

**Federal Bureau of Prisons
Health Services Division**

Pandemic Influenza Plan

Module 2: Antiviral Medications and Vaccines

October 2012

BOP Pandemic Influenza Response Stages

The BOP *Pandemic Influenza Plan* is divided into the three stages that are used for standard BOP contingency plans; in this plan, the three stages are designed to correlate with the Federal Government Response Stages for pandemic influenza.

The BOP Pandemic Influenza Response Stages are as follows:

- **PREPARATION** (Federal Response Stages 0–1). Most of the detail in this plan involves the preparation phase.
- **RESPONSE** (Federal Response Stages 2–5). This phase, which begins when it is announced that there are confirmed human outbreaks overseas, involves both making last-minute preparations and actually responding to pandemic flu.
- **RECOVERY** (Federal Response Stage 6). This phase involves recovering from the pandemic, evaluating actions taken during the pandemic, and preparing for more flu. Based on what we know from previous pandemics, subsequent waves of flu are likely to follow once the pandemic flu has subsided.

Federal Government Response Stages*		BOP Influenza Plan	
		Federal Stages	BOP Stage
0	New domestic animal outbreak in at-risk country	0-1	PREPARATION
1	Suspected human outbreak overseas		
2	Confirmed human outbreak overseas	2-5	RESPONSE
3	Widespread human outbreaks in multiple locations overseas		
4	First human case in North America		
5	Spread throughout United States		
6	Recovery & preparation for subsequent waves	6	RECOVERY

**The Federal Government Response Stages should not be confused with the World Health Organization phases of pandemic influenza.*

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Overview

Module 2 covers the following information:

- 1. Antiviral medications—stockpiling, distribution, and use*
- 2. Pandemic vaccine—preparing for mass vaccination*
- 3. Seasonal flu vaccination—increasing annual vaccination among staff and inmates*
- 4. Pneumococcal vaccination—increasing vaccination among eligible staff and inmates*

1. Antiviral Medications

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 health care and other essential services, through early treatment and limited prophylaxis.

Antivirals can be used in three ways:

- **Treatment:** To treat flu cases (ideally should 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 antiviral medication than widespread prophylaxis. Two brands of antivirals are effective for treating influenza: oseltamivir (Tamiflu®) and zanamivir (Relenza®). BOP is stockpiling both drugs.

Antiviral Treatment Recommendations

Treatment with oseltamivir or zanamivir is recommended for all persons with suspected or confirmed influenza requiring hospitalization. Treatment may be recommended for persons with suspected or confirmed influenza who are at higher risk for complications. In the event of pandemic influenza, the BOP Medical Director will issue specific guidance regarding high-risk groups to treat with antiviral medication.

The following are general recommendations regarding antiviral treatment. Prescribing information for oseltamivir and zanamivir are provided in [Attachment 2.1](#).

- Oseltamivir is the generally recommended antiviral recommended for treatment during pregnancy.
- Zanamivir is contraindicated for inmates with airway disease.
- Treatment should not wait for laboratory confirmation of influenza because laboratory testing can delay treatment and because a negative rapid test for influenza does not rule out influenza.
- Treatment should be initiated as early as possible because studies show that treatment initiated early (i.e., within 48 hours of illness onset) is more likely to provide benefit.
- Clinical judgment is an important factor in antiviral treatment decisions for all patients presenting for medical care who have illnesses consistent with influenza.
- Persons who are not at higher risk for complications or do not have severe influenza requiring hospitalization generally *do not* require antiviral medications for treatment or prophylaxis. However, any suspected influenza patient presenting with warning signs and symptoms for lower respiratory tract illness (e.g., shortness of breath, rapid breathing, unexplained oxygen desaturation) should promptly receive empiric antiviral therapy.
- Clinicians should do the following to reduce delays in initiating antiviral treatment, including:

- ▶ Inform inmates at higher risk for influenza complications about the signs and symptoms of influenza and the need for early treatment after the onset of influenza symptoms (i.e., fever, respiratory symptoms).
- ▶ Start empiric treatment of patients at higher risk for influenza complications as soon as possible. See prescribing information for additional information.

