Federal Bureau of Prisons
Health Services Division

Pandemic Influenza Plan

Module 2: Antiviral Medications and Vaccines (October 2009)

What's New in This Document?

Since the May 2008 version of Module 2, the following has been revised to reflect updated recommendations by the Centers for Disease Control and Prevention (CDC) regarding the current pandemic H1N1 influenza. Throughout the module, changes are highlighted in yellow.

Antiviral Medication

- Both Tamiflu® (oseltamivir) and Relenza® (zanamivir) can be used for influenza treatment and prophylaxis.
- Prescribing information for Relenza has been added (*Attachment 2.1*). Note that Relenza is *contraindicated* for persons with airway disease.
- Priority groups for antiviral treatment are provided in Table 1.
- Pregnant women are the highest priority group for both antiviral treatment and prophylaxis. Tamiflu is generally recommended for treatment of pregnant women. Relenza is generally recommended for post-exposure prophylaxis of pregnant women. If Relenza is contraindicated, use Tamiflu.
- Criteria for antiviral prophylaxis is provided in Table 2. Post-exposure prophylaxis should be considered for all pregnant women and for other close contacts at high risk for influenza complications (listed in Table 1). Health care workers who are close contacts to a person with ILI cannot provide care to inmates at high risk for influenza complications–for the 4 days following their exposure–*unless* they receive antiviral prophylaxis.
- Relenza has been added to *Attachment 2.2*, *Antiviral Medication – Medical Evaluation, Consent, and Prescribing* and *Attachment 2.6, Quarterly Pandemic Influenza Medication Certification*.

Pandemic Vaccine

- The BOP will obtain pandemic vaccine directly from the CDC. Local institutions should contact their local health departments regarding a back-up plan for obtaining vaccine.
- Priority groups for receipt of vaccine are listed in Table 3.
- Local institutions should aggressively pursue provision of seasonal flu vaccine for high-risk inmates and employees.
- Plans should be laid for mass vaccination with pandemic H1N1 vaccine, including storage of vaccine at a temperature of 2–8 °C. The following guidance is available. Planning for mass vaccination clinics: http://www.cdc.gov/h1n1flu/vaccination/statelocal/. Template standard orders for administering pandemic H1N1 vaccine: http://www.immunize.org/catg.d/p3074b.pdf.
- Pandemic vaccine consent/declination forms are provided for inmates and employees (*Attachment 2.3* and *Attachment 2.4*)

Federal Bureau of Prisons
Health Services Division

Pandemic Influenza Plan

Module 2: Antiviral Medications and Vaccines (October 2009)

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 that are provided as separate, modifiable, WordPerfect® files. The Standard Operating Procedures correlate with the Action Steps listed for the Preparation Stage. They are designed to standardize, guide, and simplify each facility's planning process.

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.

Bureau of Prisons Pandemic Influenza Response Stages

Federal Stage	Federal Government Response Stages*	Federal Stages	BOP Plan
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**

***Note:** The Federal Government Response Stages should not be confused with the World Health Organization phases of pandemic influenza, which are different and overlap.

Module 2: Antiviral Medications and Vaccines – Contents

Overview

This section outlines:

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

1. 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 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 the current pandemic H1N1 influenza: oseltamivir (Tamiflu®) and zanamivir (Relenza®). BOP is stockpiling both drugs.

Antiviral Treatment Recommendations

The following are general recommendations regarding antiviral treatment. Prescribing information for Tamiflu and Relenza are provided in *Attachment 2.1*.

- Treatment with Tamiflu or Relenza is recommended for all persons with suspected or confirmed influenza requiring hospitalization. Treatment is also recommended for persons with suspected or confirmed influenza who are at higher risk for complications (see list below).

Table 1. BOP Antiviral Medication – Priority Groups

Persons at High Risk for Influenza Complications

- **Pregnant women** (should generally be treated with Tamiflu)
- **Adults 65 years of age or older**
- **Persons with the following medical conditions:**
  - Chronic pulmonary disorders (including asthma) (should generally be treated with Tamiflu)
  - Cardiovascular disorders (except hypertension)
  - Renal disorders
  - Hepatic disorders
  - Hematological disorders (including sickle cell anemia)
  - Neurologic disorders
  - Cognitive disorders (e.g., serious mental health disorders)
  - Neuromuscular disorders
  - Metabolic disorders (including diabetes mellitus)
  - Immunosuppression, including that caused by medications or HIV

- Tamiflu is the generally recommended antiviral recommended for treatment during pregnancy.
- Relenza 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 judgement 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.

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 below.

Table 2. 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*** (see Table 1) are candidates for antiviral prophylaxis. 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.*** 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: Tamiflu and Relenza. Pregnant women who are close contacts to a person with ILI are high priority for prophylaxis. Relenza is generally recommended. If Relenza is contraindicated, e.g., due to underlying airway disease, then Tamiflu should be used.
- 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:

BOP will utilize CDC-defined priorities for prioritizing administration of the pandemic influenza (H1N1) 2009 vaccine.

