

**Federal Bureau of Prisons  
Health Services Division**

**Pandemic Influenza Plan**

**Appendix D**

**Module 2: Antiviral Medications and Vaccines (May 2008)**

The BOP Pandemic Influenza Plan contains the main plan and four separate modules which cover the unique health-related aspects of pandemic flu emergency response. These include:

- Module 1: Surveillance and Infection Control
- Module 2: Antiviral Medications and Vaccines
- Module 3: Health Care Delivery
- Module 4: Care for the Deceased

Each module contains template Standard Operating Procedures which are provided as separate, modifiable, WordPerfect® files. The Standard Operating Procedures correlate with the Actions Steps listed for the Preparation Stage. They are designed to standardize, guide and simplify each facility’s planning process.

The BOP Pandemic Influenza Plan is divided into 3 stages (Preparation, Response and Recovery) which correlate with the Federal Government Pandemic Influenza Stages (see page 1).

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## BOP Pandemic Influenza Response Stages

The Bureau of Prisons has based its Pandemic Influenza Plan on the federal government response stages. The BOP plan combines the federal stages to organize action steps into three different stages: Preparation, Response and Recovery.

<b>Bureau of Prisons Pandemic Influenza Response Stages</b>			
<b>Federal Stage</b>	<b>Federal Government Response Stages*</b>	<b>Federal Stages</b>	<b>BOP Plan</b>
<b>0</b>	New domestic animal outbreak in at-risk country	<b>0-1</b>	<b>Preparation</b>
<b>1</b>	Suspected human outbreak overseas		
<b>2</b>	Confirmed human outbreak overseas	<b>2-5</b>	<b>Response</b>
<b>3</b>	Widespread human outbreaks in multiple locations overseas		
<b>4</b>	First human case in North America		
<b>5</b>	Spread throughout United States		
<b>6</b>	Recovery & preparation for subsequent waves	<b>6</b>	<b>Recovery</b>
*Note: The Federal Government Response Stages should not be confused with the World Health Organization phases of pandemic influenza which are different and overlap. See Appendix A of the main BOP plan.			

## Overview

This section outlines:

- Stockpiling, distributing, and using **antiviral medications**.
- Preparing for mass vaccination with a **pandemic vaccine** (when it becomes available).
- Increasing **annual seasonal flu vaccination** among staff and inmates.
- Increasing **pneumococcal vaccination** among eligible staff and inmates.

**Antiviral Medication:** Antiviral medications may help decrease the illness and death due to influenza. Should transmission of pandemic influenza become widespread, the most important goals of using antiviral medication are (1) to prevent serious morbidity and death, and (2) to preserve the delivery of healthcare and other essential services, through early treatment and limited prophylaxis.

### **Antivirals can be used in three ways:**

- **Early treatment:** to treat flu cases (must be started within 48 hours of symptom-onset).
- **Post-exposure prophylaxis:** to prevent the flu after exposure to someone sick with flu.
- **Prophylaxis:** to prevent the flu during an ongoing outbreak.

Early treatment is a more efficient use of antivirals than widespread prophylaxis. Using antivirals to prevent individuals from getting the flu during a six-week-long outbreak would consume *four times* the number of doses as would a five-day treatment course for individuals who have become sick with flu. The BOP Medical Director will issue priorities for using stockpiled medication.

Two brands of antivirals are potentially effective for treating avian (H5N1) flu: oseltamavir (Tamiflu®) and zanamavir (Relenza®). BOP is stockpiling oseltamavir. This section outlines the steps for obtaining antivirals through the BOP regional offices and the federal stockpiles, and for developing plans for distributing and dispensing antivirals to staff and inmates.

**Pandemic Vaccine:** Experts estimate that it will be at least four-to-six months after a pandemic starts before vaccine will become available. Facilities should plan for acquiring and storing (refrigerating) the vaccine and for mass vaccination. Priorities for use will be issued by the BOP Medical Director.

**Seasonal Flu Vaccine:** Increasing the number of inmates and employees who are vaccinated for *seasonal* flu will decrease the occurrence of seasonal flu during a pandemic. It will also help the institution be prepared logistically for mass vaccination if a pandemic vaccine is available.

