- o homeless shelters would spend a total of \$1.2 million per year on respirators; and
- o homeless shelters would spend a total of \$2.8 million per year on temporary AFB isolation facilities. [\(10\)](#)

These new costs raise the following issues: 1) the feasibility of retrofitting shelters with negative isolation when so many are operated out of donated or dilapidated facilities; [\(11\)](#) 2) the possibility that these costs will force the closure of some shelters, limiting the care available to at risk populations; 3) an entity's ability to pay for transferring patients; 4) the identification of medical facilities equipped and willing to accept uninsured indigents; and 5) the likelihood of sufficient medical facilities to accommodate large numbers of homeless, especially in winter months when symptoms may be most severe.

Homeless shelters will have to choose between the following:

1. avoidance of death from employee exposure to TB in homeless shelters; and
2. avoidance of death from denying shelter, most likely in winter months, to homeless people suspected of having TB.

The conflict poses a Hobson's choice for shelters. Whatever they decide regarding compliance or non-compliance with the regulation, a significant health risk will remain - nothing will have been accomplished. The regulation is likely to be ignored; any fines levied are not likely to be paid; shelters could be out of business; and we would still have the homeless with TB.

Rules cannot always accomplish 100% of their objective. That seems to be the case here. Homeless shelters should not be covered by the rule, not because of compliance costs, but because it is very questionable that applying the rule to them will eliminate or reduce risk. The issue is best left to local health authorities and hospitals that are closer to the high risk population - employees as well as the homeless - and are better able to devise programs that meet their community health needs. We advocate this position despite OSHA's effort to mitigate the impact of the rule on the shelters by redefining "suspected TB case." We believe the rule simply will not be effective in the shelter setting.

Hospices

Hospice employees provide patient care in patients' homes and in hospices. In reviewing OSHA's economic impact data, it appears that the costs associated with in-home care are not fully estimated. For instance, only 12 percent of hospices operate on a for-profit basis, with an average profit of \$40,776. A single occupational case of TB for a hospice would eliminate the profit and possibly force the hospice to close. A worse scenario seems likely for the not-for-profits with similar compliance costs. The option to transfer an active case to another facility would fully undermine the purpose of the hospice, namely, to care for the sick. It seems OSHA might take a harder look at this sector to develop health policy alternatives which will protect the workforce while allowing hospices to continue servicing the seriously ill.

Substance Abuse Treatment Centers and Personnel Service Providers

According to OSHA, these industries face the most severe impact on their cost base. Specifically, OSHA has concluded that the costs can be minimized by passing the costs on to their customers. In describing the feasibility of the proposal for personnel services, OSHA concludes that "A 19.0 percent decline in profits, even if it were to occur, would not affect the viability of an otherwise viable firm." (12) OSHA provides no explanation for this conclusion. OSHA needs to provide substantiation. It should, for example, provide an analysis of key factors such as cash-flow constraints in the sector. In addition, if the personnel service sector increases prices as a result of the rule, these costs will be passed along to the medical community. The medical community will simultaneously be facing the same increases in regulatory costs.

According to OSHA, substance abuse centers face compliance costs of 9.9 percent of pre-tax revenues which OSHA assumes can be passed along to customers. (13) This poses problems for Medicare or Medicaid dependent facilities. These organizations (substance abuse centers in particular) often operate on a shoestring and their revenues are capped by health care plans. If increased costs cannot be recovered, the issue is whether these entities can continue client services. This issue is further exacerbated by the fact that those centers most likely to treat patients with TB cases will also be those without paying clients.

Other Regulatory Issues

Rule is Complex and Difficult to Understand

Though OSHA made strides to clarify and to simplify the rule, the rule continues to be complex. Thus, the rule will be difficult for small entities to implement, compliance will be spotty, and the rule's objective undermined. Many of the sectors regulated will have no familiarity with infectious disease control. For instance, the definition of an AFP isolation room or area gives little guidance to the shelter worker or correctional infirmary manager that may face installing such an area. AFP isolation requires negative pressure. Negative pressure shall be "qualitatively demonstrated (e.g., by smoke trails) daily while a room or area is in use for TB isolations (see appendix G to this section)." (14)

Medical Removal

The proposed standard requires each employee suspected of or confirmed to have infectious TB to be removed from the workplace (medical removal). (15) Employers are then required to provide such employees full salary and benefits for up to 18 months. The "medical removal" financial protections are also extended to employees who, for whatever reason, are unable to wear a respirator and thus can no longer perform their job functions. This could have a significant cost impact on small entities. It would be valuable to know exactly the extent of that cost burden and, more importantly, the implication for program and service delivery.

