

Overview of Proposed Federal Guidance on Antiviral Drug Strategies and Stockpiling

An influenza pandemic will affect all sectors of society; therefore, it is important that employers be engaged in preparedness and response activities for an influenza pandemic. Consequently, all sectors share responsibility to prepare for and respond to a pandemic in an effort to reduce its impact. Businesses or organizations of all sizes that provide critical infrastructure services (e.g., healthcare, public safety, utilities, transportation, etc.) have a special responsibility to plan for continued operations in the event of a pandemic. Their preparedness and effective pandemic response will help preserve community function and limit pandemic impacts on health, society, and the economy.

All employers should develop a worksite-specific pandemic influenza preparedness plan. During a pandemic, ill persons should away from the workplace until they are no longer contagious to others. Non-pharmaceutical protective measures should be used during a pandemic including changing work practices to decrease the frequency and duration of close contact among employees (social distancing), improving hand washing and cough etiquette, and using protective equipment such as masks or respirators (e.g., disposable N95s) when appropriate. Additional information on preparing workplaces for a pandemic is available at <http://www.pandemicflu.gov/plan/workplaceplanning/index.html>.

Antiviral drugs can also serve as an important part of an employer's comprehensive pandemic preparedness plan. By using multiple, layered interventions – that is, combining protective measures to achieve greater effectiveness than any single measure alone – a more effective approach to pandemic mitigation may be achieved. While pandemic influenza vaccine may offer the best and most durable protection against illness, because of the time needed to develop and manufacture the vaccine, it may be unavailable when pandemic outbreaks occur. By contrast, antiviral drugs can be acquired and stockpiled in advance and would be available to protect workers from the onset of the pandemic, although the exact magnitude of their effect against a novel pandemic strain of influenza cannot be predicted with confidence.

The Federal government has developed three key documents that provide guidance which can help employers plan antiviral drug use and stockpiling as part of their comprehensive pandemic preparedness and response plan:

- Guidance on Preparing Workplaces for an Influenza Pandemic;
- Proposed Guidance on Antiviral Drug Prophylaxis during an Influenza Pandemic; and
- Proposed Considerations for Antiviral Drug Stockpiling by Employers in Preparation for an Influenza Pandemic.

Together these documents define a framework for categorizing occupational exposure risk; provide proposed recommendations for preventive (prophylactic) antiviral drug use among workers who are at the greatest exposure risk and/or provide critical services; and identify approaches to planning and antiviral drug stockpiling that all employers can consider in order to protect workers and maintain operations during a pandemic.

Following vetting with Federal advisory committees, stakeholders and the public, it is anticipated that the proposed documents will become final interim guidance. Guidance on

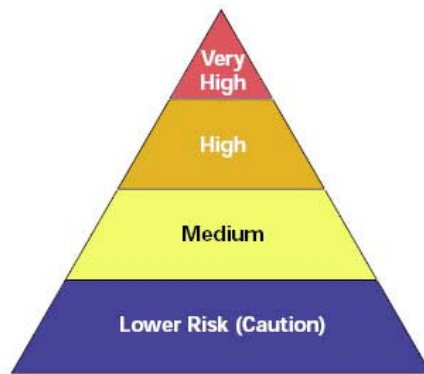
1 antiviral drug use in community settings also has been drafted and will be presented
2 separately and undergo a similar vetting process.

3
4 **Protecting Workers; Protecting Critical Operations**

5
6 In considering potential stockpiling and use of antiviral drugs, the two overriding factors
7 are the role antiviral drugs can play in *protecting workers who are at greatest occupational*
8 *exposure risk* and *protecting those workers who are critical to maintaining continuity of*
9 *essential operations*.

10
11 Existing Departments of Labor and Health and Human Services *Guidance on Preparing*
12 *Workplaces for an Influenza Pandemic*
13 (<http://www.osha.gov/Publications/OSHA3327pandemic.pdf>) has categorized certain
14 workplaces and specific work tasks into four risk zones, according to the likelihood of
15 employees' occupational exposure to pandemic influenza. We show these zones in the
16 shape of a pyramid to represent how the risk will likely be distributed. The vast majority of
17 United States workplaces are likely to be in the medium exposure risk or lower exposure
18 risk (caution) groups.