Antiviral Post-Exposure Prophylaxis Recommendations

Antiviral post-exposure prophylaxis involves providing medication to prevent development of influenza. Because use of antiviral medications for prophylaxis may contribute to the development of antiviral resistant influenza strains, antiviral prophylaxis will be provided within the BOP only under a limited number of circumstances as discussed in *Table 1* below.

Table 1. Influenza Antiviral Prophylaxis within the BOP

- **Inmates who are close contacts to persons with ILI who have medical conditions which place them at high risk for influenza complications** may be candidates for antiviral prophylaxis, based upon guidance from the Medical Director. Pregnant inmates are the highest priority.
- **In the event of significant health care shortages, health care workers (HCWs) who are close contacts to ILI cases may be offered antiviral prophylaxis.** The use of antiviral prophylaxis under this circumstance requires approval of the BOP Medical Director. Unless they take antiviral prophylaxis, exposed HCWs should not be assigned to care for inmates who are at high risk for influenza complications for the 4 days following potential exposure, i.e., 24 hours after fever resolves in the close contact(s) with ILI.
- **In the event of significant correctional staff shortages, BOP institutions can consider general antiviral prophylaxis of staff in order to maintain adequate staffing.** The use of antiviral prophylaxis under this circumstance requires the approval of the BOP Medical Director.

- For the purposes of assessing possible exposure, the infectious period—the time period when an exposure may have occurred—is one day before ILI symptoms occur until 24 hours after fever ends.
- Two drugs can be used for prophylaxis: oseltamivir and zanamivir. Pregnant women who are close contacts to a person with ILI are high priority for prophylaxis. Oseltamivir is generally recommended for pregnant women.
- Antiviral agents should not be used for post-exposure prophylaxis in healthy inmates.
- Antiviral prophylaxis generally is not recommended if more than 48 hours have elapsed since the last contact with an infectious person. Prophylaxis is not indicated when contact occurred before or after, but not during, the ill person's *infectious period* (as defined in the first bullet above). An emphasis on early treatment is an alternative to prophylaxis after a suspected exposure.

2. Pandemic Vaccine

The BOP will utilize CDC-defined priorities for prioritizing administration of a pandemic vaccine once it is developed and released for distribution. In the event of a pandemic, the BOP Medical Director will issue guidance regarding how the vaccine will be obtained and the priority groups for vaccination. Local institutions should have plans in place for mass vaccination.

Guidance on planning mass vaccination clinics is available at:
http://www.cdc.gov/flu/professionals/vaccination/vax_clinic.htm.

3. 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.

4. Pneumococcal Vaccine

It is generally recommended that pneumococcal vaccine be administered to individuals who are at high risk for complications from bacterial pneumonia (see *Table 2* below). 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.

Table 2. Risk Factors for Complications from Bacterial Pneumonia	
<ul style="list-style-type: none">• 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)	<ul style="list-style-type: none">• immunosuppressive conditions (e.g., congenital immunodeficiency, HIV infection, leukemia, lymphoma, multiple myeloma, Hodgkin's disease, generalized malignancy, or organ transplantation)• chemotherapy with alkylating agents, antimetabolites, or long-term systemic corticosteroids• cochlear implants• cerebrospinal fluid leaks• chronic alcoholism

Action Steps by Pandemic Stage

Preparation (Federal Response Stages 0–1)

(See [Standard Operating Procedures](#), which are provided for the Preparation stage only.)