Finally, the impact on the workers compensation system is unclear. Is an analysis feasible?

Limitation of Medicare and Medicaid Contributions

Health care facilities often rely on Medicare and Medicaid reimbursements to cover the cost of patient

care. These reimbursements are fixed for direct medical treatment of patients - not compliance costs incurred for protecting employees. Advocacy questions whether claims for reimbursements from Medicare and Medicaid can be adjusted unilaterally by a facility to cover the costs, such as engineering controls, incurred to implement the standard. OSHA has concluded that \$70 million of the \$245 million in annual costs of the TB standard would be from Medicare/Medicaid funding; but no basis for this number has been provided or an authority cited for this conclusion. (16) OSHA needs to revisit this issue and provide substantiation for its conclusions. OSHA should fully examine the increased costs imposed on facilities which rely on Medicare and Medicaid funding for patient care.

Extend Timeline for Implementing the Rule and Provide Compliance Guidance

Small entities should be given additional time to comply with this rule if it is finalized. This rule has costly and complex recordkeeping and engineering requirements. The initial 90-day timeline is not sufficient time for entities to implement the requirements of the rule, nor is it sufficient time to allow OSHA to conduct adequate outreach or education for small entities subject to the rule. OSHA is reminded of its obligation under the Small Business Regulatory Enforcement Fairness Act (P.L. 104-121, §212) to develop compliance guide(s) for entities affected by the rule.

Patient Care

The Office of Advocacy is concerned that the medical community's role in caring for patients with TB has been inadvertently eroded by this proposal. Historically patient care has been the exclusive purview of the medical community. Whether the proposed rule changes that role is an issue that should be addressed. Should medical treatment providers be directed to minimize the time spent with a patient to control worker exposure? Once again, these are public policy matters that must be addressed. Worker exposure should not be considered in isolation from patient care.

CONCLUSION

In addition to submitting comments to OSHA, Advocacy has requested information from the CDC on the incidents and occupations of suspected and confirmed cases of TB. Advocacy requests that, once this information is received from the CDC, it be included in the docket and that there be an opportunity for public response. A copy of Advocacy's informational request to CDC is attached.

OSHA has undertaken a major task to protect employees from exposure to TB. The nature of the issue, however, makes its task very complex, as the report of the Small Business Advocacy Review Panel clearly demonstrated. Impacts on entities servicing high risk populations appear to be significant, although not totally documented thus far in this process. Two major questions remain unanswered and they are: What will be the rule's impact on overall TB exposure risks if entities currently servicing high risk populations have to reduce or eliminate services? Are there less costly and equally effective alternatives, including non-mandatory alternatives, that should be considered?

This office urges OSHA to review the docket carefully as the agency considers options to address workplace exposure to tuberculosis. The Office of Advocacy encourages OSHA to evaluate fully the comments submitted for the record by small entities, small entity representatives and health care providers.

Please contact me or Sarah Rice of my staff with questions at (202) 205-6533.

Sincerely,

Jere W. Glover
Chief Counsel for Advocacy

cc: Donald Arbuckle, Acting Administrator, OIRA

Enclosure

Addendum

Preliminary Economic and Regulatory Flexibility Analysis

for OSHA's Proposed Rule on Occupational Exposure to Tuberculosis

Regulatory Alternatives

Under Section 603 of the Regulatory Flexibility Act, OSHA must consider the impact of the proposed rule and develop significant regulatory alternatives. For the purposes of this rule OSHA has not provided a sufficient discussion of alternatives. Most concepts identified by the Small Business Advocacy Review Panel have been given only short address. For example, the agency failed to fully investigate the use of private sector certification requirements.

In addition to alternatives recommended by the Small Business Advocacy Review Panel, additional alternatives would naturally develop if the agency considered the risk avoided and the cost incurred with each provision of the rule. These net benefit evaluations would help determine the most cost-effective methods and might eliminate certain provisions. The analysis lacks any national, sector or entity-level present-value net-benefit analysis, which would provide a powerful tool for explaining the value of this regulatory proposal.

