

1 **Proposed Considerations for Antiviral Drug Stockpiling by Employers**  
2 **in Preparation for an Influenza Pandemic**  
3

4 **Summary**  
5

6 Optimal planning and preparation for an influenza pandemic requires coordinated efforts and  
7 shared responsibilities with every part of society including individuals and families, communities,  
8 employers in public and private sectors, and all levels of government. Federal, State, and local  
9 governments will have primary responsibility for implementing strategies to protect the public in  
10 preparing for and responding to an influenza pandemic. Employers will play a key role by  
11 protecting employees' health and safety, encouraging and facilitating compliance with  
12 community mitigation efforts, as well as limiting the harm to the economy and society. As part  
13 of their comprehensive pandemic planning, some employers (from public and private sectors)  
14 have asked for guidance about whether they should stockpile or otherwise arrange for antiviral  
15 drugs to be available for their employees, and possibly their employees' families. Private  
16 stockpiles, in coordination with public health stockpiles, would extend protection more broadly  
17 than could be achieved through the public sector alone and improve the ability to achieve the  
18 national pandemic response goals of mitigating disease, suffering, and death, and minimizing  
19 impacts on the economy and functioning of society.<sup>1</sup>  
20

21 The Federal Government strongly encourages employers of all sizes to plan for a pandemic, to  
22 protect the health of employees and assure continuity of operations.<sup>2</sup> Employers that provide  
23 critical infrastructure services, such as healthcare, law enforcement, utilities, and  
24 communications, have a special responsibility to plan for continued operations in the event of a  
25 pandemic. Antiviral medications or drugs (antivirals) are one of several approaches to  
26 protecting people during a pandemic and can serve as an important part of a layered approach  
27 to pandemic mitigation. Non-pharmaceutical measures should also be used as a critical  
28 component of an employer's plan to protect employees during a pandemic. If an employer is  
29 considering stockpiling antiviral drugs, it should do so with a clear understanding of the legal,  
30 regulatory, ethical, logistical, and economic issues that will be encountered in ordering, storing,  
31 securing and dispensing prescription medications. Employers should work with their company  
32 or contracted occupational health providers/services to plan for stockpiling antivirals. This  
33 guidance does not establish the requirement or expectation that all employers stockpile antiviral  
34 drugs. Any employer that chooses to stockpile antivirals should do so as part of comprehensive  
35 pandemic preparedness and response activities in coordination with State and local pandemic  
36 preparedness plans and in conjunction with other measures to protect workers and maintain  
37 continuity of operations.  
38

39 Antiviral drug stockpiles have been established at Federal and State levels. Current  
40 recommendations focus on using stockpiled antiviral drugs as part of a comprehensive public  
41 health response to try to contain the initial pandemic outbreak, wherever in the world it occurs,  
42 to reduce transmission when cases first appear in the United States, and to use the majority of  
43 stockpiled antiviral drugs to treat persons who have pandemic illness and may benefit from  
44 therapy. Federal guidance for antiviral drug use is being reassessed and guidance on  
45 additional uses for prophylaxis (i.e., to prevent infection in persons either before or after they

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<sup>1</sup> U.S. Homeland Security Council. National Strategy for Pandemic Influenza. 2005  
[www.whitehouse.gov/homeland/nspi.pdf](http://www.whitehouse.gov/homeland/nspi.pdf).

<sup>2</sup> Pandemic planning guidance for businesses is available at  
<http://www.pandemicflu.gov/plan/pdf/businesschecklist.pdf>.

1 are exposed to pandemic influenza) will be forthcoming. Household contacts of ill persons as  
2 described in the *Community Mitigation Guidance*<sup>3</sup>, and persons who are at high risk of frequent  
3 exposure to ill persons (e.g., healthcare and emergency service providers) are groups that  
4 would particularly benefit from prophylaxis. Potential timelines and approaches to expanding  
5 stockpiles to address these uses have not been established.

6  
7 Employers may choose to purchase antiviral drugs for stockpiling for several reasons: (1) to  
8 assure early treatment to employees who become ill<sup>4</sup>; (2) to provide prophylaxis for employees –  
9 especially those who would be at increased risk of becoming infected in a pandemic or are  
10 critical for continuity of operations; and (3) to protect overseas employees and operations where  
11 U.S. government pandemic response activities will not reach. Employers may also consider  
12 offering antiviral medications to families or household members of employees, especially those  
13 whose occupations place them at increased risk of exposure to pandemic influenza. Decisions  
14 on stockpiling should be made in the context of pandemic planning and preparedness, broadly,  
15 in which a range of protective measures may be used to minimize employee infections during a  
16 pandemic, particularly for those employees at high risk for exposure to or complications of  
17 pandemic influenza<sup>5</sup>. Antiviral drugs should not be the main defense against pandemic  
18 influenza, as their ultimate effectiveness in treating pandemic illnesses cannot be predicted in  
19 advance. In addition, it is important that employers be aware of the potential impacts and  
20 potential side effects of antiviral medications, the legal requirements and strategies for  
21 stockpiling and dispensing, ethical considerations in providing antiviral medications to some  
22 portion or all of the workforce, as well as the current public sector stockpile strategies.

## 23 24 **Purpose**

25  
26 The purpose of this guidance is to provide information to employers (both public and private  
27 sector) so that informed planning and implementation decisions on antiviral drug stockpiling for  
28 pandemic influenza can be made and, if drugs are stockpiled, to assure that they are  
29 maintained and used optimally. This guidance does not establish the requirement or expectation  
30 that employers stockpile antiviral drugs. The Federal Government encourages employers to  
31 consider stockpiling antivirals for use during an influenza pandemic if stockpile plans are  
32 consistent with their overall pandemic preparedness plan and they have carefully considered  
33 the legal, ethical, regulatory, logistical, and economic implications of stockpiling antiviral  
34 medications. Employers are encouraged to coordinate their plans for antiviral stockpiling with  
35 State and local public health agencies to improve community-level response during a pandemic.  
36 It is recognized that antiviral stockpiling may not be a suitable strategy for many employers;  
37 non-pharmaceutical strategies, effectively planned and implemented can provide substantial  
38 protection for employees during a pandemic.

39  
40 The guidance included in this document was developed by an Interagency Working Group that  
41 included representatives from several Federal agencies, with input from State and local health  
42 departments, public health organizations, boards of pharmacy groups, employers and business

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<sup>3</sup> For more information on Community Mitigation Guidance see:  
[http://pandemicflu.gov/plan/community/community\\_mitigation.pdf](http://pandemicflu.gov/plan/community/community_mitigation.pdf).

<sup>4</sup> Note that currently it is the intent of the Federal Government that public sector stockpiles include sufficient antiviral drugs for treatment of persons with pandemic illness who present for care early during their illness and would benefit from such treatment.

