Memo

To: Pandemic Planning Partners

Subject: Pandemic Countermeasures Planning

Date: 2-27-08

The intent of this document is to assist local jurisdictions in planning for the receipt and use of pandemic countermeasures provided by the state during an influenza pandemic. The use of pandemic countermeasures is ultimately the responsibility of local officials, as the implementation of response strategies must take place at the local level.

The federal government and the Indiana State Department of Health (ISDH) are in the process of building a stockpile of pandemic countermeasures for use during a pandemic. This document outlines the distribution of pandemic countermeasures from the federal Strategic National Stockpile (SNS) through the Indiana Strategic National Stockpile (ISNS) to local jurisdictions.

In order for the ISNS to deliver pandemic countermeasures, the requirements in this guidance must be met. Once pandemic countermeasures are distributed to local jurisdictions, County Commissioners, Emergency Management Directors, and Local Health Officers are responsible for ensuring these resources are used in accordance with local pandemic response plans and subsequent guidance issued by the ISDH.

The mission to respond to a ubiquitous threat such as pandemic influenza may require modifications to typical emergency response plans. This guidance will be refined as additional policy decisions are made at the state and federal levels. This is a working document that may be used to assist Indiana counties in the development of local distribution plans for pandemic influenza countermeasures. Additional guidance will be released as stockpiles increase and pandemic planning advances.
Pandemic Influenza Countermeasures Distribution
Guidance for Local Planning

Indiana Strategic National Stockpile
Indiana State Department of Health

Draft
February 2008
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Overview

This plan outlines the distribution of pandemic influenza countermeasures from the Strategic National Stockpile (SNS) for use during an influenza pandemic. SNS assets will be distributed by the federal government to the Indiana State Department of Health (ISDH). The ISDH Indiana Strategic National Stockpile (ISNS) program will distribute pandemic countermeasures to each county in Indiana.

The federal government and the ISDH are in the process of building a stockpile of antiviral medications for use during a pandemic. Once stockpiles are complete, the antivirals available to Indiana will be approximately 1.5 million courses. The federal SNS will maintain 923,000 courses of antivirals earmarked for Indiana. The ISDH will maintain an in-state stockpile of 650,000 courses of antiviral medications for use during a pandemic.

The mission to respond to a ubiquitous threat such as pandemic influenza requires modifications to the typical operational planning of the ISNS. This plan will be refined as additional policy decisions are made. This plan is a working document that may be used to assist Indiana counties in the development of local distribution plans for pandemic influenza countermeasures.

Background

Federal Response

- The World Health Organization (WHO) will declare Phase 4 of an influenza pandemic when there is a confirmed small cluster of limited human-to-human transmission of a novel influenza virus, with spread being sustained but highly localized
- The Director of the CDC in consultation with the Secretary of HHS, or his/her designee, will determine when to activate the Division of National Strategic Stockpile (DSNS) to begin the distribution of critical medical material based on the WHO Phase characterization and the severity of the disease
- The DSNS pandemic influenza response will include distribution of:
  - Antiviral medications
  - Masks and respirators

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1 This document will remain in draft status and updated periodically until such time the national stockpile of pandemic countermeasures is complete and the federal allocation and distribution strategy is finalized.
Additional items in SNS inventory: Personal Protective Equipment (PPE) and medical supplies (intravenous antibiotics, ventilators)

- Federal assets available to Indiana once the federal stockpile is complete include: 1.5 million courses of antiviral medication; 885,000 Respirators (NIOSH/FDA); 881,000 Respirators (NIOSH); 1 million surgical masks; and limited PPE and ventilators
- At this time, pre-pandemic and pandemic vaccines will not be stockpiled or managed by the DSNS
- The DSNS must also remain ready to respond to a potential second event (bioterrorist or natural disaster related)