**Pneumococcal Vaccine:** It is generally recommended that pneumococcal vaccine be administered to individuals who are at high risk for complications from bacterial pneumonia (see list on page 6). Preparation for pandemic flu includes improving pneumococcal vaccine coverage, thereby reducing the number of high risk individuals who develop bacterial pneumonia after becoming sick with pandemic flu. Inmates with risk factors should be identified and vaccinated. Employees should be educated to obtain pneumococcal vaccine from their personal health care provider if they have risk factors.

## Action Steps by Pandemic Stage

### **Preparation** (Federal Response Stages 0–1)

(See page 5 for the [Standard Operating Procedures](#) for the Preparation stage.)

1. Identify a health care staff person to be responsible for the planning for antiviral medication and vaccines.
2. Increase *seasonal flu* vaccination rates for employees and inmates.
3. Increase *pneumococcal* vaccination coverage rates for employees and inmates who have risk factors for pneumococcal pneumonia. (Employees must obtain via personal health care provider.)
4. Coordinate with local health department partners to ensure inclusion in the Strategic National Stockpile for *antiviral medication* and *pandemic vaccine*.
5. Stockpile medications for community acquired pneumonia per recommendations of the BOP Medical Director.
6. Develop local plan for obtaining antivirals stockpiled in the region (coordinating with the Regional Office, in accordance with the regional distribution plan).
7. Review DHHS priority groups for receiving *antiviral medication* and *pandemic vaccine*.
8. Educate employees and inmates regarding the need and rationale for assigning priorities for receiving *antiviral medication* and *pandemic vaccine*.
9. Develop local procedures for providing *antiviral medication* and *pandemic vaccine* to employees and inmates in accordance with federal law as well as BOP policies and procedures.

### **Response** (Federal Response Stages 2–5)

***Begin when there are confirmed human outbreaks of pandemic flu anywhere in the world:***

1. Central Office guidance will be issued by the Medical Director regarding BOP-specific priority groups for receiving antiviral medication and pandemic vaccine.
2. Educate staff regarding the need for and rationale for priority groups.
3. In accordance with Central Office guidance and the Regional Office antiviral medication distribution plans, obtain antiviral medication from the BOP regional stockpile.
4. Communicate with appropriate public health agencies regarding the availability of antivirals and pandemic vaccine from the National Strategic Stockpile.
5. Assess adequacy of supplies needed for delivery of antiviral medication and vaccine.

***Begin after a suspected pandemic influenza case is diagnosed in the facility:***

6. Dispense antiviral medications and administer vaccinations according to Central Office priority groups.
7. Monitor for antiviral adverse events and report them using MEDWATCH Form FDA 3500.
8. Monitor adverse events from pandemic influenza vaccine and report them using the Vaccine Adverse Event Reporting System Form (VAERS-1).
9. Monitor efficacy and resistance patterns of antivirals.
10. Monitor efficacy of the vaccine.
11. Monitor antiviral/vaccine supplies, distribution, and use.

**Recovery (Federal Response Stage 6)**

*Previous flu pandemics have been associated with subsequent “waves” of flu after an initial wave resolves. After an initial pandemic flu outbreak, subsequent outbreaks are likely. The recovery period will involve both recovering from the pandemic emergency, evaluating the BOP response to it and preparing for subsequent waves of pandemic flu.*

1. Evaluate efficacy and resistance of antivirals and pandemic influenza vaccine.
2. Evaluate adverse reactions of antiviral medications and pandemic influenza vaccine.
3. Assess whether the supply of antiviral medication and pandemic vaccine, as well as the supplies necessary for their delivery, were adequate.
4. Assess coordination with state and local health partners, as well access to the Strategic National Stockpile.
5. Evaluate the effectiveness of the system for dispensing antivirals and administering vaccine.

