## Guidance on Antiviral Drug Use and Stockpiling of Antiviral Drugs and Respirators and Facemasks

National antiviral drug use	Ben Schwartz, HHS	
guidance	bxs1@cdc.gov	
Guidance on stockpiling	Lisa Koonin, CDC	
antiviral drugs	Imk1@cdc.gov	
Guidance on stockpiling	Jim Maddux, DOL/OSHA	
respirators and facemasks	Maddux.Jim@dol.gov	



## Meeting Agenda

- Presentation
  - Updated proposed guidance on antiviral drug use strategies
  - Proposed guidance on antiviral drug stockpiling for employers
  - Proposed guidance on stockpiling of respirators and facemasks by employers
- Discussion
  - Does the guidance align with pandemic preparedness priorities?
  - How effectively is the guidance likely to be implemented by employers?
  - What barriers may limit the ability of employers to implement the guidance?
  - What can the Federal government do to help overcome those barriers?

#### Policy Development on Antiviral Drug Use and Stockpiling of Antiviral Drugs, Facemasks, and Respirators



## Background on Antiviral Drug Use

- Treatment
  - Shortens illness duration by 1 4 days depending on how early it's begun
  - Reduces complications and hospitalization
- Prophylaxis (preventive use)
  - Types of prophylaxis
    - Before exposure for the duration of the influenza outbreak (outbreak prophylaxis) – uses up to 8 drug regimens per person
    - Post-exposure (PEP) uses 1 drug regimen per person
  - Impacts
    - Reduces risk of becoming ill by 70 90% among family contacts of an influenza patient
    - Decreases transmission among contacts and in communities

### Reconsideration of Antiviral Drug Strategies

- Current national strategies
  - Use antiviral drugs for containment and treatment
- Rationale for reconsideration
  - Allowed by increased manufacturing capacity
  - Recognizes potential value of prophylaxis to 1) maintain healthcare and other critical services; 2) reduce rates of illness as part of community mitigation
- Interagency working group on antiviral drug use
  - Representatives from Federal agencies, State/local/tribal public health
  - Consider drug effectiveness & resistance, mathematical modeling results, potential absenteeism & continuity of operations, ethics & values, and stakeholder preferences

## Antiviral Working Group Assumptions

- Severe pandemic
- Antiviral drug strategies implemented with other response measures
  - Community mitigation
  - Infection control
  - (Vaccination)
- 60% of cases will present for care and be treated and household members could receive prophylaxis
- Community outbreaks last 12 weeks

## Proposed Expansion of National Antiviral Drug Strategies

- Outbreak prophylaxis
  - Front-line healthcare workers
  - Emergency responders (EMS, Fire, Law enforcement)
  - Small cadre of unique/specialized critical infrastructure workers
- Post-exposure prophylaxis
  - Household contacts of influenza patients
  - Persons who are severely immunocompromised
  - In closed settings (nursing homes or prisons) when disease outbreaks occur

### Modeled Impact of PEP on Pandemic Influenza Illness Rate



See Community Mitigation Guidance; impact of PEP based on model by N. Ferguson

# What is Not Included as a <u>National Requirement</u>

- Prophylaxis for workers generally
  - Continuity of operations planning expected for businesses generally; especially those providing critical services
  - Various approaches to protect workers
  - May choose to include prophylaxis
  - HHS guidance will be available
- Prophylaxis for family members of healthcare or emergency response workers
  - No increased risk to families if the worker is protected
  - Treatment and PEP available for families

### Shared Responsibility for Implementation

- What is the role of government, organizations, employers, and individuals?
- If employers are responsible for a component of this national requirement...
  - How effectively is the guidance likely to be implemented?
  - What barriers may limit the ability of employers to implement the guidance?
  - What can the Federal government do to help overcome those barriers?

Proposed Considerations for Antiviral Drug Stockpiling by Employers In Preparation for an Influenza Pandemic

Draft Guidance for Stakeholder Discussion



## Role of Businesses/Employers in Pandemic Planning and Response

- Protect employees' health and safety
- Maintain business continuity
- Preserve function of critical infrastructure

How can private sector caches complement public sector stockpiles to improve community response?

### **Proposed Guidance**

 Encourage employers to consider stockpiling antiviral drugs for use during an influenza pandemic as a part of comprehensive pandemic planning



## Employers may choose to purchase antiviral drugs for stockpiling for several reasons:

- Assure early treatment to employees who are ill;
- Provide pre-exposure prophylaxis for employees:
  - probable occupational exposure/risk to ill persons,
  - essential to a business' operations,
  - certain critical infrastructure workers, or
  - all of workforce;
- Provide post-exposure prophylaxis following household\* or workplace exposure; and
- Protect overseas employees and operations where U.S. government pandemic response activities will not reach.