<sup>5</sup> The Occupational Safety and Health Administration has prepared guidance that helps employers determine appropriate work practices and precautions. See [Guidance on Preparing Workplaces for an Influenza Pandemic](http://www.osha.gov/Publications/influenza_pandemic.html#difference) at [www.osha.gov/Publications/influenza\\_pandemic.html#difference](http://www.osha.gov/Publications/OSHA3327pandemic.pdf) and <http://www.osha.gov/Publications/OSHA3327pandemic.pdf>

1 organizations.<sup>6</sup> This guidance should be considered “interim” and should be reassessed as new  
2 scientific and technological advances are made, and at the time of the pandemic when the  
3 characteristics of the pandemic virus and epidemiology of disease are known.  
4

5 **Background**

6  
7 The goals of the Federal Government's response to pandemic influenza<sup>1</sup> are to:

- 8 (1) Stop, slow, or otherwise limit the spread of a pandemic to the United States;  
9 (2) Limit the domestic spread of a pandemic, and mitigate disease, suffering, and death and  
10 (3) Sustain infrastructure and mitigate impact to the economy and the functioning of society.

11 Protecting human health is of primary importance and will enable the achievement of preserving  
12 societal function as well as mitigating the social and economic consequences of a severe  
13 pandemic.  
14

15 Federal, State, and local governments have primary responsibility for the public health response  
16 during a pandemic. The primary strategies for combating pandemic influenza are (1)  
17 vaccination, (2) use of antiviral medications to treat or prevent illness, (3) decreasing the  
18 frequency and duration of close contact among people to slow transmission of infection (social  
19 distancing), and (4) improving hand and respiratory hygiene and using protective equipment  
20 such as masks or N-95 respirators to reduce the chance of becoming infected if close contact  
21 with an infected person occurs (infection control). While a well-matched vaccine will be the  
22 most effective intervention during a pandemic, it is unlikely that such a vaccine will be available  
23 when a pandemic begins. Based on current technologies and production capacity, it will take at  
24 least 20 weeks before the first doses of a pandemic vaccine are available and there will be only  
25 limited amounts at first. Work continues to shorten the time needed for pandemic vaccine  
26 development, expand production capacity, explore strategies for using the recently Food and  
27 Drug Administration (FDA)-approved pre-pandemic vaccine, and improve vaccine effectiveness  
28 through the use of adjuvants – substances that increase the immune response to vaccination.  
29

30 By contrast, antiviral drugs can be stockpiled in advance and therefore be available when a  
31 pandemic begins. Current strategies for use of antiviral drugs from Federal and State stockpiles  
32 include containing or suppressing an initial pandemic outbreak wherever it occurs in the world  
33 and when cases are first introduced into the United States, and early treatment of persons with  
34 pandemic illness. With recent increases in antiviral drug production capacity, expanded antiviral  
35 drug use strategies beyond only treatment of ill persons are being considered. Draft Federal  
36 guidance, developed with input from multiple agencies and participation from State, local and  
37 tribal public health agencies, includes post-exposure prophylaxis (PEP) among household  
38 contacts of persons with pandemic illness; prophylaxis for the duration of a community outbreak  
39 for front-line healthcare workers, emergency service providers (e.g, ambulance personnel, fire  
40 fighters, and law enforcement personnel), and a small cadre of others who play a critical role in  
41 maintaining community functioning; and PEP for less frequently exposed healthcare and  
42 emergency response personnel, severely immunocompromised persons who cannot be  
43 protected by vaccination, and persons in closed settings such as nursing homes or prisons in  
44 the context of an outbreak. Consultation with key stakeholders on these proposed strategies,

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<sup>6</sup> Working Group members included: HHS (with representation from CDC, FDA, and the National Vaccine Program Office), Department of Commerce, Department of Defense, Department of Homeland Security, Department of Labor, Department of State, Department of the Treasury, and USDA with input from public health organizations (ASTHO, NACCHO, and IDSA); the National Association of Boards of Pharmacy, several State and local health departments and input from several business organizations (ACOEM, BENS, NBGH, and the US Chamber of Commerce) and private sector employers.

1 and on approaches to expanding existing stockpiles and effectively implementing an antiviral  
2 drug program are ongoing and policy decisions have not yet been made.

3  
4 Four antiviral drugs (amantadine, rimantadine, zanamivir, and oseltamivir) are approved by the  
5 FDA for treatment and/or prevention of influenza. Two agents, oseltamivir (Tamiflu®) and  
6 zanamivir (Relenza®), are currently being purchased for the Centers for Disease Control and  
7 Prevention (CDC's) Strategic National Stockpile (SNS) for use during a pandemic. (See  
8 Appendix for more information on these medications). Amantadine and rimantadine are not  
9 currently recommended for use against currently circulating influenza A viruses or influenza A  
10 (H5N1) viruses because many such strains are resistant to these drugs. Drug resistance to  
11 oseltamivir and zanamivir has been uncommon among currently circulating human influenza  
12 viruses to date.

13  
14 Oseltamivir and zanamivir have been shown to reduce the duration of symptoms in patients with  
15 seasonal influenza illness by 1 to 1 ½ days when begun within the first 48 hours of illness.  
16 When treatment is begun earlier, benefits are likely to be greater; a Canadian study reported  
17 that the duration of seasonal influenza was about 4 days shorter than projected historical  
18 expectations when patients presented for treatment within 12 hours of illness onset.<sup>7</sup> Thus,  
19 implementation planning for antiviral treatment in a pandemic should stress early care seeking,  
20 and rapid diagnosis and dispensing of antiviral medications. A pooled retrospective analysis  
21 reported that treatment might decrease respiratory complications of pneumonia and bronchitis  
22 and decrease rates of hospitalization for persons ill with seasonal influenza if taken within 48  
23 hours of the onset of the illness.<sup>8</sup>

24 There is no experience using oseltamivir or zanamivir during a pandemic because no pandemic  
25 has occurred since these drugs have become available. Studies of oseltamivir using animal  
26 models suggest that it has activity against certain strains of the avian H5N1 virus.<sup>9</sup> Laboratory  
27 studies of H5N1 virus strains show sensitivity to oseltamivir and zanamivir.<sup>10</sup> Observational  
28 data on oseltamivir treatment of persons influenza A(H5N1) avian influenza virus infection in the  
29 early stages of the disease suggest its usefulness in reducing mortality, but no data are  
30 available from controlled clinical trials of oseltamivir or other antiviral drugs for treatment of  
31 influenza A(H5N1) virus infected patients.<sup>11,12</sup> Recent guidance issued by the World Health  
32 Organization recommends the use of oseltamivir as the primary treatment of choice for the  
33 current situation with sporadic influenza A(H5N1) virus human infection.<sup>13</sup>

34  
35 Antiviral medications given as prophylaxis shortly after exposure to a family member with  
36 seasonal influenza have been shown to reduce the risk of illness by 70 to 90 percent<sup>14,15</sup> By

<sup>7</sup> Aoki, Macleod, Paggiaro, Carewicz et al. *Early administration of oral oseltamivir increases the benefits of influenza treatment*. Journal of Antimicrobial Chemotherapy 2003 51, 123-129

<sup>8</sup> Kaiser L, Wat C, Mills T, Mahoney P, Ward P, Hayden F. Impact of oseltamivir treatment on influenza-related lower respiratory tract complications and hospitalizations. Arch Intern Med 2003 July 28;163(14): 1667–1672.

