



United States Department of
Health & Human Services

Office of the Secretary
Office of the Assistant Secretary for
Preparedness and Response (ASPR)

HHS Perspectives on Home Stockpiling of Influenza Antiviral Medkits

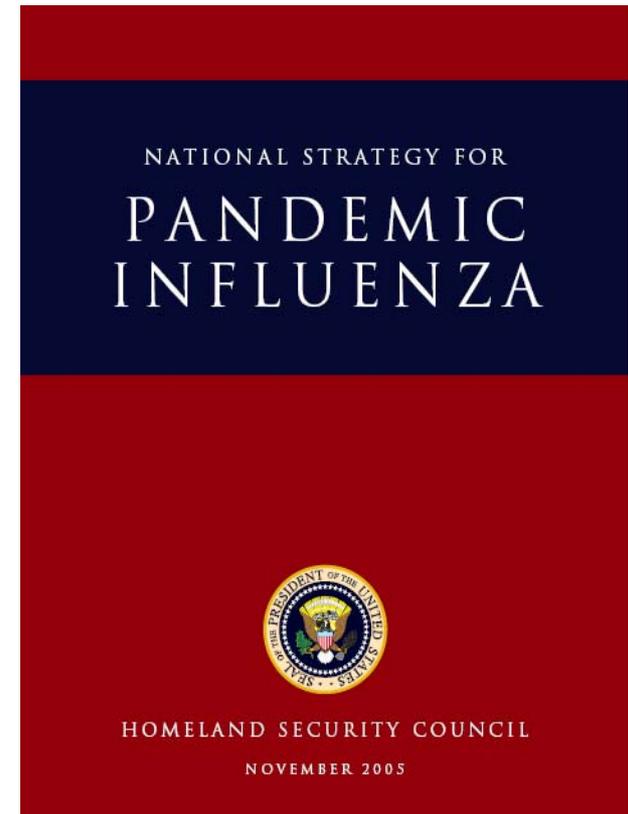
October 29, 2008

**FDA/CDER Joint Meeting of the Antiviral Drugs
and Nonprescription Drugs Advisory Committees**

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Shared Responsibility for Pandemic Preparedness

- **Shared responsibility** is a key element in the *National Strategy for Pandemic Influenza* for successful preparedness and response
- Stakeholders for this **shared responsibility** include federal, state, local governments, industry, communities, and individual citizens, who are essential for successful preparedness and response



“Any community that fails to prepare with the expectation that the federal or state government will rescue them will be tragically mistaken.”