<b>Module 2: Antiviral Medications and Vaccines</b> <b>Standard Operating Procedures - Preparation Stage</b> (Federal Response Stages 0–1)						
During the Preparation stage, adapt this Standard Operating Procedure template to the unique circumstances of your facility. A modifiable WordPerfect version is posted on: <a href="http://www.bop.gov/news/medresources.jsp">www.bop.gov/news/medresources.jsp</a>						
<b>1. Identify a health care staff person to be responsible for the planning for antiviral medication and vaccines.</b>						
In this facility, the following individual is assigned responsibility:						
<b>2. Increase <i>seasonal flu</i> vaccination rates for employees and inmates.</b>						
<b>Annually review influenza vaccination rates. Set goals for improvement for the next season.</b> The table below can be utilized to track the number of employees and inmates who were eligible for vaccine, the number that received vaccination, and the percentage of eligible who were vaccinated.						
a. Outline plan in this facility for improving <i>employee</i> vaccination rates. b. Outline plan in this facility for improving <i>inmate</i> vaccination rates.						
<b>Tracking Tool to Determine Percentage of Eligible Employees &amp; Inmates Who Receive Annual Influenza Vaccine</b>						
Group	Flu Season (year to year)	# Vaccinated	# Eligible*	# Vaccinated ÷ # Eligible*	% Vaccinated	Goal (%)
Employees	to					
	to					
Inmates	to					
	to					
* <i>All employees are eligible.</i> Inmates are eligible using priority criteria distributed annually.						
<b>3. Increase <i>pneumococcal</i> vaccination coverage rates for employees and inmates who have risk factors for pneumococcal pneumonia.</b>						
a. <b>Employees:</b> Develop strategies for promoting pneumococcal vaccine for employees with risk factors. It will not be possible to track employee pneumococcal vaccinations since they are provided by their private practitioners.  In this facility, the following plan will be utilized to promote pneumococcal vaccine for employees:						

**b. Inmates:** Develop a system for identifying inmates with risk factors for pneumococcal pneumonia (see below). The table below can be utilized to track the percentage of eligible inmates who receive pneumococcal vaccine.

In this facility the following plan will be followed to improve pneumococcal vaccine coverage for inmates:

Tracking Tool to Determine Percentage of Eligible Inmates Who Receive Pneumococcal Vaccine						
Year	# Eligible	# w/ Prior Vaccine	# Vaccinated	Total Vaccinated** ÷ # Eligible	% Vaccinated	Goal (%)

\*\*Total Vaccinated = number with prior vaccine + number vaccinated

**Inmates with the following risk factors should receive pneumococcal vaccine:** chronic pulmonary disease (excluding asthma); cardiovascular diseases; diabetes mellitus; chronic liver diseases; chronic renal failure or nephrotic syndrome; functional or anatomic asplenia (e.g., sickle cell disease or splenectomy); immunosuppressive conditions (e.g., congenital immunodeficiency, HIV infection, leukemia, lymphoma, multiple myeloma, Hodgkins disease, generalized malignancy, or organ transplantation); chemotherapy with alkylating agents, antimetabolites, or long-term systemic corticosteroids; cochlear implants; Native American or Alaskan Native ancestry.

**4. Coordinate with local health department partners to ensure inclusion in the Strategic National Stockpile for *antiviral medication and pandemic vaccine*.**

Contact local health department regarding Strategic National Stockpile. Advocate that your facility be part of the plan. Document discussions and attach to the plan.

**5. Stockpile medications for community acquired pneumonia per BOP Medical Director.**

Determine quantity and type of antibiotics to be stockpiled and plans for rotating stock.

**6. Develop local plan for obtaining antivirals stockpiled in the region (coordinating with the Regional Office, in accordance with the regional distribution plan).**

**a.** In the event of pandemic flu, plans for obtaining stockpiled antivirals are:

**b.** Identify location for storing antivirals in this facility. (For security reasons, do not record location in this document.)

**c.** Plan for securing antivirals in this facility. The plan is:

**7. Review DHHS priority groups for receiving *antiviral medication and pandemic vaccine*.**

In the event of pandemic flu, the BOP Medical Director will issue priority listings. Discuss estimates of how many individuals would fall into each priority listing.

The following process will be used to rapidly identify individuals falling into various risk categories:

**8. Educate employees and inmates regarding the need and rationale for assigning priorities for receiving *antiviral medication and pandemic vaccine*.**

Indicate how and when education about priorities for antiviral medication and pandemic vaccine will be incorporated into general training about pandemic flu:

**9. Develop local procedures for providing *antiviral medication and pandemic vaccine* to employees and inmates.**

Detail separate procedures for providing antiviral medication and administering pandemic vaccine (including identifying needed supplies and plans for obtaining them):



## Attachment 2.1. Oseltamivir Phosphate (Tamiflu™) Prescribing Information

### How Supplied and Storage

- 75 mg capsules, blister pack of 10 capsules.
- Powder for oral suspension (12 mg/ml after reconstitution), 25 ml bottle.
- Controlled room temperature; excursions permitted between 59° to 86° for both capsules and suspension.