<sup>9</sup> Govorkova, E, Ilyushina, NA, Boltz, DA, et. al *Efficacy of Oseltamivir Therapy in Ferrets Inoculated with Different Clades of H5N1 Influenza Virus*, Antimicrobial Agents and Chemotherapy (2007) 51:4, 1414-1424.

<sup>10</sup> Hurt AC, Selleck P, Komadina N, et. al. Susceptibility of highly pathogenic A (H5N1) avian influenza viruses to the neuraminidase inhibitors and adamantanes. *Antiviral Res.* 2007 Mar;73(3):228-31. Epub 2006 Nov 10.

<sup>11</sup> Schunemann HJ, Hill SR, Kakad M, et al. WHO rapid advice guidelines for pharmacological management of sporadic human infection with avian influenza A (H5N1) virus. *Lancet* 2007;7:21-31.

<sup>12</sup> Sedyaningsih E et al. Clinical features of avian influenza A(H5N1) infection in Indonesia, July 2005 – April 2007. Abstract Book: Options for the Control of Influenza VI 2007, Abstract P1532:329.

<sup>13</sup> World Health Organization. Clinical management of human infection with avian influenza A (H5N1) virus Updated Advice 15 August 2007 [http://www.who.int/csr/disease/avian\\_influenza/guidelines/ClinicalManagement07.pdf](http://www.who.int/csr/disease/avian_influenza/guidelines/ClinicalManagement07.pdf)

<sup>14</sup> Hayden FG, Gubareva LV, Monto AS, Klein TC, Elliot MJ, Hammond JM, et al. Inhaled zanamivir for the prevention of influenza in families. Zanamivir Family Study Group. N Engl J Med. 2000 Nov 2;343(18):1282-9.

1 preventing infection in close contacts of persons with pandemic illness, prophylaxis also may  
2 limit ongoing transmission within communities, reducing overall pandemic impacts. In February  
3 2007, the Centers for Disease Control and Prevention issued guidance that describes the early,  
4 targeted, and layered use of non-pharmaceutical interventions to reduce transmission of  
5 pandemic influenza coupled with the antiviral treatment of ill persons and consideration of  
6 antiviral post-exposure prophylaxis for household contacts of persons with pandemic illness.<sup>16</sup>  
7 Results from mathematical models of pandemic spread suggest that antiviral post-exposure  
8 prophylaxis in households could reduce the spread of pandemic infection in households and  
9 communities, thus reducing the total number of people who suffer pandemic illness and its  
10 consequences.<sup>17,18,19</sup> Implementation of a post-exposure prophylaxis strategy requires sufficient  
11 antiviral drug supply and effective strategies to deliver the medication shortly after exposure  
12 occurred (i.e., within 48 hours). Current SNS supplies are not sufficient to allow for household  
13 prophylaxis.

14  
15 Antiviral prophylaxis also may be considered as part of an approach to reduce occupational risk  
16 for those who are likely to be exposed to ill persons as a component of their job or to provide  
17 additional protection to workers who are needed to maintain essential services where  
18 absenteeism due to illness could affect the health and safety of others in the community or the  
19 critical infrastructures needed to sustain the community.

20  
21 Non-pharmaceutical measures should also be used to protect employees during a pandemic  
22 and include changing workplace practices to decrease the frequency and duration of close  
23 contact among workers (e.g., holding conference calls instead of in-person meetings, and  
24 promoting tele-working and flexible scheduling); encouraging employees not to report to work if  
25 ill with influenza-like symptoms and allowing leave when a worker or household member is sick;  
26 and providing education and materials to promote hand and respiratory hygiene and supporting  
27 the use of masks or N-95 respirators and other personal protective equipment, where  
28 appropriate under OSHA guidance or other recommendations.<sup>20,21</sup> Guidance on comprehensive  
29 pandemic planning for businesses and employers has been provided by the Federal  
30 Government.<sup>2,22,23</sup>

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<sup>15</sup> Welliver R, Monto AS, Carewicz O, Schatteman E, Hassman M, Hedrick J, et al. *Effectiveness of oseltamivir in preventing influenza in household contacts: a randomized controlled trial*. JAMA. 2001 Feb 14;285(6):748-54.

<sup>16</sup> For more information on Community Mitigation Guidance see:

[http://pandemicflu.gov/plan/community/community\\_mitigation.pdf](http://pandemicflu.gov/plan/community/community_mitigation.pdf)

<sup>17</sup> Ferguson NM, Cummings DA, Fraser C, Cajka JC, Cooley PC, Burke DS. Strategies for mitigating an influenza pandemic. *Nature*. 2006 Jul 27;442(7101):448-52.

<sup>18</sup> Longini IM, Jr., Halloran ME, Nizam A, Yang Y. *Containing pandemic influenza with antiviral agents*. *Am J Epidemiol*. 2004 Apr 1;159(7):623-33.

<sup>19</sup> Institute of Medicine; Committee on Modeling Community Containment for Pandemic Influenza. *Modeling Community Containment for Pandemic Influenza. A Letter Report*. Washington D.C.: The National Academies Press; 2006. p.25.

<sup>20</sup> For more information on use of masks and respirators in health-care and other occupational settings, see:

<http://pandemicflu.gov/plan/healthcare/maskguidancehc.html> and

<http://www.osha.gov/Publications/OSHA3327pandemic.pdf>

<sup>21</sup> For more information on non-occupational mask use, see:

<http://pandemicflu.gov/plan/community/maskguidancecommunity.html>

<sup>22</sup> See Pandemic Influenza Preparedness, Response, and Recovery Guide for Critical Infrastructure and Key Resources <http://www.pandemicflu.gov/plan/pdf/cikrpandemicinfluenzaguide.pdf>

<sup>23</sup> For more information on non-pharmaceutical interventions for businesses and employers as part of Community Mitigation Guidance see: [http://pandemicflu.gov/plan/community/community\\_mitigation.pdf](http://pandemicflu.gov/plan/community/community_mitigation.pdf) (Appendix 4)

## Roles and Responsibilities

The *National Strategy for Pandemic Influenza* published in November, 2005<sup>1</sup>, recognized that effectively preparing for and responding to a pandemic requires coordinated action at all levels of government and in the private sector. The National Strategy is guided by the following principles:

- The Federal Government will use all instruments of national power to address the pandemic threat.
- States and communities should have credible pandemic preparedness plans to respond to an outbreak within their jurisdictions.
- The private sector should play an integral role in preparedness before a pandemic begins, and should be part of the national response.
- Individual citizens should be prepared for an influenza pandemic, and be educated about individual responsibility to limit the spread of infection if they or their family members become ill.
- Global partnerships will be leveraged to address the pandemic threat.