19
20 **Occupational exposure risk pyramid for pandemic influenza**



21
22 Very high exposure risk:

- 23 ○ Healthcare employees (for example, doctors, nurses, dentists) performing aerosol-
24 generating procedures on known or suspected pandemic patients (for example,
25 cough induction procedures, bronchoscopies, some dental procedures, or invasive
26 specimen collection).
- 27 ○ Healthcare or laboratory personnel collecting respiratory tract specimens from
28 known or suspected pandemic patients.

29
30 High exposure risk:

- 31 ○ Healthcare delivery and support staff exposed to known or suspected pandemic
32 patients (for example, doctors, nurses, and other hospital staff that must enter
33 patients' rooms).
- 34 ○ Medical transport of known or suspected pandemic patients (for example,
35 emergency medical technicians).
- 36 ○ Performing autopsies on known or suspected pandemic patients.

1 Medium exposure risk:

- 2 ○ Employees with high-frequency contact with the general population (such as
3 schools, high population density work environments, and some high volume retail).
4

5 Lower exposure risk (caution):

- 6 ○ Employees who have minimal occupational contact with the general public and
7 other employees (for example, office employees).
8

9 In classifying occupations into exposure risk categories, a key factor is the expectation of
10 close contact (within 6 feet^{*}) with persons who have pandemic illness or with persons who
11 are not ill. If close contact with ill persons is expected, a job would be designated as high
12 or very high exposure risk. Occupations that will have frequent close contact (within 6
13 feet) with the general population – but no certainty of close contact with someone who is ill
14 – are deemed to have medium occupational exposure risk. Lower exposure risk work
15 tasks do not require close contact with persons who are ill or frequent close contact with
16 the general population. In categorizing exposure risk, employers should consider a
17 worker's duties during a pandemic and the ability to change work practices to decrease
18 close contact with others.
19

20 Whereas occupational exposure risk is a key factor in decision-making on the potential
21 use of antiviral drugs, another consideration is the occupational role and criticality of the
22 worker. Recognizing that exposures to pandemic influenza may occur in the household
23 and community as well as the workplace, those employees who must be available at work
24 because they possess skills, experience, or licensing status that makes them individually
25 very difficult to replace may warrant the additional protection that antiviral drugs can
26 provide. Employees may also be deemed critical by their employer if their work is
27 necessary to maintain the continuity of operations during a pandemic, particularly where
28 such continuity is essential to maintain communities' functions.
29

30 **Proposed Recommendations on Antiviral Drug Prophylaxis**

31
32 National and State-based antiviral drug stockpiles have been established. The goal of
33 stockpiling currently is to have sufficient drug regimens available to support treatment of
34 all persons with influenza who seek care during a pandemic and would benefit from
35 treatment. A Federal working group recently developed proposed guidance expanding
36 recommended antiviral drug uses given increased availability of antiviral drugs for
37 stockpiling and recognizing the potential benefits of prophylactic drug use to individuals
38 and society.
39

- 40 ○ In very high or high-risk exposure settings, workers should receive antiviral drug
41 prophylaxis for the duration of a community pandemic outbreak in order to maintain
42 continuity of healthcare and public safety services (Emergency Medical Services,
43 fire protection, and law enforcement) and to protect workers who are assuming
44 increased risks to fulfill their duties to society.
45

^{*} Three feet has often been used by infection control professionals to define close contact and is based on studies of respiratory infections; however, for practical purposes this distance may range up to 6 feet. The World Health Organization defines close contact as "approximately 1 meter"; the U.S. Occupational Safety and Health Administration uses "within 6 feet." For consistency with these estimates, this document defines close contact as a distance up to 6 feet.