**State Response**

- Indiana will maintain a stockpile of approximately 650,000 courses of antiviral medication
- Upon the federal decision to distribute federal SNS assets, the Indiana State Health Commissioner, or his/her designee, will determine when to begin the distribution of SNS assets to local jurisdictions
- Indiana will receive pandemic countermeasures contained in the federal SNS
- The ISNS pandemic influenza response will include distribution of:
  - Antiviral medications
  - Masks and respirators
  - Additional items in as available
- At this time, pre-pandemic and pandemic vaccines will not be stockpiled or managed by the DSNS
- The ISNS must also remain ready to respond to a secondary event (bioterrorist or natural disaster related)

**Local Response**

- Receive, store, secure, distribute, and dispense pandemic influenza countermeasures within the local jurisdiction.
- The local jurisdiction pandemic response resources from the ISNS include:
  - Antiviral drugs
  - Masks and respirators
  - Additional items as available

**General Assumptions**

It is assumed that the initial outbreak of human-to-human transmission of a novel influenza subtype will occur overseas and that the delivery of SNS pandemic countermeasures will be complete before the onset of disease in Indiana. With an international outbreak, the basic premise is that sufficient time will exist from a triggering event to allow for the distribution of pandemic countermeasures contained in the SNS.
This plan assumes that the federal DSNS has a completed stockpile of pandemic countermeasures, functional staff, and necessary resources to deliver pandemic countermeasures to Indiana. This plan assumes that Indiana has a completed stockpile of antiviral medication, functional staff, and necessary resources to receive and distribute pandemic countermeasures from the state/federal stockpile to local jurisdictions. It is also assumed that ISDH will order the distribution of pandemic countermeasures to the local jurisdiction, under non-emergency conditions, before local outbreaks occur.

ISDH acknowledges the need to have the ability to ship materiel more quickly if the scenario for the outbreak varies. For example, if the outbreak begins in the United States or spreads more rapidly than predicted, the ISDH will plan for an emergency distribution scenario that targets distribution of allocated quantities of antiviral drugs to the affected regions in the state first.

It is assumed that all prerequisites set forth in the federal contracts between Department of Health & Human Services, GlaxoSmithKline, and Roche Laboratories, Inc. regarding the dispensing and administration of the antivirals have been met.

**Response Operations**

**Federal Response**

CDC/SNS assets will be delivered to one location in each of the 62 Project Areas in 3 parts over successive days:

- Part 1 – Antiviral drugs
- Part 2 – Masks and respirators
- Part 3 - Additional PPE (protective face shields, gowns, and gloves), IV antibiotics, ventilators and other medical items needed at the time of a pandemic influenza outbreak

The CDC/DSNS distribution strategy for antiviral drugs, masks and respirators, and additional supplies distribution strategy will be a *pro rata* (based on population) deployment, pushing product proactively to a single location in Indiana.

Pushing product to the Project Areas will allow the federal government to be proactive and anticipate State and local needs increasing the chance of a successful response. Shipping product out at the first signs of a pandemic and before a Project Area request will also ensure that the DSNS staff and federal transportation partners are available in full capacity to aid in the federal response, and be ready to respond to other events. During a pandemic there is a high likelihood that resources such as personnel and trucks will be in limited supply, possibly impacting the DSNS response time.

**State Response**

Part I: Antiviral Distribution
The ISDH antiviral distribution strategy will be a *pro rata* (based on population) deployment, pushing product proactively to a *single location in each County* within Indiana. By delivering antiviral drugs to Indiana Counties prior to receipt of a request, the ISDH will be able to ensure that supplies are received before the need for assets becomes critical. Thus, this will be the first asset to be delivered to Indiana Counties and will comprise Part 1 of the pandemic ISNS response, estimated to take 7-10 days.