National Pandemic Influenza Antiviral Drug Program Goals

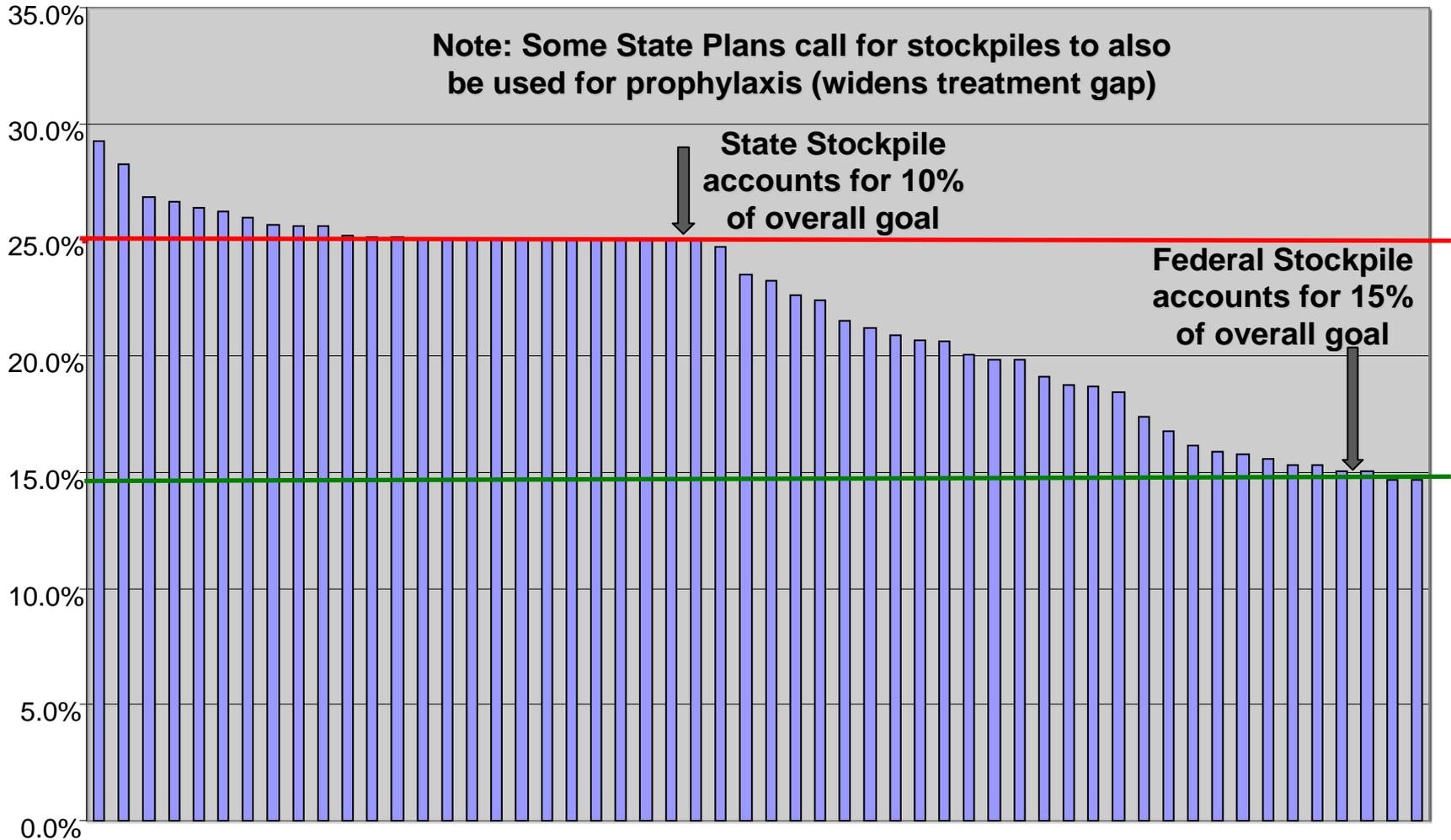
- Antivirals Goal #1: To provide influenza antiviral drug stockpiles for pandemic treatment of 25% of U.S. population (75 M treatment courses)
- Antivirals Goal #2: To provide influenza antiviral drug stockpile for strategic limited containment at onset of pandemic (6 M treatment courses)

Flu Antivirals Stockpile Source	Purpose	Goals Treatment Courses	Current Status Treatment Courses
Federal	Treatment	44 M	44 M
Federal	Onset Containment	6 M	6 M
State	Treatment	31 M	23 M
Totals		81 M	73 M

Proposed National Antiviral Drug Strategies

- Proposed national antiviral drug strategies
 - Containment of an initial pandemic outbreak & first U.S. cases
 - Treatment of all persons with pandemic influenza who present for care early in their illness
 - Prophylaxis of healthcare and emergency services workers
 - Post-exposure prophylaxis to control outbreaks in closed settings and for severely immunocompromised persons
 - Other businesses may stockpile to protect employees
- CDC community mitigation guidance highlights value of household post-exposure prophylaxis but not recommended as a national strategy due to unclear feasibility of implementation

Proportion of States Meeting 25% Treatment Goal Threshold

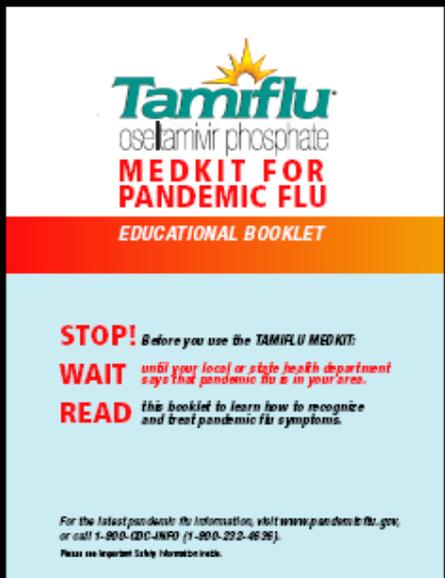


All States (includes local jurisdictions, excludes U.S. Territories)

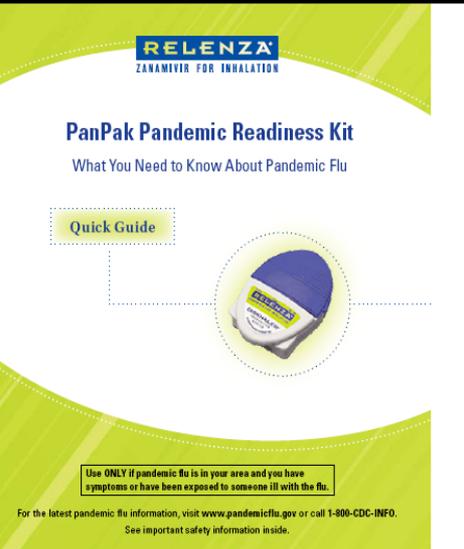
Concept of Pandemic Influenza Personal Preparedness