- 1 ○ For other workers in healthcare and emergency services who would not have
2 regular high risk exposures but who may infrequently or intermittently have close
3 contact with ill persons, post-exposure prophylaxis is recommended– that is,
4 antiviral drugs used in an effort to prevent an illness that may have been acquired
5 through close exposure to a person with pandemic illness within a 48 hour period.
6
- 7 ○ In occupational settings other than healthcare and emergency services,
8 prophylaxis for the duration of a community pandemic outbreak should also be
9 given for a small cadre of workers who are so individually critical that their absence
10 would jeopardize the maintenance of essential community services. Examples
11 may include nuclear power plant engineers or the regulatory personnel who assure
12 safe operation of the facilities; air traffic controllers; and persons critical to
13 maintaining the electric power grid or liquidity of the money supply. The
14 Department of Homeland Security is working with businesses to conduct a sector-
15 by-sector analysis to identify workers who meet this narrow definition of critical.
16
- 17 ○ In other occupational settings with medium or lower exposure risk, antiviral drug
18 prophylaxis may be considered to provide additional protection to that afforded by
19 non-pharmaceutical measures, as part of an employer’s comprehensive pandemic
20 preparedness plan.
21

22 Antiviral drug requirements for prophylaxis for the duration of a community outbreak and
23 for post-exposure prophylaxis are shown in the table below.
24

25 **Description of antiviral drug prophylaxis strategies¹**
26

| Type of prophylaxis | Description | Number of drug doses and 10-dose regimens |
|---|---|--|
| Prophylaxis for the duration of a community outbreak (“outbreak prophylaxis”) | Single daily dose triggered by the onset and continued for the duration of a community outbreak | Up to 80 doses (8 regimens) per person for an outbreak duration of up to 12-weeks ^{2,3} |
| Post-exposure prophylaxis | Single daily dose for 10 days begun within 48 hrs of exposure to a case | 10 doses (1 regimen) per exposure |

27 ¹Guidance on dosing for antiviral drug prophylaxis is based on labeling for seasonal influenza and is intended
28 to guide pandemic planning; it is possible that dosing regimens for a pandemic influenza virus strain could be
29 different.

30 ²Current FDA approval of oseltamivir (Tamiflu) is for up to 6 weeks of prophylaxis; studies of longer oseltamivir
31 prophylaxis are ongoing. As a legal matter, Federal recommendations for an unapproved course of
32 prophylaxis must be supported by an IND or, if the statutory criteria for issuance are met, may be supported by
33 an Emergency Use Authorization during a declared emergency.

34 ³Guidance is for a single pandemic wave; although more than 1 wave is likely, stockpiling for multiple waves is
35 not recommended due to ongoing antiviral drug production and likely availability of pandemic influenza vaccine.
36

37 **Proposed Recommendations on Antiviral Drug Use and Stockpile Planning for**
38 **Employers**
39

40 Proposed Federal guidance recommends antiviral drug prophylaxis in specific settings to
41 help achieve national pandemic response goals. More broadly, employers may consider
42 whether maintaining an antiviral stockpile and planning antiviral drug use for their
43 employees, and possibly other groups, should be included as a component of their overall,

1 comprehensive pandemic plan. In addition to providing protection for workers with very
2 high and high risk occupational exposure, antiviral drug use can provide an additional
3 layer of protection for workers who support critical operations or business continuity, who
4 have medium-risk occupational exposures, or where an employer chooses to offer this
5 type of protection to workers. However, there is no expectation that all employers will
6 stockpile antiviral drugs.

7
8 The “Proposed Considerations for Antiviral Drug Stockpiling by Employers in Preparation
9 for an Influenza Pandemic” was developed by a Federal working group to provide
10 information to employers to inform planning and implementation decisions on antiviral drug
11 stockpiling and, if drugs are stockpiled, to assure that they are maintained and used
12 optimally. The document provides guidance to help employers plan antiviral drug
13 strategies and reviews logistical, regulatory, legal, and management issues and options to
14 aid in implementing the strategy. Because the regulations on storing and dispensing
15 medications differ between States and given the importance of coordinating antiviral drug
16 use by health departments with that of businesses or other organizations, employers
17 should consult with State and local public health and regulatory agencies for more specific
18 guidance on planning an antiviral drug strategy.

19 20 **Conclusions**

21
22 An effective response to a pandemic requires planning and preparedness by government,
23 communities, employers, families, and individuals. Prophylactic use of antiviral drugs can
24 be an important component of a strategy to protect workers and maintain critical services
25 that will reduce the health, social, and economic impacts of an influenza pandemic.
26 Federal guidance that categorizes occupational exposure risk, combined with proposed
27 guidance defining settings where antiviral prophylaxis is recommended or where it may be
28 used, provides a basis for employers to consider and plan antiviral drug strategies and
29 stockpiling.