**Part II: Masks and Respirator Distribution**

Masks and respirators are available at hospitals and healthcare entities, but will be utilized rapidly in an influenza pandemic. Indiana Counties will have a minimum surge capacity for these supplies. Due to logistical challenges associated with product configuration and quantities, the masks and respirators will not be able to be distributed simultaneously with the antiviral drugs. Thus, masks and respirators will be allocated *pro rata* and delivered immediately after the antiviral drug distribution to Indiana Counties as Part 2 of the response. This second deployment of assets is estimated to take an additional 7 -10 days after Part 1 is completed.

**Part III: Additional Resources**

Part 3 of the response will be a shipment from federal DSNS of assets such as ventilators, other PPE (protective face shields, gowns, gloves), and IV antibiotics. Ventilators, intravenous antibiotics, and other limited resources will be allocated and distributed by ISDH on the basis of availability and need.

Supplies from Part III will be held back by the ISDH and allocated via a case-by-case approval process based on State needs. This reserve capacity will allow for the ISNS to maintain response capability in the event that a separate simultaneous public health emergency (i.e., bioterrorist event, natural disaster) should occur.

**Please note that these plans are subject to change as the stockpile increases**

**Additional Information for Project Areas**

The ISDH/ISNS pandemic response plan is different from the normal ISNS response model routinely used in training scenarios. Assets will be allocated on a *pro rata* basis. In order for ISDH/ISNS to be able to execute this pandemic distribution plan, every Indiana County must be prepared to receive pandemic assets upon notification from ISDH.

- The quantity of antiviral drugs for each Indiana county will be based on population
- It is critical that all Indiana counties pre-identify receiving and storage sites for pandemic countermeasures distributed through the ISNS
• When assets are delivered, Indiana counties must be prepared to accept them in accordance with the ISNS policies. Once an Indiana county accepts State assets, they will become the responsibility of that jurisdiction.

• Additional guidance regarding the quantities and pallet configurations of materiel that Indiana counties will receive will be released as stockpiles are complete and allocation strategies are finalized.
WHO Phase characterization and severity of disease.
HHS & CDC issue order to begin distribution of critical medical materiel for States.

CDC Director or Designee confirms SNS asset allocations for States and distributes federal SNS assets to States.

ISDH/ISNS receives federal SNS assets and prepares for distribution to Indiana Counties.

Part 1
ISNS ships to Indiana Counties pro rata antiviral allocation using non-emergency shipping (delivery 7-10 days after initiation).

Part 2
Begins immediately after part 1 – Shipping of masks & respirators (delivery 7-10 days after initiation).

Part 3
Part 3a: ISNS maintains a stockpile of medical materials.
Part 3b: ISDH evaluates the situation and allocates medical materials on the basis of need.

Part 1 and Part 2

Part 3

ISNS Director reviews and approves medical materials requests from ISDH.

ISNS ships approved medical materials to designated locations.
State Distribution Strategy

Strategic 1

- ISDH allocates and distributes the majority of antiviral medications, respirators, and surgical masks to each County government based on a percentage by population. ISDH maintains a stockpile in reserve for distribution as needed
- For planning purposes, Indiana counties can assume that they will receive an allocation based on 10-20% of their county population. This range is for planning purposes only. The actual allocation strategy during the pandemic will consider additional factors such as current stockpile levels, population density, severity of disease, and impacted areas

<table>
<thead>
<tr>
<th>Allocation</th>
<th>Trigger</th>
<th>Authority</th>
<th>Distribution</th>
<th>Guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Antiviral: by %</td>
<td>Upon the federal decision to distribute SNS</td>
<td>Local government is responsible for resources</td>
<td>ISDH will deliver to 1 location in each county.</td>
<td>ISDH will provide guidance on receipt and storage</td>
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<tr>
<td>based on county</td>
<td>assets, the ISDH will push materials out to</td>
<td>after receipt from ISDH.</td>
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<td>requirements</td>
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<tr>
<td>population</td>
<td>local jurisdictions. (WHO Phase 4 or 5)</td>
<td>A Plan must be developed and approved by the</td>
<td></td>
<td>ISDH will provide guidance on resource distribution.</td>
</tr>
<tr>
<td>Respirators: by %</td>
<td></td>
<td>following:</td>
<td></td>
<td>ISDH will provide guidance on dispensing antivirals</td>
</tr>
<tr>
<td>based on population</td>
<td></td>
<td>• County Commissioners</td>
<td></td>
<td>and use of respirators and masks.</td>
</tr>
<tr>
<td>Masks: by %</td>
<td></td>
<td>• Local Health Officer(s)</td>
<td></td>
<td></td>
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<tr>
<td>based on population</td>
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<td>• EMA Director</td>
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</table>