The States and Federal Government are currently stockpiling 81 million courses of antiviral medications as part of public health preparedness for a pandemic. The Federal Government through CDC's Strategic National Stockpile (SNS) currently expects to maintain 50 million courses of antiviral drugs. An additional 31 million courses are targeted for purchase by the States under a Federal contract that subsidizes by 25 percent of the cost of the antiviral drugs.<sup>24</sup> Together, Federal and State antiviral stockpiles (if States buy their full allocation) are predicted to be sufficient for treatment of all who are ill with pandemic disease, seek and receive care within the first 48 hours of illness, and are considered to need treatment.

## Issues for Planning for an Antiviral Stockpile

### Public sector strategies for antiviral medications

Evolving Federal strategies for antiviral drug stockpiling and use are described above. Currently, States are developing plans for allocating, distributing, and dispensing antiviral medications during a pandemic.<sup>25</sup> Distribution of antivirals from Federal and State stockpiles will be primarily the responsibility of State and local authorities. Potential venues for dispensing antiviral medications from these stockpiles during a pandemic include pharmacies, public health sites, community health centers, outpatient offices and clinics, emergency departments, hospitals, occupational clinics, workplaces, prehospital emergency medical services<sup>26</sup> and other locations.

Plans and strategies will be periodically reviewed and re-assessed at the time of a pandemic when characteristics of the pandemic are known, including its severity and the groups at highest risk of influenza complications and death. Recommendations may also be updated if more is learned about the effectiveness of antiviral use strategies and when an effective influenza vaccine becomes available during a pandemic.

<sup>24</sup> For more information on States antiviral stockpiles see: <http://pandemicflu.gov/plan/states/antivirals.html>

<sup>25</sup> Draft State pandemic plans are posted on <http://www.pandemicflu.gov/plan/states/stateplans.html>.

<sup>26</sup> Emergency Medical Services Pandemic Influenza Guidelines for Statewide Adoption. US Department of Transportation. May 3, 2007 discusses the potential role of EMS in pandemic influenza community mitigation.

**Relationship between public sector and employer antiviral stockpiles**

Increased antiviral drug availability provides the opportunity for employers to establish stockpiles to protect their workers as part of a comprehensive pandemic plan. Until recently, due to limited global production capacity and scarce supply of antiviral drugs, the U.S. Government recommended against private sector stockpiling because it could delay our ability to meet national goals and divert supply needed to treat persons with seasonal influenza illness. Now, global antiviral drug production capacity has been substantially increased making stockpiling by employers feasible. Including antiviral stockpiling as part of a comprehensive pandemic preparedness plan may contribute to employee health and safety, business continuity, and community preparedness generally. Prior to establishing stockpiles, employers should contact the applicable State/local public health authorities to ensure compliance with existing State laws and regulations on the receipt, storage, and dispensing of drugs. Employers are encouraged to communicate and coordinate their comprehensive pandemic preparedness plans (including strategies for stockpiling antivirals) with local and State public health officials. Sharing information on antiviral drug plans can lead to coordinated use to best meet common public and private sector pandemic response goals. Employers also are encouraged to ask health providers and healthcare facilities that are dispensing antivirals on the employer's behalf to report cases of pandemic illness to State and local health agencies. At the time of a pandemic, CDC and State and local health officials will provide specific guidance to healthcare providers for timing and appropriate use of antiviral medications based on the emergent pandemic virus strain and epidemiologic characteristics of the pandemic.

The Federal Government recognizes that one perceived barrier to employer antiviral stockpiling is the question of whether a government agency might seize an employer's supply during a pandemic. Because of the magnitude of the threat that a severe pandemic poses to public health and society, Federal doctrine posits that an optimal response will require the effective and coordinated action by all levels of government, the private sector, communities, and individuals and families. In this context, actions that might inhibit planning and preparedness are counterproductive. The Federal Government, therefore, discourages the potential appropriation of privately held stockpiles of antiviral medications by governmental authorities but acknowledges the responsibility of a State to coordinate all assets within its jurisdiction and within its legal authorities to effectively contribute to the national response to public health emergencies such as a pandemic. Employers engaged in stockpiling activities are strongly encouraged to work with relevant State health agencies to coordinate activities and investigate opportunities to establish agreements on this issue. Increasing supplies and availability of these medications in both the public and private sectors may create an opportunity for complementary public-private activities for antiviral distribution to enhance community preparedness and response.

**Legal issues**

Employer purchasing and stockpiling of antiviral drugs must comply with applicable Federal and State laws and regulations regarding the receipt, storage and dispensing of pharmaceuticals. These laws and regulations provide important public health protections by, among other things, establishing standards for the storage, handling, distribution, securing and dispensing of drugs; providing appropriate regulatory oversight to ensure that standards are met; and ensuring that licensed health professionals are involved in determining and prescribing specific drugs that are medically appropriate for the needs of specific patients. Employers that are considering stockpiling antiviral drugs or are arranging for others to provide or store drugs for the use of their employees should consider consulting with healthcare and legal professionals to determine

1 whether they should include antivirals in the company's pandemic planning strategy, whether to  
2 stockpile, and how to ensure compliance with all applicable legal requirements. Compliance  
3 with these storage and stockpiling requirements helps ensure that these drugs retain their  
4 safety and effectiveness for use in the event of an influenza pandemic.  
5

6 The legal requirements that apply to employers interested in stockpiling and dispensing  
7 antivirals as part of preparing for an influenza pandemic will vary, depending on what approach  
8 to these activities is pursued. Given that storage and dispensing prescription medications are  
9 significantly regulated by States (practices of medicine and pharmacy, wholesale distribution of  
10 drugs, and dispensing of drugs), it is recommended that employers review State laws and  
11 consult with their State Boards of Pharmacy, or as appropriate, other State health offices, to  
12 determine what laws and regulations would be implicated by various approaches under  
13 consideration. Federal laws may also be implicated. Employers also may want to consult with  
14 their legal counsel, health insurance, and other insurance carriers as they consider planning for  
15 stockpiling antivirals. In addition, employers should address any applicable privacy and  
16 discrimination<sup>27</sup> issues that may arise in deciding who will receive antivirals or in dispensing the  
17 drugs.  
18