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 *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. Educate employees and inmates regarding the need and rationale for assigning priorities for receiving *antiviral medication* and *pandemic vaccine*.
8. 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. Provide seasonal flu vaccine to high priority inmates and staff.
2. Review the priority groups for antiviral medication and criteria for prophylaxis as defined by the Medical Director.
3. Educate staff regarding the need for and rationale for priority groups.
4. All facilities should maintain a recommended stock of antiviral medication per direction of the BOP Medical Director. Facilities that house women should maintain an adequate stock of oseltamivir to provide treatment and prophylaxis to all pregnant inmates.
5. Review plans for accessing the Regional stockpile of antiviral medications (if demand exceeds local supply).
6. Finalize plans for mass vaccination, including arrangements for storage of vaccine.

(continued on next page)

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

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

Recovery (Federal Response Stage 6)
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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 as access to the Strategic National Stockpile.
5. Evaluate the effectiveness of the system for dispensing antivirals and administering vaccine.

Module 2: Standard Operating Procedures for Preparation Stage (Federal Response Stages 0–1)

During the Preparation stage, adapt this Standard Operating Procedure template to the unique circumstances of your facility. A modifiable Word version is posted on:
www.bop.gov/news/medresources.jsp.

1. Identify staff persons responsible for planning for the planning for antiviral medication and vaccines.

In this facility, the following individual is assigned responsibility:

2. Increase seasonal flu vaccination rates for employees and inmates.

Annually review influenza vaccination rates. Set goals for improvement for the next season.

- a. Outline plan in this facility for improving employee vaccination rates.
- b. Outline plan in this facility for improving inmate vaccination rates.

3. Increase *pneumococcal* vaccination coverage rates for employees and inmates who have risk factors for pneumococcal pneumonia.

- a. **Employees:** 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.

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

4. Coordinate with local health department partners to ensure inclusion in the Strategic National Stockpile for *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. Educate employees and inmates regarding the need and rationale for assigning priorities for receiving <i>antiviral medication</i> and <i>pandemic vaccine</i>.
Indicate how and when education about priorities for antiviral medication and pandemic vaccine will be incorporated into general training about pandemic flu:
8. Develop local procedures for providing <i>antiviral medication</i> and <i>pandemic vaccine</i> to employees and inmates.
Detail separate procedures for providing antiviral medication and administering pandemic vaccine (including identifying needed supplies and plans for obtaining them):

Attachments

Attachment 2.1: Prescribing Information for Zanamivir and Oseltamivir

Attachment 2.2: Antiviral Medication – Medical Evaluation, Consent, and Prescribing

Attachment 2.3: Guidance for Acquisition, Storage, and Use of Antiviral Medication Procurement

Attachment 2.4: Quarterly Pandemic Influenza Medication Certification

Attachment 2.1. Prescribing Information for Zanamivir and Oseltamivir

Zanamivir (Relenza®)

How Supplied and Storage

Relenza (GlaxoSmithKline) **Powder**. Blister for inhalation. Four 5 mg blisters of powder on a ROTADISK® for oral inhalation via DISKHALER®. Packaged in carton containing 5 ROTADISKS (total of 10 doses) and 1 DISKHALER inhalation device.

Store DISKHALER and blister packs at 77°F (excursions permitted from 59° to 86°F). Do not puncture any blister until just before inhaling a dose.

Indications and Administration Dose

Uncomplicated acute illness caused by influenza A and B virus in adults and children 7 yr of age and older who have been symptomatic for no longer than 2 days; prophylaxis of influenza in adults and children 5 yr of age and older. For oral inhalation only (not nasal inhalation).

Influenza Treatment: *Adults and children 7 years of age and older:* Oral inhalation: Two 5 mg inhalations (10 mg total) twice per day for 5 days. Treatment generally should begin within 2 days of onset of influenza. Two doses should be taken on the first day of treatment whenever possible, provided there is at least 2 hours between doses. On subsequent days, doses should be about 12 hours apart at approximately the same time each day.

Influenza Post-Exposure Prophylaxis: *Adults and children 5 yr of age and older:* Oral inhalation: 2 inhalations (one 5 mg blister per inhalation) once daily for 10 days. Treatment should begin within 2 days of exposure.