### Indications and Administration Dose

**Treatment:** For uncomplicated acute illness from influenza viruses type A and B, in patients greater than 12 months old who have been symptomatic  $\leq 2$  days.

**Adults and Adolescents > 13 years old:**

- 75 mg *twice daily* for 5 days. Begin treatment within 2 days of onset of symptoms.

**Children  $\geq 12$  months old:**

- Safety and efficacy of treatment in children less than 12 months old have not been established.

Treating Children $\geq 12$ Months Old		
Body Weight	Dose for 5 days	Bottles of Suspension Needed
$\leq 33$ lbs (15 kg)	30 mg twice daily	1
$> 33$ to 51 lbs (15–23 kg)	45 mg twice daily	2
$> 51$ to 88 lbs (23–40 kg)	60 mg twice daily	2
$> 88$ lbs (40 kg)	75 mg twice daily	3

**Renal Function Impairment (creatinine clearance between 10–30 ml/min):**

- 75 mg *once daily* for 5 days.

**Prophylaxis:** For influenza type A and B in adults and adolescents  $\geq 13$  years of age. The two situations in which prophylaxis can be used are (1) after a discrete exposure (one 10-day course) and (2) in the context of ongoing exposure (up to 6 weeks).

**Adults and Adolescents  $\geq 13$  years old:**

- 75 mg *once daily* for at least 10 days. Therapy should start within 2 days of exposure. Safety and efficacy in a community outbreak setting have been demonstrated for up to 6 weeks.

**Children < 13 years old:**

- Safety and efficacy of prophylaxis in this age group have not been established.

**Renal Function Impairment (creatinine clearance between 10–30 ml/min):**

- 75 mg *every other day*
- 30 mg *or* oral suspension *every day*

## Pharmacology and Pharmacokinetics

- Oseltamivir inhibits the influenza virus neuraminidase, with possible alteration of virus particle aggregation and release.
- The medication is a pro-drug that is metabolized within the body, via hepatic esterases, to the active drug oseltamivir carboxylate.
- Medication can be given with or without food. Food may enhance tolerability in some patients.
- Oseltamivir is not a substrate for, nor inhibitor of, cytochrome P450 isoenzymes.
- Oseltamivir is eliminated in the urine.

## Contraindications

- Hypersensitivity to any component.

## Warnings and Precautions

- Should not affect the evaluation of individuals for annual influenza vaccination.
- **Pregnancy Category C:** Animal studies suggest that fetal risk is possible, but there is no evidence that Oseltamivir is harmful in humans. Benefits should outweigh risks.
- **Lactation:** Excretion through lactation was mild in animal studies, but it is not known whether Oseltamivir is excreted in human milk. Benefits should outweigh risks.

## Drug Interactions

- No influenza vaccine interactions have been studied or identified.
- Oseltamivir is not a substrate for, or inhibitor of, cytochrome P450 isoenzymes.
- Clinically significant drug interactions are unlikely.

## Adverse Reactions

- **Most Common ( $\geq 1\%$ ):** Nausea, vomiting, bronchitis, insomnia, vertigo, diarrhea, abdominal pain, dizziness, headache, cough, fatigue
- **Less Common ( $< 1\%$ ):** Unstable angina, anemia, pseudomembranous colitis, humerus fracture, pneumonia, pyrexia, peritonsillar abscess
- **Overdosage:** Limited data. Single doses up to 1000 mg are associated with nausea and vomiting.