### 19 **Ethical concerns**

20  
21 If an employer is considering purchasing and stockpiling antiviral medications for use during a  
22 pandemic, there are several key ethical issues that must be included in the planning process.<sup>28</sup>  
23 Decisions regarding which employees receive medications and under what circumstances may  
24 raise concerns about equity. Ethical principles that can guide planning for antiviral stockpiling  
25 should include:

- 26 • Decision-making processes must be informed by science, be transparent, and be  
27 inclusive of a range of community values.
- 28 • Employers should carefully consider which employee sub-populations or groups would  
29 be provided antiviral medications and the business reasons for selecting some groups  
30 versus others. Targeting resources, such as antivirals, to specific groups may help  
31 reduce the overall impact of a pandemic and help preserve the health, safety, and  
32 essential functioning of the community. If certain workers are needed to perform  
33 essential functions for which their risk of illness is increased, protection by the use of  
34 antivirals and other means may be warranted.
- 35 • If antivirals are provided only to workers who have occupational exposure or who  
36 perform critical job functions (or based on other criteria), but not other workers, the  
37 employer should be explicit to all employees regarding the exposure criteria and other  
38 objective reasons for this strategy.

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<sup>27</sup> If employers are choosing which employees may receive antivirals, they should do so pursuant to a company policy and this policy should be applied in a nondiscriminatory manner. (Under federal law, employers cannot discriminate on the basis of race, sex, age (40 years and over), color, religion, national origin, disability, or veteran status.) For example, the [Americans with Disabilities Act](#) (ADA) may prohibit an employer from disfavoring employees who have a compromised immune system when deciding which employees will receive antiviral drugs. In addition, a question about whether an employee has a compromised immune system may be a disability-related inquiry (i.e., a question likely to elicit information about a disability) under the ADA. Generally, an employer may not make such inquiries to employees, unless they are job-related and consistent with business necessity. However, disability-related inquiries may be permitted when made as part of a voluntary employee health or wellness program. For information see: EEOC. Disability-related Inquiries and Medical Examinations of Employees under the Americans with Disabilities Act, <http://www.eeoc.gov/policy/docs/guidance-inquiries.html>.

<sup>28</sup> For more information see: CDC. Ethics Subcommittee of the Advisory Committee to the Director. *Ethical Guidelines in Pandemic Influenza* February 15, 2007 [http://www.cdc.gov/od/science/phec/panFlu\\_Ethic\\_Guidelines.pdf](http://www.cdc.gov/od/science/phec/panFlu_Ethic_Guidelines.pdf)



- 1 • A principle of fairness requires that all persons who are in a similar situation have similar  
2 access to the medication. Providing antivirals should not be based on gender, race or  
3 ethnicity and all persons within a defined target group should have similar access.  
4 • Other issues regarding equity may arise as employers develop their plans for antiviral  
5 stockpiling in settings located overseas—these ethical and equity considerations must  
6 be incorporated into an overall plan that is consistent with anti-discrimination policies,  
7 the laws and culture of the overseas location, standard business practices, and  
8 corporate culture.  
9

### 10 **Determining the amount of antivirals to stockpile**

11  
12 Decisions on the amount of antiviral drug to purchase for a stockpile should be made in the  
13 context of overall pandemic planning by the organization and should reflect the Federal  
14 recommendations for use. Considerations by employers in determining stockpile size may  
15 include:  
16

- 17 • Treatment—How many employees will be targeted for treatment?<sup>29</sup>  
18 • Prophylaxis-- Are there employees who may have significant risk of exposure to persons ill  
19 with pandemic influenza as part of their job? How will risk be determined? What methods  
20 (pharmacologic and other interventions) will be used to protect that workforce? Will drugs  
21 be used for prophylaxis and, if so, would prophylaxis be given following exposure to an ill  
22 person (post-exposure prophylaxis) or would it be given before exposure for the duration of  
23 the pandemic outbreak in the community?<sup>30</sup>  
24 • Which other employees will be targeted to receive antivirals (e.g., persons supporting  
25 essential business functions, critical infrastructure workers, persons who will have exposure  
26 to sick individuals at home or elsewhere, persons based in or traveling to countries with  
27 limited healthcare or pandemic response capacity, or others)?  
28 • Will other non-employees (e.g. contractors, community members, employees of other  
29 business entities, family members of persons at occupational risk of exposure) be included?  
30 • What are the State and local government plans for stockpiling antivirals and use of that  
31 stockpile? What plans can be developed to coordinate stockpiling plans with local and State  
32 public health agencies?  
33 • What capacity does the employer (or its agents) have for rapidly dispensing antivirals under  
34 medical supervision during a pandemic?  
35

### 36 **Antiviral drug storage and dispensing from an employer stockpile**

37  
38 Planning also must include appropriate receipt and storage of the stockpile and appropriate  
39 dispensing in accordance with applicable law. Prescription drugs such as antivirals held by  
40 employers must be legally dispensed according to State and Federal law. Under State law and  
41 the Federal Food, Drug, and Cosmetic Act (FDCA), prescription drugs may be dispensed only  
42 to individuals upon a written prescription or an oral prescription promptly reduced to writing that  
43 complies with State law, or by refilling such a prescription.<sup>31</sup> Thus, under applicable law, an  
44 employer could not directly distribute a prescription drug to its employees without a prescription

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<sup>29</sup> Note that currently it is the intent of the Federal Government that public sector stockpiles include sufficient antiviral drugs for treatment of persons with pandemic illness; de-centralized stockpiles of antiviral medications may afford a more rapid response for treatment and prophylaxis.

<sup>30</sup> Tamiflu® (oseltamivir) is approved by the FDA for up to a 6 week prophylaxis course based on the duration of prophylaxis in studies conducted before FDA approval. The safety of repeated or prolonged courses of Tamiflu® has not been established.

<sup>31</sup> See 21 U.S.C. § 353(b)(1) (<http://www.fda.gov/opacom/laws/fdcaact/fdcaact5a.htm>).