2 This strategy is subject to change as the stockpile of pandemic countermeasures increases and/or the federal strategy changes. As a result local plans should be scalable and flexible.
Local Jurisdiction Responsibilities:
Receipt of Pandemic Countermeasures

For Indiana County to receive pandemic influenza countermeasures as distributed through the ISNS, they must develop a pandemic countermeasures response plan (annex) to the County Pandemic Response Plan that includes the following:

- **Signing Authority**: Review and approval by the Local Health Officer, the EMA Director, and the County Commissioners (these individuals or their official designee are eligible to “sign” for pandemic countermeasures during a pandemic)

- **Receiving Location**: A designated receiving site must be identified and communicated to the ISNS program before a delivery can be made.

- **Storage Site**: A storage site must be capable of supporting pandemic operations.

- **Security**: Security plans must be in place for the 1) Receipt, 2) Storage, 3) Distribution, 4) Dispensing of pandemic countermeasures.

- **Monitoring**: Temperature control is necessary to support antiviral medications.

- **Distribution**: A plan that identifies where pandemic countermeasures will be dispersed throughout the county is required.

- **Dispensing**: A plan that identifies personnel/organizations/response mechanisms utilized for dispensing antiviral medications during the pandemic is required.
Local Storage Requirements Guidance

Objective:

Provide guidance to assist Indiana counties in identifying the basic storage requirements for pandemic influenza countermeasures. Please note this guidance only pertains to pandemic countermeasures identified in the SNS, not to other assets contained in the SNS.

- Pandemic Influenza response countermeasures include:
  - Antiviral drugs
  - Personal protective equipment (PPE)

This document details basic requirements to receive and store SNS assets that are specific to pandemic influenza. Detailed information on storage dimensions/footprints is included.

Basic assumptions considered:

- Indiana counties will provide their own material handling equipment (MHE).
- 16 square feet per pallet. Standard pallets 40” wide x 48” long x 48” high.
- For planning purposes and space estimations, pallets are single stacked.
- As currently planned, SNS countermeasures will be delivered to one pre-determined location in each Indiana County for a pandemic influenza response.

Current Pandemic Influenza response plans call for multiple line items to be shipped out pro rata (in proportion to population) to Project Areas when the Department of Health and Human Services (DHHS) and the Centers for Disease Control and Prevention (CDC) make the decision to do so. This document provides information on the current SNS line items for the Pandemic Influenza response only, not all SNS line items.

Pandemic Influenza Response

For responding to a Pandemic Influenza event, the following countermeasures will be procured for inclusion in the federal SNS:

- Antiviral Drugs
- Personal protective equipment (PPE) (N95 respirators and surgical masks)

NOTE: This storage requirement document will be updated as SNS assets are procured and additional product information is available.

There are two antiviral drugs stored in the SNS for a Pandemic Influenza event. Each of these products should be stored at 25°C (77°F); excursions are permitted from 15° to 30°C (59° to 86°F).

- Tamiflu (oseltamivir)
- Relenza (zanamivir)
Once all planned SNS antiviral procurements are completed, the ratio of Tamiflu to Relenza delivered to Project Areas will be approximately 80:20. 80% of antiviral drugs will be Tamiflu and 20% will be Relenza.