### For more information:

Antiviral medication information from CDC: <http://www.cdc.gov/flu/professionals/treatment/>

Full Prescribing Medication Package Insert: <http://www.rocheusa.com/products/tamiflu/pi.pdf>

**Attachment 2.2. Form for Tamiflu™ – Medical Evaluation, Consent, and Prescribing**

<b>Last Name:</b>	<b>First:</b>	<b>MI:</b>	<b>DOB:</b> ___/___/___
<input type="checkbox"/> <b>Inmate</b>	<b>Reg #:</b>	<b>Unit #:</b>	
<input type="checkbox"/> <b>Staff</b>	<b>Telephone #:</b>	<b>Position:</b>	
<b>What medical problems have you had?</b>			
<input type="checkbox"/> <b>No</b> <input type="checkbox"/> <b>Yes</b>	<input type="checkbox"/> Do you have allergies to any medications? List:		
<input type="checkbox"/> <b>No</b> <input type="checkbox"/> <b>Yes</b>	<input type="checkbox"/> Do you have a history of kidney disease? Describe:		
<input type="checkbox"/> <b>No</b> <input type="checkbox"/> <b>Yes</b>	<input type="checkbox"/> Are you allergic to Tamiflu?		
<input type="checkbox"/> <b>No</b> <input type="checkbox"/> <b>Yes</b>	<input type="checkbox"/> Are you pregnant? If yes, what is your due date? ___/___/___		
<input type="checkbox"/> <b>No</b> <input type="checkbox"/> <b>Yes</b>	<input type="checkbox"/> Are you planning on becoming pregnant within the next year?		
<input type="checkbox"/> <b>No</b> <input type="checkbox"/> <b>Yes</b>	<input type="checkbox"/> Are you nursing (breast feeding)?		
<input type="checkbox"/> <b>No</b> <input type="checkbox"/> <b>Yes</b>	<input type="checkbox"/> Do you currently have flu symptoms? If yes, check all that apply: <input type="checkbox"/> fever <input type="checkbox"/> cough <input type="checkbox"/> shortness of breath <input type="checkbox"/> sore throat When did your symptoms start? ___ hours ago   ___ days ago		
<input type="checkbox"/> <b>No</b> <input type="checkbox"/> <b>Yes</b>	<input type="checkbox"/> Have you been in contact with anyone who has flu symptoms? If yes, how long ago? _____ days		
<b>List medications that you currently take (medication/dose):</b>			
<b>Health Care Provider Only</b>			
<input type="checkbox"/> <b>Patient has contraindications to Tamiflu and is not approved. List reasons:</b>			
<input type="checkbox"/> <b>Patient has no contraindications to Tamiflu and is approved.</b> <i>Prescription: Tamiflu 75 mg as checked below.</i>			
<input type="checkbox"/> <b>Treatment:</b>		<input type="checkbox"/> twice daily for 5 days	
( <input type="checkbox"/> Renal impairment:             )		<input type="checkbox"/> once daily for 5 days	
<input type="checkbox"/> <b>Post-exposure:</b>		<input type="checkbox"/> once daily for 10 days	
( <input type="checkbox"/> Renal impairment:             )		<input type="checkbox"/> once daily every other day for 10 days	
<input type="checkbox"/> <b>Prophylaxis (ongoing):</b>		<input type="checkbox"/> once daily x ___ weeks	
( <input type="checkbox"/> Renal impairment:             )		<input type="checkbox"/> once daily every other day x ___ weeks	
_____ <i>BOP Healthcare Provider Signature</i>			
I have been provided and have read the Patient Package Insert information regarding Tamiflu. (Tamiflu Patient Package Insert: <a href="http://www.rocheusa.com/products/tamiflu/ppi.pdf">http://www.rocheusa.com/products/tamiflu/ppi.pdf</a> ). I am aware that in order to be eligible to receive Tamiflu, I must participate in this medical evaluation. I have been advised to call my personal physician if signs and symptoms of the flu develop. I was offered the opportunity to ask questions during the visit. The medical information I provided above is complete and accurate to the best of my knowledge. I am aware that this medication is being prescribed for my personal use only, and that I am not to sell it or give it to anybody else. I am also aware that I am to contact my personal physician if any changes to my medical status occur, or if I am experiencing adverse effects from Tamiflu.			
Patient Signature: _____		Date: _____	
Witness Signature: _____		Date: _____	

### **Attachment 2.3. Pandemic Flu Vaccination – General Information**

**Note:** Consult the Centers for Disease Control for updates concerning information on pandemic flu vaccine.

The pandemic influenza vaccine may prevent influenza. However, because the pandemic influenza virus may change (or “shift”), the pandemic influenza vaccine might not offer complete protection. Vaccinated people who do get the pandemic influenza may have a milder case than those who did not get the vaccination. Many people call any illness with fever and cold symptoms “the flu” and may expect the pandemic influenza vaccine to prevent these illnesses. The pandemic influenza vaccine is effective only against illness that is caused by certain pandemic influenza viruses, and not against other “flu-like” maladies.