1 or outside the lawful dispensing process established under State law. An individual healthcare  
2 provider may prescribe a drug to his or her individual patient for use as directed by the  
3 healthcare provider (potentially including for use at a later time, if consistent with State law).  
4 Additionally, prescription drugs must be dispensed with labeling that complies with State and  
5 Federal law.<sup>32</sup>

### 7 **Stockpiling and dispensing models for consideration**

9 There are several models that may be used by employers for stockpiling and dispensing  
10 antivirals during a pandemic.<sup>33</sup> Selection of the best model for an employer to use should be  
11 made in coordination with healthcare providers who will be prescribing the antiviral medications.  
12 These models include:

#### 14 A. Using existing healthcare or pharmacy facilities

16 Storing and dispensing antiviral drugs from an on-site or off-site State-licensed pharmacy is a  
17 method that will assure that drugs are stored in an appropriately maintained, secure  
18 environment and dispensed according to State law. Other facilities from which drugs may be  
19 legally dispensed include occupational healthcare facilities, healthcare practices/physician's  
20 offices<sup>34</sup>, or clinics. Requirements for the storage and dispensing of drugs from these sites vary  
21 from State to State. Employers interested in this approach should review with their existing  
22 pharmacies, occupational health providers or other healthcare providers, or healthcare facilities,  
23 all proposed stockpiling plans to determine whether existing law allows them to store and  
24 dispense drugs, under what conditions such storage and dispensing is allowed and whether  
25 additional licenses or standards must be obtained or met. This option, using a company or  
26 contracted pharmacy or occupational medical services for stockpiling, might afford an employer  
27 the most practical approach to stockpiling antivirals.

#### 29 B. Contracting with a wholesale drug distributor

31 An employer may choose to contract with a wholesale distributor to hold a predetermined  
32 quantity of antiviral drugs and then transfer these drugs to an appropriate entity (such as a  
33 pharmacy, healthcare clinic or physician's office) for dispensing to employees and potentially  
34 other targeted groups by prescription during a pandemic. Wholesale distributors of drugs are  
35 subject to Federal and State laws and regulations. State regulations for wholesale distributors  
36 must meet minimum Federal standards, although States may adopt regulations that are more  
37 stringent.<sup>35</sup> Any employer contemplating utilizing the wholesale distributor model should contact  
38 the appropriate State Board of Pharmacy or other appropriate State licensing authority to  
39 ascertain the applicable State legal requirements, including identifying to whom a wholesale  
40 distributor may provide drugs.

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<sup>32</sup> Federal law requires labels on dispensed prescription drugs to include the following minimum information for the drug to be exempt from numerous other labeling requirements: the name and address of the dispenser, the serial number of the medication, date of the prescription or of its filling, the name of the prescriber, the name of the patient (if stated in the prescription), the directions for use and cautionary statements, if any, contained in the prescription. See 21 U.S.C. § 353(b)(2) for more information <http://www.fda.gov/opacom/laws/fdact/fdact5a.htm>.

<sup>33</sup> Employers should consult with State and local public health agencies and healthcare providers about specific guidance for planning an antiviral stockpile.

<sup>34</sup> Some States require dispensing physicians to be licensed by the State board of pharmacy and a few States severely restrict or preclude physicians from dispensing medications.

<sup>35</sup> The minimum federal requirements that State regulations must require a wholesale distributor to meet are: Title 21 of the Code of Federal Regulations (CFR); Part 205 - Guidelines for State Licensing of Wholesale Prescription Drug Distributors (<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcr/CFRSearch.cfm?CFRPart=205>)

1 C. On-site stockpiling by employers

2  
3 Employers that do not have healthcare facilities or pharmacies on their premises and are  
4 considering stockpiling drugs on-site should be aware that storing antiviral drugs would subject  
5 them to State and Federal regulation. Depending on what activities the employer is engaged in,  
6 it could be subject to different regulatory oversight, including State pharmacy laws, Federal  
7 requirements governing drug manufacturers, and/or wholesale distributor requirements. These  
8 State and Federal requirements would, among other things, address the proper procurement,  
9 storage, handling, distribution, and dispensing of drugs.<sup>36</sup> Employers need to consult with State  
10 Boards of Pharmacy or as appropriate, other State health offices for specific guidance on this  
11 approach.

12  
13 D. Pre-pandemic dispensing

14  
15 Some employers are considering acquiring, prescribing, and dispensing antiviral drugs to  
16 employees before a pandemic rather than maintaining them in a stockpile. Decisions to pursue  
17 a pre-pandemic distribution model have arisen from multiple concerns including whether there  
18 will be sufficient time after a pandemic has emerged for distribution and dispensing, as well as  
19 concerns about possible public sector appropriation of employer stockpiles. (See previous  
20 section regarding this issue). Dispensing drugs during a pandemic outbreak for treatment or  
21 post-exposure prophylaxis may be challenging because of the burden that a pandemic will  
22 place on healthcare and the need to provide treatment for patients and prophylaxis for their  
23 contacts soon after the onset of illness. As of the date of this guidance, however, the Federal  
24 Government does not consider a large-scale pre-pandemic dispensing model by employers,  
25 prior to the emergence of an imminent pandemic, to be a preferred approach. Planning  
26 effective prescribing and dispensing strategies is beyond the scope of this guidance and should  
27 be done in conjunction with the healthcare providers who will be undertaking these activities.

28  
29 If physicians are prescribing antivirals using a pre-pandemic dispensing model, dispensing  
30 should be based on individual physician-patient consultations. Continuity of interaction between  
31 the patient and healthcare provider prescribing the antiviral in advance of a pandemic is  
32 recommended, to promote the appropriate use of the drug and to provide a point of contact to  
33 monitor medication administration and potential adverse effects. Dispensing medications prior  
34 to an event without physician-patient consultation should not be part of the company's strategy  
35 (i.e., dispensing drugs based on 'blanket prescriptions'). Dispensing should take place from a  
36 licensed pharmacy or licensed facility, such as an occupational healthcare facility, healthcare  
37 practice/physician's office, or clinic, depending on applicable State law.

38  
39 Unresolved concerns with the pre-pandemic dispensing model include: potential for mistimed  
40 use of antivirals (too early or too late in the course of illness or potential exposure),  
41 inappropriate storage leading to reduced potency; potential for inappropriate use (this may  
42 include use for a respiratory infection other than influenza in which case the drug would be  
43 wasted or non-compliance with the treatment schedule for an influenza illness in which case  
44 development of antiviral resistance may be promoted), potential for changes in health status of  
45 the individual from time of prescription to time of use, and potential for secondary unauthorized  
46 distribution.

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<sup>36</sup> For example, under Federal law, the methods used in and the facilities or controls used for the manufacture, processing, packing, or holding of drugs must conform with and must be operated or administered in conformity with current good manufacturing practice. See 21 U.S.C. § 351(a)(1)(B) (<http://www.fda.gov/opacom/laws/fdcact/fdcact5a.htm>).

1 An approach that avoids the potential problems of pre-pandemic dispensing related to  
2 inappropriate storage or use while also avoiding the concern that disruption of healthcare  
3 services during a pandemic may compromise timely dispensing, would be to prescribe and  
4 distribute stockpiled antiviral drugs under the care of a healthcare provider (consistent with the  
5 above described models) when the pandemic is imminent – i.e., when an initial pandemic  
6 outbreak first occurs anywhere in the world.