Influenza Prophylaxis Community Outbreak: *Adults and adolescents:* Oral inhalation: 2 inhalations (one 5 mg blister per inhalation) once daily for 28 days.

Contraindications

Do not use in patients with history of allergic reactions to any ingredient of Relenza® including lactose (which contains milk proteins).

Warnings and Precautions

- **Pregnancy:** Category C.
- **Lactation:** Undetermined.
- **Bronchospasm:** Serious, sometimes fatal cases have occurred. *Not recommended in individuals with underlying airway disease* (including asthma and chronic obstructive pulmonary disease). Discontinue Relenza® if bronchospasm or decline in respiratory function develops.
- **Hypersensitivity:** Allergic-like reactions, including oropharyngeal edema, serious skin rashes, and anaphylaxis, have been reported in postmarketing experience, including in patients sensitive to lactose (milk proteins).
- **High-risk patients:** Safety and efficacy not demonstrated in patients with high-risk underlying medical conditions.
- **Neuropsychiatric events:** Delirium and abnormal behavior leading to injury have been reported in postmarketing experience.

Zanamivir (Relenza®) — continued

Adverse Reactions

The most common adverse events reported in >1.5% of patients treated with Relenza® and more commonly than in patients treated with placebo are:

- **Treatment Studies:** dizziness, sinusitis
- **Prophylaxis Studies:** fever and/or chills, arthralgia and articular rheumatism

Drug Interactions

Live attenuated influenza vaccine, intranasal:

- Do not administer until 48 hours following cessation of Relenza®.
- Do not administer Relenza® until 2 weeks following administration of the live attenuated vaccine, unless medically indicated.

Pharmacology and Pharmacokinetics

- Inhibition of influenza virus neuraminidase, affecting release of virus particles.
- **Absorption:** About 4% to 17% of orally inhaled dose is systemically absorbed. C max is 17 to 142 ng/mL, and T max is 1 to 2 hours following a 10 mg dose. The AUC is 111 to 1,364 ng·h/mL.
- **Excretion:** Renally excreted as unchanged drug in urine. Serum half-life is 2.5 to 5.1 h. Total Cl is 2.5 to 10.9 L/h. Unabsorbed drug is excreted in feces.

Oseltamivir (Tamiflu®)

How Supplied and Storage

- 30 mg capsules, blister pack of 10 capsules
- 45 mg capsules, blister pack of 10 capsules
- 75 mg capsules, blister pack of 10 capsules.
- Powder for oral suspension (12 mg/ml after reconstitution), 25 ml bottle.

Store at 77°F (with excursions allowed 59° to 86°) for both capsules and suspension.

Indications and Administration Dose

Influenza Treatment: For uncomplicated acute illness from influenza viruses type A and B, in patients greater than 12 months old who have been symptomatic for no more than 2 days.

- **Adults and Adolescents ≥ 13 years old:** 75 mg twice daily for 5 days. Begin treatment within 2 days of onset of symptoms.
- **Renal Function Impairment (creatinine clearance between 10–30 ml/min):** 75 mg once daily for 5 days.

Post-Exposure Prophylaxis: For adults and adolescents exposed to influenza type A and B in there are two situations in which prophylaxis can be used: (1) after a discrete exposure (one 10-day course); and (2) in the context of ongoing exposure.

- **Adults and Adolescents > 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 in immunocompetent patients and up to 12 weeks in immunocompromised patients.
- **Renal Function Impairment (creatinine clearance between 10–30 ml/min):** 75 mg capsule every other day or 30 mg every day

Oseltamivir (Tamiflu®) — continued

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.
- Cases of anaphylaxis and serious skin reactions including toxic epidermal necrolysis, Stevens-Johnson Syndrome, and erythema multiforme have been reported in postmarketing experience. Treatment should be stopped and appropriate therapy instituted if an allergic-like reaction occurs or is suspected.
- There have been postmarketing reports (mostly from Japan) of delirium and abnormal behavior leading to injury, and in some cases resulting in fatal outcomes, in patients with influenza who were receiving oseltamivir.

