

July 3, 2008

U.S. Department of Health and Human Services
Room 434E
200 Independence Avenue, SW
Washington, DC 20201

Via e-mail to: panflucomments3@hhs.gov

Attn: Pandemic Influenza Employer Antiviral Comments

The American Trucking Associations (ATA)¹ is pleased to offer its comments on the Department of Health and Human Services (HHS) Proposed Considerations for Antiviral Drug Stockpiling by Employers in Preparation for an Influenza Pandemic (Guidance). ATA strongly supports HHS' and others pandemic preparedness efforts, but there are a number of issues pertaining specifically to cost, liability and seizure that must be addressed before businesses can reasonably choose to stockpile antiviral drugs as part of their overall pandemic preparedness efforts.

The trucking industry is a critical sector of the U.S. economy, employing 8.7 million people, including 3.48 million truck drivers. Every commodity moved in the U.S. touches a truck at some time – even products that start out on a train, an airplane, an ocean vessel or a pipeline. For this reason, incidents of pandemic influenza in the driver population will likely have cascading effects on the functioning of the population at large as deliveries of food, fuel, medicine and other essential materials cease without qualified drivers to transport them. ATA's members understand their need to take care of their employees and to ensure continuity of operations. Each business should have a pandemic influenza preparedness plan, but the Guidance, as issued, discourages businesses from adding antiviral stockpiles as a tool in that plan.

HHS should modify the proposed Guidance in several areas:

¹ ATA is a federation of motor carriers, state trucking associations, and national trucking conferences that promotes and protects the interests of the trucking industry. Directly, and through its affiliated organizations, ATA represents more than 37,000 motor carriers of every size, type, and class in the U.S., Canada and Mexico.

- HHS should clarify that the proposed Guidance is voluntary for all employers, including Critical Infrastructure employers;
- HHS should take the cost and legal and ethical implications of antiviral treatment into account and work to mitigate them in issuing the Guidance; and
- HHS should preempt State and local government seizure of private antiviral stockpiles or work with affected parties to find realistic solutions to the seizure issue.

Stockpiling: Recommended or Required?

Because of the trucking industry's impact in ensuring the continuity of America's commerce, the truck mode of transportation is recognized by the Department of Homeland Security (DHS) as a Critical Infrastructure/Key Resource (CI/KR) sector in the U.S. economy. The eighteen CI/KR sectors play a special role in ensuring that basic economic processes and societal functions occur. CI/KR sectors are highly interdependent and the transportation sector is equally intradependent between the various modes.

In the Guidance, HHS appears to separate considerations for stockpiling between CI/KR businesses and those which are not. While HHS clearly states, "This Guidance does not establish the requirement or expectation that all employers will stockpile antiviral drugs,"² the document does reference an "obligation" to prepare for continued operations in the event of a pandemic:

Businesses that provide goods or services essential to community health, safety, or well-being have an obligation to plan and prepare for continued operations in the event of a pandemic. These critical infrastructure employers should strongly consider providing antiviral prophylaxis for the small number of employees who are critical to essential operations as part of comprehensive pandemic preparedness planning.³

Such confusing statements are repeated over the course of the Guidance. While the first statement is clear that following this proposed Guidance is a recommended voluntary industry practice, the second statement goes further and creates an implied requirement for CI/KR businesses to prepare for a pandemic. This ambiguous language which might require or might only encourage CI/KR businesses to stockpile antiviral drugs leaves motor carriers dangerously exposed to post-incident legal liability from customers, employees and potentially from consumers who would have purchased a product that was not delivered. ATA believes that because this Guidance is meant to supplement businesses' pandemic preparedness plans, which are themselves voluntary, HHS intends antiviral stockpiling to be just one voluntary measure of many in a business' overall pandemic preparedness toolbox.

The Guidance should explicitly state that antiviral stockpiling is an ancillary addition to a company's greater pandemic influenza preparedness efforts regardless of that business' CI/

² Department of Health and Human Services. *Proposed Considerations for Antiviral Drug Stockpiling by Employers in Preparation for an Influenza Pandemic* at p. 2 (June 3, 2008). <http://aspe.hhs.gov/panflu/stockpiling.pdf>.

³ *Ibid.* 1.

KR status. As such, no legal liability should attach to companies that implement pandemic influenza preparedness strategies but choose not to include antiviral stockpiling as a part of their overall efforts. ATA suggests that HHS also develop a simple flowchart, similar to the already existing *Planning Guide for Employer Stockpiling Antiviral Drugs for Prophylaxis During a Pandemic* in Appendix 2 of the proposed Guidance, advising companies about which, if any, employees' functions are most appropriate to stockpiled antivirals.⁴

Cost and Ethical Concerns of Stockpiling

While ATA and its member companies have been proponents of pandemic influenza preparedness plans, we note that the antivirals useful in treating pandemic influenza cost over seventy dollars for a standard ten dose therapy regimen. A preventative prophylaxis regimen would cost over five hundred dollars per employee covered. Because antivirals are immediately available, but far more expensive than a vaccine, the ethical issues surrounding who has access to antiviral treatment and in what order play out in a highly rarefied environment.

