WHAT DO YOU NEED TO KNOW?

ASTHO, in collaboration with the Centers for Disease Control and Prevention (CDC) and the National Association of County and City Health Officials (NACCHO), has been investigating ways to improve distribution and dispensing of federal Strategic National Stockpile (SNS) antivirals during an influenza pandemic. This report summarizes a proposed model, along with the studies ASTHO has done to determine the feasibility and acceptability of this model from a public health perspective. We don’t have all the answers yet but wanted to share our progress with you along with the question:

How will this new model address your state’s needs?
# At-A-Glance

<table>
<thead>
<tr>
<th><strong>Background</strong></th>
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<tr>
<td>• ASTHO, CDC and NACCHO are exploring how to improve plans for distribution and dispensing of federal SNS antivirals in the event of another flu pandemic.</td>
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<td>• The exploration focuses on a CDC proposal for an alternative distribution and dispensing method using everyday private systems designed for rapid distribution and delivery of pharmaceuticals.</td>
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<td>• Feasibility analysis of legal and policy requirements, tracking and monitoring needs, and two pharmacy dispensing throughput simulations suggests this approach could work; however, further exploration of some aspects of this model are needed.</td>
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<tr>
<th><strong>Proposed Distribution and Dispensing System</strong></th>
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<td>• Splits responsibility for federal SNS distribution between state and local health departments and existing pharmaceutical distribution systems</td>
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<td>- Private systems manage distribution and dispensing targeted to the general population.</td>
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<td>- State and local health departments manage distribution and dispensing to unique populations best served by the public health community.</td>
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<th><strong>Feasibility Studies</strong></th>
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<td>ASTHO studies suggest this model is feasible, with proper planning:</td>
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<td>• Policy and legal reviews indicate advance planning and agreements could smooth antiviral distribution during a pandemic.</td>
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<td>• ASTHO members have identified some important measures to guide tracking and monitoring of antivirals during a pandemic response.</td>
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<th><strong>Questions to Explore</strong></th>
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<td>• How does CDC determine the breakdown of distribution to pharmaceutical distributors and state and local public health departments? (CDC is currently conducting a distribution optimization modeling study, which ASTHO members will have an opportunity to review.)</td>
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<td>• What are the cost implications for this new model? (CDC is currently exploring these)</td>
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<td>• How will pharmacies, CDC, and state and local health departments share data to allow timely situation awareness? (This should continue to be explored if model is approved for continued consideration)</td>
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<th><strong>Consumer Benefit</strong></th>
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<td>Possibly improve access to federal SNS antivirals and allow public health officials to focus on other pressing public health needs such as epidemiologic investigations, surveillance, vaccinations, public messaging, and serving unique populations.</td>
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<th><strong>ASTHO Member Benefit</strong></th>
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<td>Could reduce the burden of antiviral distribution on the public health community, allowing a focus on core public health activities during a pandemic.</td>
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<th><strong>The Question for You</strong></th>
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<td>How will this new model address your state’s needs?</td>
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Federal, state, and local public health departments plan and prepare to protect lives during a global influenza pandemic. The federal Strategic National Stockpile was created to quickly deliver critical medicine and medical supplies during just such an emergency situation.

The release of federal SNS assets during the 2009 H1N1 pandemic response was one of the largest SNS deployments to date. This national health emergency tested resources, plans, and infrastructure of state and local health departments. Executing carefully crafted plans allowed state and local health departments to respond to population needs.

It also provided a valuable opportunity to learn for future, potentially more severe pandemics. ASTHO, in collaboration with the CDC and NACCHO, analyzed the 2009 H1N1 pandemic to determine how we can better prepare for the future.

Here you’ll find the results of our analysis to date, with hopes to inform you on the current thinking and potential changes to federal SNS planning.

ASTHO, CDC, and NACCHO joined together to find solutions as a team. Each organization took a lead for a different aspect of the project, with the overall purpose of:

**Improving availability and access to antivirals during an influenza pandemic.**
Goals:

Expand understanding of how antiviral distribution and dispensing was managed through the state and local public health system during the 2009 H1N1 pandemic.

Explore alternative, scalable ways to more effectively distribute and dispense antivirals during a pandemic emergency, including ways to leverage relevant private sector systems already in place.

Contribute to the knowledge base for an effective countermeasures enterprise as called for by the National Health Security Strategy.

Key Activities:

Explore the feasibility, acceptability, cost, and impact of leveraging existing systems by sending federal SNS antivirals to pharmaceutical distributors and pharmacies to distribute and dispense.

Develop processes to align with usual commercial system practices (inventory control, pharmacy ordering, tracking, billing).

Explore innovative financing mechanisms, including how dispensing fees could be covered for the uninsured/underinsured.

Explore an alternative distribution and dispensing model that leverages pharmaceutical distributors and pharmacies, as well as the options available to determine how much of the stockpile should be allocated to the public health and commercial pathways.