\* As described by the *Community Mitigation Guidance* 

# Special considerations for U.S. businesses with overseas operations

- "American citizens should take note that the Department of State cannot provide Americans traveling or living abroad with medications or supplies even in the event of a pandemic."
- "U.S. embassies and consulates do not have supplies of this drug [oseltamivir (Tamiflu ®)] for use by private American citizens abroad."

For more information see:

http://www.travel.state.gov/travel/tips/health/health\_1181.html

### Key Issues for Employer Planning for Antiviral Stockpiles

- Plan for collaboration with State/local public health
- Comply with State/Federal prescribing and dispensing laws and regulations
- Consider ethical and equity concerns
- Cost and logistical concerns
- Develop stockpiling and dispensing models
  - Utilize existing health care or pharmacy facilities (preferred)
  - Contract with a wholesale drug distributor
  - Stockpile onsite by businesses
  - Dispense pre-pandemic
- Educate employees

## Final thoughts

- Guidance does not establish the requirement or expectation that all businesses/employers stockpile antiviral drugs.
- Key considerations for employer stockpiling include issues of: risk of exposure and continuity of operations
- If antivirals are stockpiled, assure drugs are used:
  - As part of a comprehensive pandemic planning strategy in conjunction with other measures (e.g. *Community Mitigation* measures, PPE, hand hygiene)
  - In compliance with State laws and regulations
  - With consideration to ethical issues
  - In coordination with State and local pandemic plans

Proposed Considerations for Respirator and Facemask Stockpiling by Employers In Preparation for an Influenza Pandemic

Proposed Guidance for Stakeholder Discussion

### Earlier Guidance

- Earlier this year, DOL-OSHA in collaboration with HHS published a guidance product titled, *Preparing Workplaces for an Influenza Pandemic*.
  - Provides guidance for general industry employers
- DOL-OSHA also published a guidance product titled, *Pandemic Influenza Preparedness and Response Guidance for Healthcare Workers and Healthcare Employers.* 
  - Provides guidance for healthcare employers



### Occupational Risk Pyramid for Pandemic Influenza



### Proposed Respirator and Facemask Stockpiling Guidance

- Encourages employers to stockpile respirators and facemasks so they can protect employees during a pandemic.
- Discusses various types of respirators and facemasks available for use.
- Provides estimates of the quantity of N95 respirators and/or facemasks employers should stockpile.

### **Device Estimates for Employees**

Occupational setting Occupational setting Occupational setting Occupational setting Occupational setting Occupational setting Occupational setting Occupational setting Occupational setting Occupational setting	-	Number of respirators or facemasks per employee per work shift		Number of respirators or facemasks per employee for a pandemic (120 work days)	
	N95 Respirators (high or very high risk)	Facemasks (medium risk)	N95 Respirators (high or very high risk)	Facemasks (medium risk)	
Healthcare Hospital Outpatient office/clinic Long term care Home healthcare Emergency medical services	67% 67% 25% 90% 100%	2 4 1 2 8	0 0 3 4 0	240 480 120 240 960	0 0 360 480 0
First responders Law enforcement Corrections Fire department (non- EMS, career and volunteer)	90% 90% 90%	2 1 2	2 3 2	240 120 240	240 360 240
Medium risk employees	NA	0	2	0	240

### Facemasks Estimates for Patients and Other Contacts in High Exposure Risk Settings

Occupational setting	Facemasks needed		
Healthcare			
Hospital (inpatient)	2 per patient per day		
<b>Essential visitors</b>	<b>3 per visitor per day</b>		
<b>Emergency Rooms</b>	1 per ill person		
<b>Outpatient office/clinic</b>	2 per patient visit		
Long term care	1 per patient per day		
Home healthcare	1 per patient visit		
<b>Emergency medical services</b>	1 per ill person		
First responders			
Law enforcement	1 per ill person		
Corrections	2 per ill inmate per day		
Fire department	1 per ill person		

### **Questions for Discussion**

- Does the guidance align with pandemic preparedness priorities?
- How effectively is the guidance likely to be implemented by employers?
- What barriers may limit the ability of employers to implement the guidance?
- What can the Federal government do to help overcome those barriers?