- Home stockpiling of medical countermeasures allows individuals to make responsible choices for personal preparedness against man-made and natural disasters, threats, and diseases
- Extend total amount of antiviral drug in communities narrowing gaps in total available supply (may extend the life of public stockpiles)
- Reduce burden on public health and healthcare system to implement early antiviral drug treatment
 - Emergency Departments and healthcare providers may be overwhelmed, delaying diagnosis and prescribing
 - Few States have detailed plans for stockpile distribution & rapid dispensing
 - Antiviral Medkits serve as community mitigation measures for pandemic influenza
- MedKits for first responders and/or individuals contain product and usage instructions (e.g., antibiotics for anthrax attacks, influenza antivirals for pandemic influenza)
- Home stockpiling of antiviral drugs also may promote family preparedness, increasing resiliency and recovery

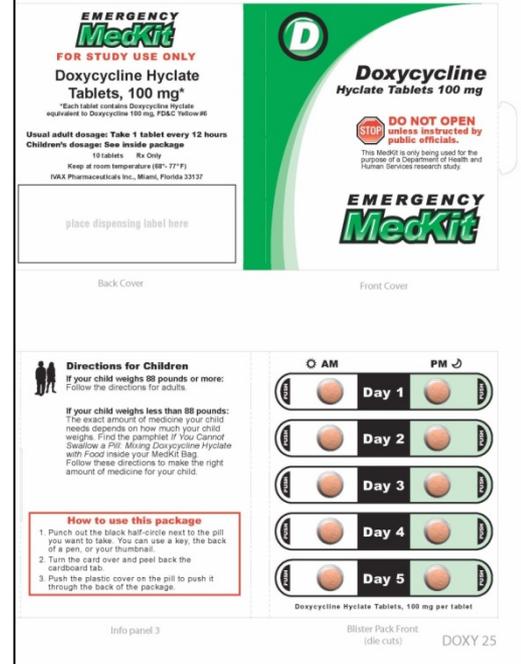
Medkit Products in Development



- Antiviral medkits (pan flu) neuraminidase inhibitors
- Roche proprietary antiviral Tamiflu® (oseltamivir)
- GSK proprietary antiviral Relenza® (zanamivir)



- Antibiotic medkit (Anthrax) doxycycline (generic)
- St. Louis antibiotic medkit study planted seed for antiviral medkits



Antiviral Medkit Program Fact Sheet

- Licensure anticipated for use in home settings (adults and children)
- Personal preparedness is key to program and not uptake
- Program designed for access and availability
- Current program requires Rx to obtain medkit
- Each medkit will contain a single regimen (treatment or prophylaxis)
- HHS will issue guidance document for home stockpiling of antivirals when products achieve licensure
- Both antiviral drugs have 5 year or greater expiry (currently applies to public stockpiles only)
- Antiviral Medkit paradigm is similar to that of other anti-infectives for travelers (e.g., Peace Corps volunteers may keep anti-infectives at home to use when needed)

Antiviral Medkit Program Challenges

- Antiviral medkits are hybrid model of cross between Rx and OTC – will present unique challenges for regulatory process to evaluate safety and effectiveness of home stockpiling (covering new ground)
- Public health strategy that results in distribution inequities given business reality of proprietary antiviral drug pricing
- Possibility of inappropriate use
- Possible occurrence of adverse events
- Potential for increased resistance due to antiviral medkit use
- State Pharmacy laws that indicate Rx expires one year from being filled (“discard after one year”)
- Proper storage and retention of antiviral medkits