Partners:

American Pharmacists Association, National Association of Chain Drug Stores, National Community Pharmacists Association, Rx Response, Professor James G. Hodge (Arizona State University)
WHAT DID WE LEARN FROM THE 2009 H1N1 PANDEMIC?

In many ways, the 2009 H1N1 pandemic was a success story. Years of planning and exercises paid off, while partnerships with pharmacies, in some cases, eased distribution and dispensing. Lives were saved and people were spared the pain and expense of hospitalization. According to plan, federal SNS antivirals were distributed to state and local health departments, who then worked to distribute and dispense products throughout communities across the country. It also provided a test run of emergency plans and revealed some challenges to address in future efforts.

Challenges

- **Logistics:** During the 2009 emergency, state, and local health departments did a good job of managing antiviral distribution on a relatively small scale. Traditional pharmaceutical distributors and dispensers have much more expertise than public health departments to receive, store, distribute, dispense, dispose, and track major shipments of medications.

- **Tracking:** With antivirals distributed by the federal SNS and commercial pharmacies, tracking demand and use of antivirals was a challenge. Lack of tracking mechanisms, clear communication and bi-directional data exchange with community partners limited the health departments’ ability to track spread of the disease as indicated through antiviral prescribing, and anticipate demand for federal SNS antivirals.

- **Scale:** The 2009 H1N1 pandemic was a moderate outbreak rather than the severe outbreak anticipated; however, most emergency plans were developed with a severe outbreak in mind. The entire public health enterprise, including health departments, may need to revise plans to address a spectrum of pandemic situations.
WHAT IS THE PROPOSED ALTERNATIVE MODEL?

CDC created an alternative approach building from the lessons learned from the 2009 H1N1 pandemic. This proposed approach would shift most of the responsibility for antiviral distribution and dispensing to private sector systems that already handle distribution, dispensing, and tracking of pharmaceuticals on a daily basis. State and local health departments would focus on distribution to populations they are designed to support, including public health clinics and unique populations for which mainstream systems may not be suitable or easily accessible. The proposed model, making federal supplies of antiviral drugs available through pharmacies with a prescription — known as controlled dispensing — may be a possible solution to increase product access for an influenza response that requires distribution and dispensing of a prescription drug over the course of several months. This proposed model is not currently being considered for other responses that may require a rapid, short-term mass dispensing campaign for drugs without a prescription in an event like a biological attack (e.g. anthrax).

*Graphic below provided courtesy of the Centers for Disease Control and Prevention.*
What Are the Key Differences?

**Current**
State and local health departments are responsible for all aspects of distributing federal SNS antivirals to the population.

**Proposed**
Pharmaceutical distributors would be responsible for distributing to mainstream dispensing facilities (pharmacies, hospitals, nursing homes, and medical offices/clinics).

Pharmaceutical distributors manage distribution of medications every day, providing next-day, same-day, or emergency delivery due to their expertise in meeting demand, ordering, forecasting, inventory management, tracking, and distribution.

State and local health departments would be responsible for distributing federal SNS antivirals to the public health clinics and populations they are uniquely qualified and positioned to reach.
WHAT ARE THE CORE PUBLIC HEALTH BENEFITS?

**Improve access to antiviral medicine** through faster, more streamlined distribution and dispensing of these drugs during a pandemic. Pharmaceutical distributors and pharmacies already have the processes and resources in place to distribute, dispense, and track pharmaceuticals.

**Relieve state and local health departments** from the logistical burden of distributing and dispensing large quantities of antiviral medications. State and local public health departments would not have to make elaborate arrangements for receiving deliveries, storing/managing medication inventory, allocating product, and distributing, dispensing and tracking for all antiviral drugs needed by their populations.

**Allow public health departments to focus their efforts on key mission-critical activities**, such as outbreak response, coordination and management of vaccination campaigns, reaching underserved populations and epidemiological investigation and tracking of the disease.
HOW FEASIBLE IS THIS PROPOSED MODEL?

To explore the feasibility of this proposed model, we’ve conducted a variety of studies addressing the legal, reporting and tracking, and logistics considerations, as well as conducting two pharmacy dispensing throughput simulations.

Key Legal Considerations

Understanding the legal and policy issues related to antiviral distribution and dispensing are essential for success of any model. Professor James G. Hodge of Arizona State University Law School conducted a thorough review of legal and policy issues that could affect adoption of the proposed distribution system, as well as general legal and policy issues that affect federal SNS antiviral distribution.

This review ultimately determined that the proposed distribution system is legally possible, but will require careful, advance planning with need for tremendous cooperation with private entities. Developing advance, yet flexible, agreements before an emergency situation arises will help this public-private partnership model succeed. These agreements should take into account a spectrum of scenarios, including different emergency declarations, varying demand for product, licensing requirements, and liability restrictions.

Current Challenge

Without careful planning, existing laws and policies may thwart effective antiviral distribution and dispensing in emergencies.
Overarching Reporting and Tracking Considerations

Tracking and reporting of antiviral distribution and dispensing is essential in an efficient emergency response. It provides vital information about the spread of disease and allows for visibility on the uptake of antivirals. We conducted an assessment among a subset of state and local public health practitioners to help inform future tracking and reporting needs for pharmaceutical distributors and community pharmacies.