Tamiflu (oseltamivir)
- Unit of use bottles of 10 capsules (one bottle equals one regimen)
- 48 bottles per case
- 90 cases per pallet
- 4,320 regimens per pallet
- Case dimensions: 13” wide x 8” long x 6” high (3 lbs.)

Relenza (zanamivir)
- 1 kit = 1 regimen, (5 Rotadisks and 1 Diskhaler)
- 16 kits per case
- 60 cases per pallet
- 960 regimens per pallet
- Case dimensions: 17” wide x 6” long x 9” high (4 lbs.)
- Case weight: 4 lbs.

Personal Protective Equipment (PPE):
Currently, the SNS includes the following PPE items:
- N-95 respirators
- Surgical masks

There are multiple types of N-95 respirators and surgical masks on hand in the SNS. Depending on the particular model and manufacturer, the number of items per pallet may vary. The following information is provided for planning purposes.

N-95 Respirators:
One pallet is comprised of at least 4,800 N-95 respirators. N-95 pallets cannot be double stacked.

Surgical Masks:
One pallet is comprised of at least 18,000 surgical masks. Pallets of surgical masks can be double stacked to reduce the overall space required to store the product.

Additional Materials:
Current plans state that SNS ventilators, intravenous antibiotics, and other limited resources will be allocated and distributed by ISDH on the basis of availability and need.

Please note that this is subject to change as the stockpile increases.

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3 Please note that the products Project Areas receive from the manufacturers (for Project Area procured antiviral stockpiles) may vary in dimension and configuration. All federally procured products will be specially packaged in unit of use containers.
Guidance for Antiviral Distribution & Administration

Once the pandemic influenza virus has been confirmed in Indiana, the State Health Commissioner or his/her designee will authorize the use of antiviral medication distributed from the federal cache. These guidelines do not prohibit the routine writing of prescriptions for local pharmacies to fill.

Key Points

• The county as a whole is responsible for the safe storage, distribution, and use of antiviral medication
• Antivirals are currently to be used only for people who are ill with the specific pandemic influenza symptoms
• Using antivirals for post exposure prophylaxis may be permitted as stockpiles expand and more medication is available. Guidance for prophylaxis is under development at the federal level
• The traditional Points of Dispensing (PODs) may not be used for mass dispensing of antiviral medication

Local Plans

Because antiviral medication can only be used for treatment at this time; ill people must be diagnosed by a healthcare provider (such as physician or nurse practitioner) as being ill with the pandemic influenza virus prior to receiving the medication. The list of pandemic influenza symptoms will be released after the pandemic has started and key symptoms are identified. In developing local plans for distribution and administration of antiviral medication during a pandemic, consideration must be given to maintaining proper social distancing among patients and staff and the use of personal protective equipment (PPE).

Local plans must include the following:

• The parties responsible for the receipt, storage, distribution and administration of the antivirals
• The location for receipt of delivery of the medication from the State
• The process by which medication will be distributed to treatment locations
• A list of material handling equipment that may be necessary to distribute medication to various locations in the county
• A list of locations where antiviral medication will be provided for treatment (e.g. hospitals, clinics, physician offices, pharmacies, alternate care site, or temporary treatment sites)
• Instructions for health professionals and the public that include qualifying symptoms and where to report for treatment
• How treatment locations will be announced to the public
• How security will be provided at the treatment locations, if needed
• Instructions for the recipients of the medication to report adverse or allergic reactions
• How the demand or need for more medication will be handled.
Interim Public Health Guidance for the Use of Facemasks and Respirators in Non-Occupational Community Settings during an Influenza Pandemic

Information on the use of facemasks and respirators for the control of pandemic influenza in community settings is extremely limited. Thus, it is difficult to assess their potential effectiveness in controlling influenza in these settings. In the absence of clear scientific data, the interim recommendations below have been developed on the basis of public health judgment and the historical use of facemasks and respirators in other settings.