### 7 8 **Special considerations by employers with overseas operations**

9  
10 U.S. employers with overseas operations or locations may have special considerations when  
11 planning for a pandemic.<sup>37</sup> Employers need to determine if in-country medical services and/or  
12 medications will be available for employees during a pandemic. Employers also need to  
13 understand local and national pandemic policies and plans and coordinate their plans with the  
14 host country and embassy. There is no current Federal plan for allocation of public sector  
15 stockpiles to employers or employees located outside the United States, nor are such  
16 provisions anticipated. Employers should consider a wide range of issues when evaluating  
17 whether to include antiviral medications in a pandemic plan for overseas employees and  
18 particularly include ethical and equity considerations in determining which employees will  
19 receive antiviral medications provided by the employer. In addition to importing, storing and  
20 dispensing medications consistent with local laws and regulations, employers should consider  
21 potential implications of antivirals being available for employees but unavailable to the local  
22 community. Additional considerations regarding enhanced security requirements and the  
23 possibility that antiviral supplies could be seized by either the host government or by other  
24 national entities at borders during transportation may be applicable depending on the location.  
25 The U.S. Department of State, Consular Affairs has issued the following statements that may  
26 help US businesses with overseas operations understand the availability and limitations of US  
27 Government assistance abroad during the time of a pandemic:

28  
29 *“American citizens should take note that the Department of State cannot provide Americans*  
30 *traveling or living abroad with medications or supplies even in the event of a pandemic.”*

31  
32 *“U.S. embassies and consulates do not have supplies of this drug [oseltamivir (Tamiflu ®)] for*  
33 *use by private American citizens abroad.”<sup>38</sup>*

### 34 35 **Additional issues**

#### 36 37 Working collaboratively with the public sector

38  
39 Collaborative planning and response efforts between the public sector and employers will afford  
40 communities the best chance to protect lives and preserve the functioning of the community  
41 during the time of an urgent public health crisis, like a severe influenza pandemic, and to  
42 maximize cooperation between employers and the community in the aftermath of a pandemic.  
43 Although planning for a pandemic is complex and requires a significant amount of time,  
44 resources, and effort, the recommended approach includes ongoing communications regarding  
45 pandemic planning strategies between public health agencies and employers. By working  
46 together, assets and resources such as antiviral stockpiles can be best utilized to protect the  
47 public’s health.

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<sup>37</sup> A number of these planning issues are addressed in the *Pandemic Preparedness Planning for US Businesses with Overseas Operations Checklist* (<http://pandemicflu.gov/plan/workplaceplanning/businessoversea.html>).

<sup>38</sup> For more information see: [http://www.travel.state.gov/travel/tips/health/health\\_1181.html](http://www.travel.state.gov/travel/tips/health/health_1181.html)

### Possible antiviral resistance

The effectiveness of antivirals against a new pandemic influenza virus cannot be predicted. Influenza viruses may become resistant to antiviral drugs, particularly with improper use during treatment. Four approved influenza antiviral agents are available in the United States: amantadine, rimantadine, zanamivir, and oseltamivir. However, two of these agents (amantadine and rimantadine) are not currently recommended for use against currently circulating influenza A viruses or influenza A(H5N1) viruses because many such strains are resistant to these drugs. Resistance to zanamivir or oseltamivir has been infrequent and resistant viruses have been reported as less virulent in limited animal studies with little evidence for person-to-person transmission to date. It is unknown whether resistance to zanamivir or oseltamivir may become a problem with widespread use of the drugs. Employers that are stockpiling antivirals to treat ill employees should arrange for healthcare providers to monitor those patients (and collect laboratory specimens) for signs of failed treatment (e.g. symptoms worsening during therapy) as those patients may be infected with viruses resistant to the antivirals and/or may have other complications needing different diagnostic and therapeutic interventions.

### Appropriate environmental conditions for stockpiling

Storage and distribution of antiviral drugs by on-site or off-site State-licensed pharmacies will ensure that appropriate environmental conditions are maintained. For antiviral drugs stored in other licensed facilities, such drugs must be stored under appropriate conditions as stated in the FDA approved package insert. As with all medications, keep out of the reach of children.<sup>39</sup>

### Approved expiration dates for antiviral drugs

The current FDA-approved expiration date for oseltamivir (Tamiflu®) and zanamivir (Relenza®) is 5 years from the date of manufacture, and can be found on the bulk product's immediate container label and/or outer package. Please note that State pharmacy laws often require assignment of a shorter expiration date (typically 6 months to 1 year from the date of dispensing) once a drug is dispensed to patients. Once expired, all products should be disposed of per State regulations (please contact State pharmacy boards or appropriate State authority for regulatory requirements associated with disposal of expired pharmaceutical drugs).

### Stockpile Security

A large-scale public health emergency such as a severe pandemic will likely produce widespread anxiety, fear, and possibly panic. By law, pharmacies are required to be constructed to prevent unauthorized access to drugs. For antiviral drugs stored in other on-site licensed facilities, the stockpiling plan should ensure adequate security to protect not only the drugs but also the people who oversee the medications, and the transportation system that delivers them (depending on the quantity stockpiled). An employer planning to stockpile antivirals in an on-site licensed pharmacy or other healthcare facility may want to conduct a security risk assessment of the areas occupied by and adjacent to the licensed pharmacy or other healthcare facility to determine additional security needs. Additional security may be needed to facilitate movement of drugs from one location to another and to protect personnel, if

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<sup>39</sup> For further information on storage conditions see <http://www.fda.gov/cder/drug/antivirals/influenza/default.htm#drugs>

1 needed, when drugs are dispensed. Financial and personnel resources should be identified to  
2 reduce risks to stockpiled assets, personnel, and general operations.

### 3 Education and information for employees and families

4  
5 Employers that choose to stockpile and distribute antiviral medications should work with  
6 healthcare providers and/or occupational health services to include an education component as  
7 an important part of their antiviral drug program.<sup>40</sup> Providing education and information will  
8 assure that the medications are used appropriately and the use of the drugs will be safe as  
9 possible. Important components of an educational program for employees include information  
10 on the proper use of the medication, including directions for when to start taking the drug, the  
11 importance of taking all of the prescribed doses, and advice to seek medical care for serious  
12 adverse effects. Persons who receive post-exposure prophylaxis should be given clear  
13 instructions as to when and where they should seek care for treatment of suspected pandemic  
14 influenza. In addition, persons should be given instructions that the medications should not be  
15 used for any other illness (e.g., for “self treatment”) or to treat family or friends.