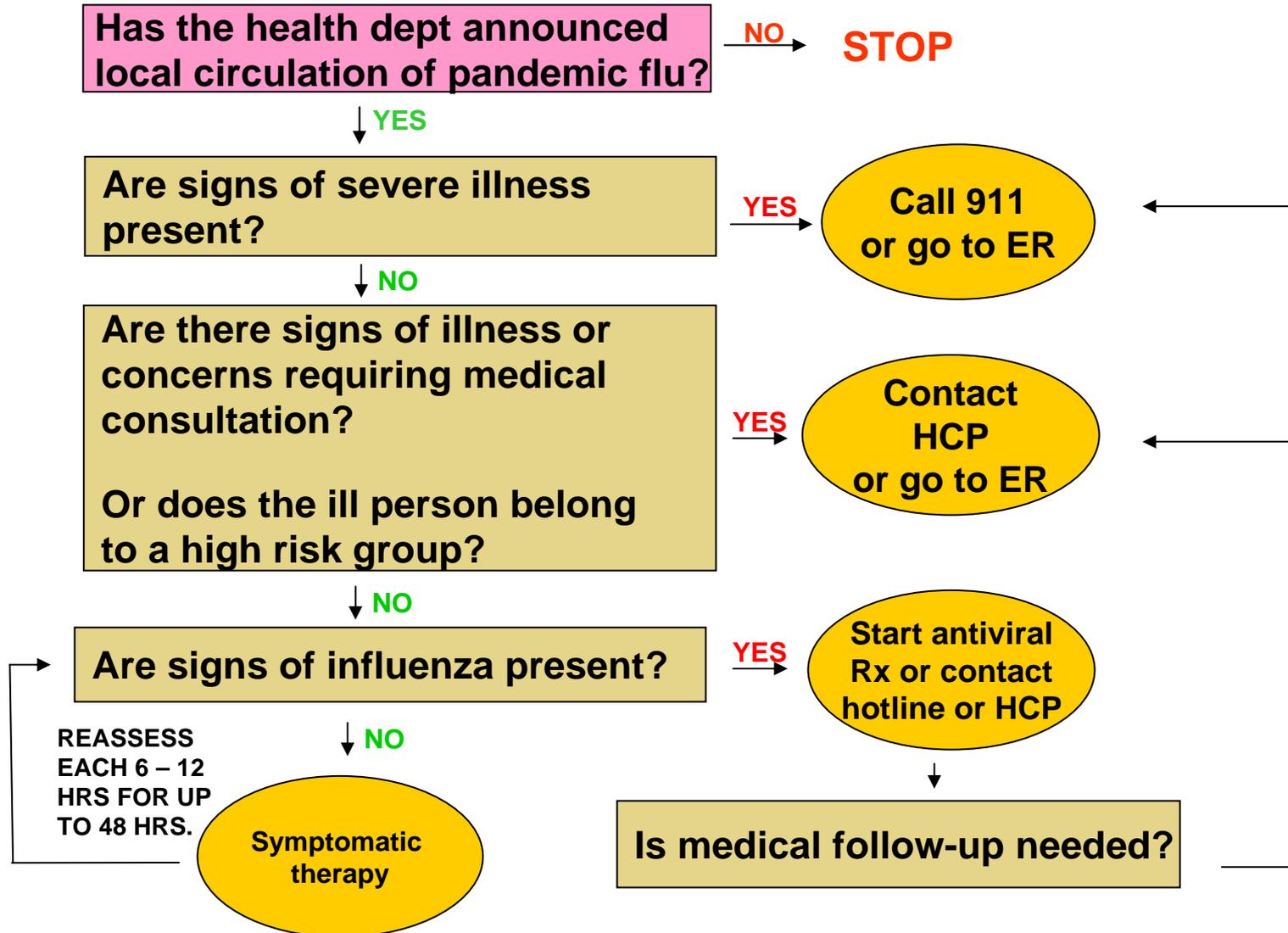
Mitigation of Potential Risks: Increasing Safe & Effective Use

- Special packaging and labeling for stockpiling and pandemic use
- Instructions for when to use or not use the Medkit
 - Diagnostic algorithm developed by HHS, CDC, and representatives of medical societies (AAP, AAFP, AMA, IDSA)
 - Emphasis on patient safety – when to seek medical care rather than self-diagnose and treat
 - Diagnostic criteria are simple and sensitive
 - Instructions for re-assessment if diagnostic criteria are not met and for follow-up with a healthcare provider if not improved further enhance patient safety
- Industry studies of label comprehension (series of pilot studies), compliance with stockpiling, and simulations of when to use
- Advisory Committee meetings

Diagnostic Influenza Algorithm

- Developed initially by CDC/Influenza Division working group in conjunction with the medical societies (AAP, AAFP, AMA, IDSA) and public health partners
- Allows for diagnosis and either treatment or prophylaxis for oneself or family member
- Affords individuals the ability to determine need for immediate medical care, or to initiate treatment or prophylaxis, if needed
- Vetted with industry and Contract Research Organizations to adopt best practices for communication to general public
- Optimized for patient safety, flu diagnostic sensitivity, and reasonable Positive Predictive Value

Draft Diagnostic Algorithm Outline



Chronology: Antiviral Medkit Home Stockpiling Program