The cost of these requirements should be considered in light of other public policy objectives that are sacrificed, such as drug abuse rehabilitation. Without such an evaluation, it is impossible to know the strength or weakness of alternatives that still offer protection for all workers (albeit as voluntary measures for some). For example, OSHA references a regulatory approach consisting mainly of administrative controls used in one hospital. (17) OSHA should examine the cost-efficiency of this approach and seek comment on it as a basic regulatory alternative, especially for small entities.

Another obvious alternative is to delay implementation of this rule until alternatives can be obtained from sectors which are still unaware of this rulemaking. Examples could include correctional facilities and immigration centers.

Costs for Key Provisions Should Not Be Averaged

Similar to medical treatment costs, work practice controls which include the transfer of individuals with suspected or confirmed TB should not be averaged over the entire sector. These costs can be expected to fall on a few entities. If those entities are non-profits or low-profit private groups, the single cost of an ambulance ride for a patient may impose such a large cost that the entity will not comply with the transfer requirement. (Alternatively, the entity might place the patient in a cab and send them off to the hospital, perhaps, increasing risk to the public). OSHA should show what the costs to a typical affected small entity would be, and examine the economic impact on that representative facility. If the impact would undermine viability, OSHA should generate additional alternatives that might apply in such cases.

Costs by Size Categories

As recommended by the Small Business Advocacy Review Panel, the Preliminary Economic and Regulatory Flexibility Analysis provides data on entities with fewer than 20 employees. However, the report does not break down costs by additional size categories. In some cases, OSHA defines the complete universe of entities as small. Usually there are economic break-points above which economies of scale significantly alter the meaning of economic impacts. This point may be at 20 employees, but often is not. Such an analysis may identify sub-categories deserving special regulatory attention and others deserving further regulatory relief. For instance, the analysis showed that 97% of the risk avoided by the rule arise in entities with 20 or more employees, it seems likely that the remaining entities may have extremely low risk potential, and those potentially least able to afford the regulations. (18)

Costs by Service Sector

Non-profit small homeless shelters, substance abuse treatment centers and home health care providers constitute 20 percent of the total number of small entities affected by this rule. [\(19\)](#) The analysis of such entities' economic practices and viability remain inadequately described. The public should be aware and able to comment on data expressing the probability of closure of some small entities, thus, eliminating the social value inherent in these entities. This data could also provide information of the economic feasibility of sectors to comply with the rule. If compliance is not going to occur, based on economic unfeasibility, the agency should move towards an alternative, such as providing guidelines.

ENDNOTES

1. Fed. Reg., Vol. 62, No. 201 (October 17, 1997).
2. 5 U.S.C. §§601 et seq.
3. Preliminary Economic and Regulatory Flexibility Analysis for OSHA's Proposed Rule on Occupational Exposure to Tuberculosis, (September 30, 1997), ES-5.
4. October 29, 1996 letter to Honorable Jere W. Glover, Chief Counsel for Advocacy, Office of Advocacy from Dr. Kenneth G. Castro, Director, Division of Tuberculosis Elimination.
5. As required by the [Small Business Regulatory Enforcement Fairness Act of 1996](#), representatives of OSHA, the Office of Information and Regulatory Affairs (OIRA) of the Office of Management and Budget (OMB) and the Chief Counsel for Advocacy prepared a report incorporating recommendations from affected small entities on the potential impacts of OSHA's proposed standard.
6. Fed. Reg., Vol. 62, No. 201, 54229-54231.
7. *Ibid.*, VI-33.
8. *Ibid.*, ES-40.
9. *Ibid.*, VI-10.
10. *Ibid.*, V-2.
11. Advocacy has been informed by the regulated community that OSHA inspectors have incorrectly directed them to use fans to blow air out the windows to meet this requirement. This procedure is neither correct nor safe according to medical infectious control experts.
12. Preliminary Economic and Regulatory Flexibility Analysis, VI-7.
13. *Ibid.*, VI-7.
14. Fed. Reg., Vol. 62, No. 201, 54286.
15. *Ibid.*, 54289.
16. Preliminary Economic and Regulatory Flexibility Analysis, VI-8
17. Preliminary Economic and Regulatory Flexibility Analysis, IV-13.
18. *Ibid.*, VI-6.
19. *Ibid.*, VI-2