#### **In general, what are the risks from influenza vaccine?**

A vaccine, like any medicine, is capable of causing serious problems such as severe allergic reactions. The risk of a vaccine causing serious harm, or death, is extremely small. Almost all people who get influenza vaccine have no serious problems. Because the viruses in the vaccine are killed, you cannot get influenza from the vaccine. Mild side effects can include soreness, redness, or swelling where the injection was given, as well as fever and body aches. If these problems occur, they usually begin soon after the vaccination and last only one-to-two days. Life-threatening allergic reactions are very rare. If they do occur, it is within a few minutes to a few hours after the injection.

#### **What are the risks during pregnancy?**

Pregnancy can increase the risk for complications from the flu, and pregnant women are more likely to be hospitalized from complications of the flu than non-pregnant women of the same age. In previous worldwide outbreaks of pandemic flu (the pandemics of 1918–19 and 1957–58), deaths among pregnant women were associated with the pandemic. Pregnancy can affect the mother’s immune system, as well as her cardiovascular system (heart and lung function). These changes in particular may place pregnant women at increased risk for complications from the flu. Because the flu vaccination is made from inactivated viruses (the viruses are killed), many experts consider flu vaccinations to be safe during any stage of pregnancy. However, experts traditionally have not given flu vaccinations during the first trimester.

Women who will be beyond the first three months of pregnancy during the flu season should get a flu vaccination, after their first trimester. Pregnant women who have medical problems that increase their risk for complications from the flu should get a flu vaccination before the flu season, no matter what stage of pregnancy they are in.

**Attachment 2.4. Form for Pandemic Flu Vaccine – Medical Evaluation and Consent**

<b>Last Name:</b> _____		<b>First:</b> _____	<b>MI:</b> _____	<b>DOB:</b> ___/___/___
<input type="checkbox"/> <b>Inmate</b>	<b>Reg #:</b> _____		<b>Unit #:</b> _____	
<input type="checkbox"/> <b>Employee</b>	<b>Telephone #:</b> _____		<b>Position:</b> _____	
<input type="checkbox"/> <b>No</b> <input type="checkbox"/> <b>Yes</b>	<b>Are you currently ill with a fever greater than 100.4 degrees F or 38.0 degrees C?</b> ■ Last documented fever was: _____ F or C			
<input type="checkbox"/> <b>No</b> <input type="checkbox"/> <b>Yes</b>	<b>Have you developed flu-like symptoms or a cough in the past week?</b>			
<input type="checkbox"/> <b>No</b> <input type="checkbox"/> <b>Yes</b> <input type="checkbox"/> <b>No</b> <input type="checkbox"/> <b>Yes</b> <input type="checkbox"/> <b>No</b> <input type="checkbox"/> <b>Yes</b>	<b>Have you ever experienced or had any of the following?</b> ■ Allergic reaction to eggs? ■ Reaction to any vaccine that required medical care? ■ History of Guillain-Barre Syndrome?			
<input type="checkbox"/> <b>No</b> <input type="checkbox"/> <b>Yes</b> <input type="checkbox"/> <b>No</b> <input type="checkbox"/> <b>Yes</b> <input type="checkbox"/> <b>No</b> <input type="checkbox"/> <b>Yes</b> <input type="checkbox"/> <b>No</b> <input type="checkbox"/> <b>Yes</b> <input type="checkbox"/> <b>No</b> <input type="checkbox"/> <b>Yes</b> <input type="checkbox"/> <b>No</b> <input type="checkbox"/> <b>Yes</b>	<b>Current Medical Status:</b> ■ Pregnant or planning to become pregnant in the next 4 weeks? If pregnant, when is your due date? _____ ■ Are you breast feeding? ■ Immunocompromised ( including HIV/AIDS, chemotherapy, transplant patient, lupus, lymphoma, leukemia, platelet disorder, thrombocytopenia)? ■ Chronic lung disease or severe breathing problems? ■ Severe asthma? ■ Uncontrolled or fever-induced seizures, or a neurological disease? ■ Other serious health problems or surgeries in the last 6 months? If so, describe:			
<input type="checkbox"/> <b>No</b> <input type="checkbox"/> <b>Yes</b>	<b>Are you presently taking <u>any</u> medications</b> (including prescription and over-the-counter, as well as herbal or dietary supplements)? <b>Please list:</b>			
<input type="checkbox"/> <b>No</b> <input type="checkbox"/> <b>Yes</b>	<b>Any allergies to medication that you are aware of? Please list:</b>			
I have been provided with the facts about the pandemic flu vaccine, and I and have read and understood them. I am aware that in order to be eligible to receive the pandemic flu vaccine, I must participate in this medical evaluation. I have considered my own health status, as well as the health status of my household members and close physical contacts. I have been advised to call my personal physician if I experience any adverse effects thought to be related to the pandemic flu vaccine. I was offered the opportunity to ask questions during the visit. The medical information that I provided above is complete and accurate, to the best of my knowledge. I understand that the decision to be vaccinated is voluntary, and I agree to proceed with the pandemic flu vaccination.				
<b>Patient Signature:</b> _____			<b>Date:</b> _____	
<b>Witness Signature:</b> _____			<b>Date:</b> _____	
<b>Disposition:</b> <input type="checkbox"/> <b>Referred for vaccination</b> <input type="checkbox"/> <b>Deferred due to medical contraindications</b> <input type="checkbox"/> <b>Vaccination refused</b>				
_____			_____	
<b>Medical Screener's Name (Print)</b>			<b>Medical Screener's Signature</b>	
			<b>Date</b>	

