

08-04

## STATEMENT OF POLICY

### Pandemic Influenza Antivirals

#### Policy

The National Association of County and City Health Officials (NACCHO) is concerned with (1) the availability of antivirals for the treatment of influenza cases and prophylaxis of at-risk and/or high-risk contacts of cases; (2) the improvement of systems to assure antivirals are available during seasonal influenza outbreaks and accessible by the public during pandemics; (3) the improvement of timely access to antivirals; and (4) the health risks of home stockpiling. The recommendations in this policy statement are framed around the Centers for Disease Control and Prevention (CDC) models for a severe pandemic influenza outbreak, which estimate between 64 to 96 million individuals becoming ill and potentially needing access to antivirals nationwide.<sup>1</sup>

Much has changed since antivirals were approved for preventing and treating influenza more than a decade ago. Antivirals are now prescribed regularly by physicians and are readily available in commercial pharmacies. In addition, they are covered in insurance company drug formularies, and some are available in generic form to reduce out-of-pocket costs. In part because of the broader availability and increasing costs to procure and maintain local and state stockpiles, in 2014 the federal policy on stockpiling shifted from a joint federal and state stockpiling model to a federal only model.<sup>2</sup>

In a severe pandemic, the CDC is likely to impose restrictions on the use of federally stockpiled antiviral medications.<sup>3</sup> These restrictions may target groups who are uninsured, underinsured or unable to afford the cost of these medications. They may prioritize access for first responders, first receivers or critical infrastructure personnel to assure continuity of essential services, or may be recommended to protect those most vulnerable to infection or complication (e.g., pregnant women, children, or those with chronic disease). Yet another strategy may be to attempt to slow community spread of disease by providing target prophylaxis to case contacts during early outbreaks, or nodes of transmission (school age children, travelers). State and local health authorities request maximum flexibility from CDC when developing guidance for use of the federally stockpiled antivirals to accommodate frontline needs.

Although both Tamiflu and Relenza are approved by the Food and Drug Administration (FDA) for use as prophylaxis, and CDC clinical guidance documents address the use of antivirals for prophylaxis, clinical guidance differs from usage policy.<sup>3,4</sup> Clinical antiviral guidance (which supports use of federally stockpiled antivirals for prophylaxis) focuses on considerations for the individual patient, while drug usage policy (which highly restricts the use of federally stockpiled antivirals for prophylaxis) considers community-based circumstances and takes into account issues related to drug supply and other factors.<sup>4</sup> Prophylaxis for influenza consumes very large quantities of antivirals per person as compared to their use in treatment. However, use as



prophylaxis has occurred during past influenza outbreaks and may still be justified for very specific instances.

While antivirals may be available during a pandemic through both government-purchased stockpiles and commercial pharmacies, there may be spot shortages as was seen in 2018 H3N2 severe flu season. During that year, the nation saw high levels of outpatient clinic and emergency department visits for influenza-like illness, high influenza-related hospitalization rates and deaths, and elevated and geographically widespread influenza activity for an extended period. As most pharmacies rely on just in time inventory methods designed to cut costs and decrease waste by receiving goods only as they are needed, this can result in widespread shortages. Under these conditions, federal guidance may be extremely useful in informing the use and allocation of such supplies. The opportunities and challenges associated with antiviral access will vary depending on the severity of the illness and may require the cooperation of the antiviral manufacturers, pharmaceutical distributors, large pharmacy chains, or intervention by the federal government.<sup>5,6</sup> The following policy recommendations are focused on severe influenza pandemics for which federally stockpiled antivirals are projected to be available for treatment only.<sup>3</sup>

NACCHO recommends the following with regard to stockpiling and distribution of oral antivirals for influenza pandemics:

- NACCHO supports the U.S. Department of Health and Human Service Assistant Secretary for Preparedness and Response's (ASPR) maintenance of sufficient quantities of a range of FDA-approved antiviral medications in the Strategic National Stockpile (SNS) for use during a pandemic.<sup>7</sup> ASPR should also consider establishing antiviral stockpiles with uniform extended shelf life, similar to those managed by the Department of Defense. Consideration should be given to establishing regional antiviral caches under management of the SNS, or assigned to states to manage like the Chempack Program, to minimize cache management, coordination, and rotation costs, and optimize access.
- Since federal stockpiles of antivirals will likely be limited in a severe pandemic scenario, state and local agencies that wish to make medications available for prophylaxis of first responders and critical infrastructure should procure, maintain, and properly manage their own stockpiles for this purpose in accordance with manufacturer instructions. To assist with implementation of this directive, state and local governmental public health agencies wishing to procure influenza antiviral caches using alternative sources of funding should have access to the best pricing available negotiated by the federal government or public purchasing collectives with the antiviral manufacturers. Although federal policies such as the permissibility of using Public Health Emergency Preparedness funds to purchase antivirals should be continued, additional federal funding will be needed to adequately prepare for responding to future pandemics.
- In addition, using CDC Emergency Use Instructions (EUI) authority to communicate any applicable FDA extensions of antiviral expiration dating beyond a manufacturer's labeled expiration dating (e.g., under FDA's expiration dating extension authority) may be helpful in facilitating state and local stockpiling efforts.<sup>5,7,8,9</sup> State and local governmental agencies currently holding antivirals stockpile should maintain such caches to the extent possible by replacing expiring medications with those with longer shelf lives and follow FDA/ASPR