During an influenza pandemic, the risk for influenza can be reduced through a combination of simple actions. No single action will provide complete protection, but an approach combining the following steps may help decrease the likelihood of infection: hand washing, isolation and treatment with antiviral medications of persons with confirmed or probable influenza, voluntary home quarantine of members of households with confirmed or probable influenza cases, reduction of unnecessary social contacts, and avoidance whenever possible of crowded or congested social settings.

When it is absolutely necessary to enter a crowded setting or to have close contact with persons who might be infectious, the time spent in that setting should be as short as possible. If used correctly, facemasks and respirators may help prevent some exposures, but they should be used along with other preventative measures, such as social distancing and hand hygiene. When crowded settings or close contact with others cannot be avoided, the use of facemasks or respirators should be considered as follows:

- Whenever possible, rather than relying on the use of masks or respirators, close contact and crowded conditions should be avoided during an influenza pandemic.
- Facemasks should be considered for use by individuals who enter crowded settings, both to protect their nose and mouth from other people's coughs and to reduce the wearers' likelihood of coughing on others; the time spent in crowded settings should be as short as possible.
- Respirators should be considered for use by individuals for whom close contact with an infectious person is unavoidable. This can include selected individuals who must care for a sick person (e.g., family member with a respiratory infection) at home.

The CDC has prepared the Interim Public Health Guidance for the Use of Facemasks and Respirators in Non-Occupational Community Settings during an Influenza Pandemic to assist in planning for decisions regarding the use of facemasks and respirators in “non-occupational community settings” during a pandemic.

For more information please see the entire document at:
http://www.pandemicflu.gov/plan/community/maskguidancecommunity.html
Interim Guidance on Planning for the Use of Surgical Masks and Respirators in Health Care Settings during an Influenza Pandemic

Since the publication of the *HHS Pandemic Influenza Plan* (www.hhs.gov/pandemicflu/plan/) in November 2005, the U.S. Department of Health and Human Services (HHS) has received numerous comments and inquiries regarding infection control recommendations that relate to surgical mask and respirator use (e.g., N95 respirator) during an influenza pandemic. Development of authoritative responses is hampered by the lack of definitive data about the relative contributions and importance of short-range inhalational exposure, large droplet mucosal exposure, and direct inoculation via hands or inanimate objects contaminated with virus (i.e., fomites) on influenza transmission. There is only limited information on optimal interventions to prevent influenza transmission and the effectiveness of interventions on an individual basis. The lack of scientific consensus has led to conflicting recommendations by public health partners. Moreover, a large amount of incorrect, incomplete, and confusing information about surgical mask and respirator use has been disseminated on the Internet and by other popular media.

The Centers for Disease Control and Prevention (CDC) is aware of no new scientific information related to the transmission of influenza viruses since the drafting of the *HHS Pandemic Influenza Plan* (www.hhs.gov/pandemicflu/plan/). As stated in the plan, the proportional contribution and clinical importance of the possible modes of transmission of influenza (i.e., droplet, airborne, and contact) remains unclear and may depend on the strain of virus ultimately responsible for a pandemic. Nevertheless, in view of the practical need for clarification, CDC has re-reviewed the existing data, as described below, and has prepared interim recommendations on surgical mask and respirator use. The purpose of the *Interim Guidance on Planning for the Use of Surgical Masks and Respirators in Health Care Settings during an Influenza Pandemic* is to provide a science-based framework to facilitate planning for surgical mask and respirator use in health care settings during an influenza pandemic.

This document, *Interim Guidance on Planning for the Use of Surgical Masks and Respirators in Health Care Settings during an Influenza Pandemic*, augments and supersedes recommendations provided in Part 2 of the *HHS Pandemic Influenza Plan* (www.hhs.gov/pandemicflu/plan/#part2). This interim guidance document will be updated and amended as new information about the epidemiologic characteristics of the pandemic influenza virus becomes available.

For more information please see the entire document at: http://www.pandemicflu.gov/plan/healthcare/maskguidancehc.html