Drug Interactions

Live attenuated influenza vaccine, intranasal:

- Do not administer until 48 hours following cessation of Oseltamivir.
- Do not administer Oseltamivir until 2 weeks following administration of the live attenuated vaccine, unless medically indicated.
- Oseltamivir is not a substrate for, or inhibitor of, cytochrome P450 isoenzymes.
- Clinically significant drug interactions are unlikely.

For more information ...

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

Relenza® – Full Prescribing Medication Package Insert: <http://www.gsk.com/products/prescription-medicines/relenza.htm>

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

Attachment 2.2. Antiviral Medication – Medical Evaluation, Consent, and Prescribing

What medical problems have you had?		
<input type="checkbox"/> No	<input type="checkbox"/> Yes	Do you have allergies to any medications? List:
<input type="checkbox"/> No	<input type="checkbox"/> Yes	Do you have a history of kidney disease? Describe:
<input type="checkbox"/> No	<input type="checkbox"/> Yes	Are you allergic to Tamiflu® (oseltamivir) or Relenza® (zanamivir)?
<input type="checkbox"/> No	<input type="checkbox"/> Yes	Are you pregnant? If yes, what is your due date? ___/___/___
<input type="checkbox"/> No	<input type="checkbox"/> Yes	Are you planning on becoming pregnant within the next year?
<input type="checkbox"/> No	<input type="checkbox"/> Yes	Are you nursing (breast feeding)?
<input type="checkbox"/> No	<input type="checkbox"/> Yes	Do you have asthma or chronic obstructive pulmonary disease? (<i>Do not use Relenza®.</i>)
<input type="checkbox"/> No	<input type="checkbox"/> Yes	Do you 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"/> No	<input type="checkbox"/> Yes	Have you been in contact with anyone who has flu symptoms? If yes, how long ago? ___ days
List medications that you currently take (medication/dose):		
Health Care Provider Only:		
Patient has contraindications to antiviral therapy and is not approved. List reasons:		
	Prescription for Tamiflu® (oseltamivir)	Prescription for Relenza® (zanamivir)
Influenza treatment	<input type="checkbox"/> 75 mg twice daily for 5 days <input type="checkbox"/> Renal impairment: once daily for 5 days	<input type="checkbox"/> 10 mg (2 puffs) twice daily for 5 days
Influenza post-exposure prophylaxis	<input type="checkbox"/> 75 mg twice daily for 5 days <input type="checkbox"/> Renal impairment: once daily for 5 days	<input type="checkbox"/> 10 mg (2 puffs) once daily for 10 days
Influenza prophylaxis (ongoing)	<input type="checkbox"/> 75 mg twice daily for ___ days <input type="checkbox"/> Renal impairment: 75 mg once daily every other daily for ___ weeks	<input type="checkbox"/> 10 mg (2 puffs) once daily for ___ weeks
Provider signature and stamp:		Date: ___/___/___
<ul style="list-style-type: none"> • I have been counseled regarding antiviral medication therapy. I am aware that in order to be eligible to receive antiviral medication, I must participate in 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 antiviral medication. 		
Patient signature: _____		Date: ___/___/___
Witness signature: _____		Date: ___/___/___
Institution		Identification

Attachment 2.3. Guidance for Acquisition, Storage, and Use of Antiviral Medication Procurement

Each regional HSA will maintain a stockpile of Tamiflu® and Relenza® per guidance from the BOP Medical Director.

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* ([Attachment 2.4](#)). 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 (ACDC@) 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 and documented in BEMR. Once an influenza outbreak has been resolved, return unused antiviral medication to the Regional Office stockpile within 6 to 8 weeks.

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.