• **Use:** The most important use noted for tracking and reporting data is for real-time situational awareness during a pandemic emergency.

• **Medication Information:** Tracking the National Drug Code of each antiviral regimen may alleviate the reporting burden of entering multiple data elements as it covers many important elements on its own.

• **Patient Information:** The most important tracking element is priority group identification followed by zip code, status as a healthcare worker and age.

• **Dispensing Data:** The amount of product dispensed is the most critical element in this category. Dispensing location, product dosage, number of prescriptions unable to be filled, and date dispensed also rank as important.

• **Reports:** Preferred frequency of reporting varies according to severity of the outbreak. Additionally, respondents would most prefer to receive antiviral reports from community pharmacies, followed closely by aggregated reports from CDC.

**Current Challenge**

Tracking is a patchwork of private and public mechanisms, with different measurement, timing and reporting criteria.
PHARMACY SIMULATION FINDINGS

ASTHO (in conjunction with CDC and other partners), recently conducted two pharmacy throughput simulations: one in Independence, Missouri this spring and one in Chicago, Illinois this summer to explore if community pharmacies can handle a surge of people seeking antivirals during a pandemic, along with regular, maintenance prescriptions. Overall, the exercises appeared to be successful. During the simulations, both pharmacies were able to dispense 1.75 to 2.4 times their respective normal dispensing throughput. The pharmacies were able to handle the simulated surge of community need for federal SNS-provided antivirals as well as routine prescriptions. Of the challenges encountered, some are assumed to have occurred because this was a new situation for pharmacy staff; many of these challenges could be addressed at the beginning of the pandemic leading to more efficient operations as the pandemic peaks.

Average number of prescriptions dispensed per year per pharmacy location:

61,200 CHAIN PHARMACIES
(NACDS CHAIN PHARMACY INDUSTRY PROFILE 2011-2012)

64,635 INDEPENDENT PHARMACIES
(2010 NCPA DIGEST)
ASTHO ANTIVIRAL ADVISORY COMMITTEE

Ensuring public health input from the beginning of this project, ASTHO convened its Antiviral Advisory Committee to provide technical expertise in the development and evaluation of proposed alternative approaches to antiviral dispensing during a pandemic. This committee brought public health’s perspective to the table, having an understanding of the unique populations that are often best served by the public health community during a pandemic.
1. State and local health departments need bi-directional, accurate, and timely information about federal SNS antiviral distribution and dispensing

2. Allocation should be developed with input from overall health system and adapted as the epidemic progresses

3. Continued exploration of the needs of unique populations is critical

4. The model must address key cost issues, specifically management of prescription dispensing fees

5. Continued collaboration among CDC, ASTHO, and NACCHO will ensure stakeholder views are adequately represented

6. Tracking and reporting criteria should include standardized data in alignment with other CDC efforts

7. Data should interface with existing health data systems (i.e., Medicare, Medicaid, insurance companies)

8. The model must support state and local public health leadership and authority during an emergency including a clear understanding of criteria or “triggers” to activate and demobilize the proposed system, based on the progression of the pandemic
NEXT STEPS:

Once all of the exploratory components of this project are completed, CDC and HHS leadership, with input from ASTHO and NACCHO, will determine whether this project should progress to policy development. If approved, ASTHO will collaborate with CDC and NACCHO to inform and educate state and local public health practitioners about the new model. If further work is needed, CDC will conduct additional exploration of this and other alternative models. ASTHO will maintain its role as an engaged stakeholder representing state needs and priorities in future project activities.

- Distribution optimization modeling (CDC)
- State-by-State Legal and policy analysis related to antiviral management (CDC)
- Analysis of cost and payment issues (CDC/ASTHO)
- Project awareness activities (ASTHO/NACCHO)
FOR ADDITIONAL INFORMATION ON THESE STUDIES, PLEASE VISIT
http://www.astho.org/Programs/Infectious-Disease/Antiviral-Distribution/

• Professor James G. Hodge, Jr. Antiviral Distribution Assessment and Optimization Project: A Review of Legal and Policy Issues. (Spring 2012)

• ASTHO and NACCHO. Pandemic Influenza Antiviral Distribution Exploratory Project: Frequently Asked Questions (Spring 2012)

• ASTHO and NACCHO. Managing Antiviral Medication during the 2009 H1N1 Influenza Pandemic: State and Local Public Health Department Responsibilities (Coming Soon - Fall 2012)

• ASTHO (IEM, Inc.). Scripted Surge Antiviral Dispensing Simulation: Summary Report (Coming Soon - Fall 2012)

FOR LOCAL HEALTH DEPARTMENT PERSPECTIVES

• NACCHO Antiviral Distribution and Dispensing Project: http://www.naccho.org/topics/emergency/pandemicinfluenzaprep/antiviral_dist-and-disp.cfm