SNS guidance on MCM expiration dating extensions, holding on to expired antivirals until additional testing is conducted or further data evaluations are made by FDA.

- NACCHO supports increasing accessibility of antivirals to state and local partners.<sup>6</sup> NACCHO also supports state and local agencies further refining their capability to store and redistribute antivirals within their jurisdictions to eligible partners (e.g., healthcare facility or pharmacy) due to shortages that may occur in their traditional supply-chains.<sup>6</sup> Further reductions in the time required to distribute antivirals from federal stockpiles to the dispensing nodes should improve healthcare providers' ability to provide them to their patients.<sup>5</sup> Quantities and timeframes for delivery of resources shipped by ASPR should be coordinated in the moment between ASPR SNS, pharmaceutical manufacturers and distributors, and receiving health departments.
- NACCHO does not encourage individual home stockpiling of antivirals due to concerns about safety, proper storage, and increased drug resistance.

### **Justification**

The use of antivirals is efficacious in countering an influenza pandemic. The timely administration of antivirals will be a critical factor in mitigating the health consequences and impact of a pandemic influenza.<sup>10</sup> Consequently, antiviral stockpiling is a helpful preparedness tool for mitigation and response to pandemic influenza. However, NACCHO recognizes that antiviral caches can be costly and that there is no guarantee that currently available medications will be effective against future pandemic strains.<sup>1</sup> Also, antivirals have a finite shelf-life. State and local health departments must assess the cost-effectiveness of maintaining antiviral stockpiles based upon their jurisdiction's current and future needs.

The federal government has set a goal of stockpiling sufficient quantities of antivirals to treat 25% of the nation's population (the percentage projected to become ill) during a severe pandemic.<sup>5,6</sup> The CDC is regularly updating guidance for state and local governmental agencies on antiviral stockpiling and use during a pandemic. Despite advances in medical countermeasure distribution and dispensing planning, health departments still face significant challenges in rapid distribution of antivirals to pharmacies and healthcare facilities, where they can be pre-positioned to treat ill individuals.<sup>5,6</sup>

Federal guidance on state and local antiviral stockpiling and use should include a realistic assessment of logistical challenges to use of antivirals during an influenza pandemic. Such challenges could include: (A) Reductions in the available workforce as individuals become ill or stay home to care for family members; (B) Balancing demands for antivirals for treatment and prophylaxis; (C) Space and appropriate conditions to properly store the medications for an extended period; (D) Limited access to sufficiently trained and experienced logistical staff for a surge response; and (E) Record-keeping requirements.<sup>5,6</sup> However, these challenges are balanced by the likelihood of advanced warning of a pandemic and the potential to leverage highly developed state and local public health medical countermeasure capabilities for other public health threats.

## **References**

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2. Pandemic and All-Hazards Preparedness Reauthorization Act of 2013. (2013), United States Public Law 113-5.
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6. National Association of County and City Health Officials. (2010). Public Health Use and Distribution of Antivirals: NACCHO Think Tank Meeting Report.
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8. Centers for Disease Control and Prevention. (2017). Funding Opportunity Announcement CDC-RFA-TP17-1701; 2017-2022 Hospital Preparedness Program (HPP) - Public Health Emergency Preparedness (PHEP) Cooperative Agreement.
9. Occupational Safety and Health Administration. (2009). Guidance on Preparing Workplaces for an Influenza Pandemic, OSHA 3327-02N 2007.
10. Koonin, L. & Patel, A. (2018) Timely antiviral administration during an influenza pandemic: Key components. *AJPH*

## **Record of Action**

*Proposed by NACCHO Medical Countermeasures Workgroup*

*Approved by NACCHO Board of Directors September 2008*

*Updated November 2016*

*Updated December 2019*