## **Attachment 2.5. Guidance for Acquisition, Storage, and Use of Antiviral Medication Procurement**

Each regional HSA will purchase an initial stockpile of antiviral medication (Tamiflu<sup>®</sup>), enough to provide a ten-day course of medication for 15% of inmates and staff. Project Code 42Y will be used for these purchases.

**Storage:** Each regional HSA will designate a central storage facility within their respective region. Medication will be properly stored in accordance with the current Pharmacy Program Statement, PS6360.01. Each storage site will store product in a secured and proper temperature-controlled area, and will segregate pandemic stock from inventory intended for inter-pandemic use. Verification of proper storage temperature must be maintained on site.

**Verification:** On a quarterly basis, each regional HSA or designee is to complete the “Quarterly Pandemic Influenza Medication Certification” (next page). Certification will verify the quantity on hand, expiration date, and appropriate storage conditions (temperature). The original is to be maintained on site, with a copy forwarded to the BOP Chief Pharmacist or designee.

**Restricted Use:** Product cannot be dispensed for inter-pandemic use. Product may only be dispensed once Phase VI of the World Health Organization (WHO) influenza pandemic phase is declared by the WHO, as referenced in Section 1, Part V, of the *Pandemic Influenza Preparedness and Response Plan* issued by the U.S. Department of Health and Human Services in August 2004. A national and state-specific pandemic influenza declaration by the U.S. Department of Health and Human Services (“CDC”) will also allow release of product under this agreement. Only the BOP Medical Director can authorize the use of stockpiled medication. In the event of a pandemic outbreak, the Medical Director will issue written notice of authorized use.

**Distribution:** Each regional HSA will develop a plan to distribute medication from the stockpile site to individual institutions in the event of a pandemic outbreak, with staging at the direction of the BOP Medical Director or designee.

**Dispensing:** The BOP Medical Director will authorize dispensing and distribution of antiviral medication, once a pandemic is declared as defined above. Dispensing will occur by designated health care staff according to PS6360.01. A dispensing log will be maintained of all medication dispensed to inmates and staff.

**Record Keeping:** All records of procurement, storage, distribution, and dispensing must be kept on site for a period of at least five years beyond the purchase agreement terms. In the event of an audit, copies of all records will be requested to be sent to the Central Office within 10 days of request. A perpetual inventory will be maintained from procurement, through distribution and dispensing to the patient, documenting the appropriate chain of custody.

/s/

RADM Newton E. Kendig, Director  
Health Services Division