Per the draft Guidance, some employees or classes of employees will be covered and others—those judged not critical to essential operations—will not. This exposes businesses to tremendous litigation threats. HHS suggests decisions about which employees will receive antiviral drugs “must be informed by science, be transparent, and be inclusive of a range of community values.”⁵ These criteria provide a basis for non-covered employees to bring suit against a business for non-inclusion even before a pandemic outbreak occurs. Businesses and their legal departments must make decisions that not only provide for continuity of operations through a pandemic but that also ensure that any stockpile distribution policy incorporates a vaguely termed “range of community values.” Meanwhile, post-incident legal claims from affected non-covered employees or survivors of deceased non-covered employees remain.

Other ethical concerns about antiviral stockpiling and treatment are beyond management's control. Leaving aside all ethical and legal considerations about stockpiling and stockpile management, once a business distributes a course of antivirals to an employee, it has no method to ensure that the employee will actually follow the treatment. An employee might choose to pass their regimen on to another they deem as more needy. This could easily be the case with an employee who gives their drugs to a spouse, child, or ailing parent he or she deems that person as having a greater need for the drugs. A motor carrier with a stockpiling plan could easily find itself shorthanded simply because its employees decided to pass their antiviral drugs to another party. If enough covered employees fall ill to impact the motor carrier's business, the company will be vulnerable to liability for failing to perform its contractual duties to its shippers. This issue is doubly salient in CI/KR companies whose failure to perform could cause significant damage to the nation's long-term ability to function.

⁴ Ibid. 19.

⁵ Ibid. 9.

Antiviral Seizure

ATA commends HHS for the recognizing the reality of the antiviral stockpile seizure issue. Almost all states and localities grant their officials the ability to seize assets in a time of emergency. Unfortunately, the current proposed Guidance merely repeats recommendations that industry has repeatedly noted as inadequate. Under the proposed Guidance, businesses that inform their State and local governments of private stockpiles will simply be the first seized should public stockpiles prove insufficient.

Without significant revisions that strongly disincentivize seizing private stocks or the introduction of new programs that require State and local governments to bolster public stockpiles far beyond presently recommended levels, trucking companies will be reluctant to adopt antiviral stockpiling as a tool in their pandemic preparedness plans. HHS should examine innovative strategies that encourage States and local governments to implement policies that encourage private stockpiles. Unless HHS can remove the risk of seizure and incentivize stockpiling, businesses will not stockpile drugs.

One such option could include requiring States to compensate businesses for lost revenues due to indirect costs in addition to those of purchasing and storing antivirals that are seized. Businesses incur heavy costs in implementing a pandemic influenza continuity of operations plans. In addition to the obvious costs of purchasing and storing antivirals, businesses must also spend funds on conferring with attorneys about compliance; managing antiviral expirations and restocking; educating their employees; and regularly exercising their plan.

HHS must guide State and local governments to finding a common ground about seizure. Such a solution should be found as quickly as possible. As the public stockpile procurement process showed, developing a stockpile requires time and planning. In the absence of a clear solution to the seizure issue, businesses lack the ability to accurately judge their risk. Without a clear policy, carriers cannot make informed decisions about adding an antiviral stockpiling effort to their pandemic preparedness plans. In the absence of a mutually acceptable resolution, businesses will either choose not to stockpile or will not inform the State about any stockpile's existence or location. ATA looks forward to future Guidance that eliminates uncertainty and creates an environment where businesses can be confident in adding stockpiles to their influenza preparedness plans.

Conclusion

ATA has been an active participant in pandemic preparedness efforts. As part of the Highway and Motor Carrier Sector Coordinating Council's Pandemic Working Group, ATA and other industry officials worked with DHS and HHS to develop the *Pandemic Influenza Preparedness, Response, and Recovery Guidelines for Critical Infrastructure and Key Resources Highway and Motor Carrier Sub-Sector Annex*.⁶ ATA is pleased to partner with HHS in helping to prepare the trucking industry for the anticipated influenza

⁶ <http://www.truckline.com/NR/rdonlyres/6C3D6007-B8B7-414A-9A55-73F2D952C3DE/0/HighwayandMotorCarrierGuideline91407.pdf>.

pandemic. To facilitate this important goal, HHS must revise portions of its Guidance as follows:

- HHS should clarify that the proposed antiviral stockpiling Guidance is voluntary for all private sector businesses;
- HHS should holistically address cost and ethical considerations of adding antiviral stockpiling to an employers' pandemic preparedness plan; and
- HHS should preempt State and local seizure of private antiviral stockpiles or provide significant incentive programs that encourage private stockpiles and discourage public seizure.

ATA and its members look forward to collaborating with HHS and its inter-agency working group towards a response plan that most effectively allows the U.S. to minimize and mitigate the effects of pandemic influenza. Thank you for considering ATA's concerns on this issue. Should you have any questions related to these issues, please contact the undersigned at 703-838-7982 or bstephenson@trucking.org.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'B. Stephenson', with a long horizontal flourish extending to the right.

Boyd Stephenson
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