### 16 17 Use of antiviral medications in children and other populations

18  
19 Oseltamivir is approved for use as treatment and prophylaxis in children  $\geq 1$  year of age.  
20 Zanamivir is approved for use as treatment in children aged  $\geq 7$  years and for prophylaxis in  
21 children aged  $\geq 5$  years. No influenza antiviral agents are currently approved for use in infants  
22 younger than 12 months of age.<sup>41</sup> Limited information is available on the safety of antiviral  
23 drugs in women who are pregnant (FDA pregnancy Category C). Employers should be aware  
24 that healthcare providers, when considering prescribing to pregnant women, will evaluate the  
25 potential benefit versus the potential risk. See Appendix for package insert information about  
26 precautions and prescribing guidelines.

### 27 28 Monitoring antiviral drug use and serious adverse reactions

29  
30 Tracking recipients of antiviral drugs through an employer’s stockpile is important to ensure  
31 coordination with public sector programs. If dispensing is done through a licensed pharmacy,  
32 appropriate records of dispensing and patient counseling will be maintained. For those  
33 employers that choose to stockpile and distribute antivirals using another licensed healthcare  
34 facility, policies, and procedures should be in place to ensure a method of tracking of who  
35 receives antivirals and assures that all recipients of the employer’s antiviral stockpile receive  
36 education about proper use and potential side effects associated with the medication.

37  
38 New information about drug safety issues may become apparent when antivirals are used more  
39 extensively or in different populations from previous experience. For example, Relenza®  
40 labeling has been updated over time to reflect post-marketing reports of bronchospasm. In  
41 2006, the warning section of Tamiflu® labeling was updated to include post-marketing reports  
42 (mostly among pediatric patients and mostly from Japan) of self-injury and delirium with the use  
43 of oseltamivir in patients with influenza, although the contribution of the drug to these events is  
44 not known. Patients experiencing serious adverse events that may be associated with the use  
45 of antiviral drugs for prophylaxis and treatment of influenza should seek medical attention and  
46 report the incident to FDA, through the MedWatch<sup>42</sup> program. Responsibility for detecting,

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<sup>41</sup> Committee on Infectious Diseases, American Academy of Pediatrics. Antiviral Therapy and Prophylaxis for Influenza in Children. Pediatrics 2007 April Vol.119(4), 852-860.

<sup>42</sup> MedWatch at [www.fda.gov/medwatch](http://www.fda.gov/medwatch) is the Food and Drug Administration's (FDA) program for voluntary reporting of serious reactions, product quality problems, and product use errors with human medical products, such as drugs

1 managing, and reporting serious adverse events should be shared by healthcare provider and  
2 public health professionals as well as patients.

### 3 4 **Conclusions**

5  
6 It is essential that U.S. employers be engaged in preparedness and response activities for a  
7 pandemic reflecting a shared responsibility with all levels of government, communities, and  
8 individuals and families to protect the health of the workforce and reduce adverse  
9 consequences of a pandemic. Successful planning and response require a comprehensive  
10 strategy including the application of multiple interventions initiated early and consistently for the  
11 duration of the pandemic. Federal Government and States are stockpiling antiviral drugs for  
12 use as part of the public health response to a pandemic. Employers should consider whether  
13 maintaining an antiviral stockpile or otherwise arranging for antiviral drugs to be available for  
14 their employees, and possibly other groups, should be a component of their overall,  
15 comprehensive pandemic plan.

16  
17 Antiviral strategies may be most useful for employers that have employees who will have  
18 frequent exposure to persons with pandemic illness, in critical infrastructure sectors, and those  
19 that have overseas locations and operations. Employees with increased exposure, who are  
20 essential to the provision of critical community services, or who occupy business-critical roles  
21 may benefit from antiviral use, especially coupled with other protective interventions such as  
22 infection control, social distancing, and other interventions. Strategies ensuring workplace  
23 safety may increase worker confidence, protect health, and may discourage unnecessary  
24 absenteeism during a pandemic.

25  
26 This guidance does not establish a requirement or expectation that employers stockpile antiviral  
27 drugs. Non-pharmaceutical approaches to protecting workers may have substantial benefit  
28 when effectively applied. The Federal Government encourages employers to consider  
29 stockpiling antivirals for use during an influenza pandemic if stockpile plans are consistent with  
30 their overall pandemic preparedness plan and they have carefully considered the legal, ethical,  
31 regulatory, logistical, and economic implications of stockpiling antiviral medications. Employers  
32 should coordinate the planning and use of antiviral stockpiles with public health agencies in their  
33 communities to assure optimum use that aligns with the public health strategy for that  
34 community.

35  
36 The Working Group recommends a continuation of dialogue among employers, public health  
37 agencies, government agencies, and healthcare and occupational health providers to address  
38 outstanding issues and concerns and to develop templates for employer use for planning  
39 antiviral stockpiling. This Federal document was developed based on the best available  
40 information to date; it should be considered “interim” and should be reassessed as new  
41 scientific and technological advances are made, and at the time of the pandemic when the  
42 characteristics of the pandemic virus and epidemiology of disease are known.

43  
44 Planning and preparedness for a pandemic are complex undertakings and require a significant  
45 level of effort by all sectors of society. While the challenge is formidable, our best chances of  
46 protecting health and maintaining community functioning during a pandemic rely on a  
47 coordinated response between public sector and private sector partners.

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and medical devices. FDA uses these data to maintain safety surveillance of all FDA-regulated products, including antiviral drug products.

## Appendix

### Information about the use of antiviral drugs, approved indications, and potential impacts

Tamiflu® (oseltamivir) and Relenza® (zanamivir) will likely be the antiviral medications used if antiviral treatment of pandemic influenza is indicated.<sup>43</sup>

- Package insert for Tamiflu® (oseltamivir):  
<http://www.rocheusa.com/products/tamiflu/pi.pdf>
- Consumer Information Sheet Tamiflu® (oseltamivir)  
[http://www.fda.gov/cder/drug/InfoSheets/patient/oseltamivir\\_phosphatePIS.pdf](http://www.fda.gov/cder/drug/InfoSheets/patient/oseltamivir_phosphatePIS.pdf)
- <http://www.fda.gov/cder/drug/infopage/tamiflu/default.htm>
- Package insert for Relenza® (zanamivir):  
[http://us.gsk.com/products/assets/us\\_relenza.pdf](http://us.gsk.com/products/assets/us_relenza.pdf)
- Consumer Information Sheet Relenza® (zanamivir)  
<http://www.fda.gov/cder/consumerinfo/druginfo/relenza.htm>

Contact Information for State Departments of Public Health  
<http://www.pandemicflu.gov/plan/states/statecontacts.html>

Contact for State Boards of Pharmacy  
<http://www.nabp.net/index.html?target=/howeare/boards3.asp&>

For more information about planning for pandemic influenza, please see:  
[www.pandemicflu.gov](http://www.pandemicflu.gov)

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<sup>43</sup> Further information on Influenza (Flu) Antiviral Drugs can be found at  
<http://www.fda.gov/cder/drug/antivirals/influenza/default.htm>.



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