Table 3. BOP Pandemic (H1N1) 2009 Vaccine Priority Groups

Priority 1

- Pregnant women
- Adults who live with or care for children younger than 6 months of age
- Health care and emergency medical services personnel

Priority 2

- All persons ages 18 to 24
- Persons ages 25 or older at high risk for influenza complications (Table 1)

Priority 3

- All persons ages 25 to 64

Priority 4

- All persons ages 65 and above

The BOP will obtain vaccine directly from the CDC for all institutions. Only injectable, inactivated vaccine will be supplied. The CDC will provide all needed supplies with the vaccine, i.e., needles/syringes, alcohol pads, and sharps disposal containers.) However, in addition, institutions should communicate with their local health departments regarding a back-up plan for obtaining vaccine locally.

Local institutions should have plans in place for mass vaccination, including storage of vaccine at a temperature of 2–8°C. Guidance on planning mass vaccination clinics is available at: http://www.cdc.gov/H1N1flu/vaccination/statelocal/. Institutions can utilize template standing orders for administering 2009 H1N1 vaccine which are available at: http://www.immunize.org/catg.d/p3074b.pdf. A BOP consent/declination form for 2009 H1N1 vaccine for inmates is provided in *Attachment 2.3*. A staff consent/declination form is provided in

Attachment 2.4. Employees should be provided a copy of the CDC Vaccine Information Statement which can be obtained from: http://www.immunize.org/vis/vis_h1n1inactive.asp.

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 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 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 *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 BOP 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. Provide seasonal flu vaccine to high priority inmates and staff.
2. Review priority groups for antiviral medication and pandemic vaccine outlined in Table 1 and Table 3 in the Overview. Review criteria for prophylaxis in the BOP in Table 2.
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 Tamiflu and Relenza 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 at a temperature of 2–8 °C.

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)

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: Antiviral Medications and Vaccines

Standard Operating Procedures - 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 WordPerfect version is posted on: www.bop.gov/news/medresources.jsp.

1. Identify a health care staff person to be responsible 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. 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 *employee* vaccination rates.

b. Outline plan in this facility for improving *inmate* vaccination rates.

Tracking Tool to Determine Percentage of Eligible

Employees & Inmates Who Receive Annual Influenza Vaccine

Group	Flu Season (year to year)	# Vaccinated	# Eligible*	# Vaccinated ÷ # Eligible*	% Vaccinated	Goal (%)
Employees	to					
	to					
Inmates	to					
	to					

* *All employees are eligible.* Inmates are eligible using priority criteria distributed annually.

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 (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.

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

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. Prescribing Information for Relenza® and Tamiflu®

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 controlled room temperature (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). ***Unlabeled use(s):*** H1N1 Influenza A (Swine Flu): For treatment and chemoprophylaxis of H1N1 influenza A (swine flu) virus infection. This includes patients with confirmed, probable, or suspected H1N1 influenza A (swine flu) virus infection and their close contacts. For more information, refer to the CDC guidelines at: http://www.cdc.gov/h1n1flu/recommendations.htm

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 7 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.

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, with the possibility of alteration of virus particle aggregation and release.
- 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

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

Store at controlled room temperature (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 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 (up to 6 weeks).

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.

Renal Function Impairment (creatinine clearance between 10–30 ml/min): 75 mg capsule every other day or 30 mg oral suspension every day.

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.

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. Antiviral Medication – Medical Evaluation, Consent, and Prescribing

What medical problems have you had?	
☐ **No** ☐ **Yes**	Do you have allergies to any medications? List:
☐ **No** ☐ **Yes**	Do you have a history of kidney disease? Describe:
☐ **No** ☐ **Yes**	Are you allergic to Tamiflu or Relenza?
☐ **No** ☐ **Yes**	Are you pregnant? If yes, what is your due date? ___/___/___
☐ **No** ☐ **Yes**	Are you planning on becoming pregnant within the next year?
☐ **No** ☐ **Yes**	Are you nursing (breast feeding)?
☐ **No** ☐ **Yes**	Do you have asthma or chronic obstructive pulmonary disease? (Do not use Relenza.)
☐ **No** ☐ **Yes**	Do you currently have flu symptoms? If yes, check all that apply: ☐ fever ☐ cough ☐ shortness of breath ☐ sore throat When did your symptoms start? ___ hours ago ___ days ago
☐ **No** ☐ **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	☐ 75 mg twice daily for 5 days ☐ Renal impairment: once daily for 5 days	☐ 10 mg (2 puffs) twice daily for 5 days
Influenza post-exposure prophylaxis	☐ 75 mg twice daily for 5 days ☐ Renal impairment: once daily for 5 days	☐ 10 mg (2 puffs) once daily for 10 days
Influenza prophylaxis (ongoing)	☐ 75 mg once daily for __ weeks ☐ Renal impairment: 75 mg once daily *every other* day for __ weeks)	☐ 10 mg (2 puffs) once daily for __ weeks

Provider signature and stamp: Date:

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 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 antiviral medication.

Patient Signature: _____ Date: _____

Witness Signature: _____ Date: _____

Institution	Identification

Attachment 2.3 Information on Vaccination (Consent/Declination) for Influenza A (H1N1) 2009 Monovalent Inactivated Vaccine

The form on the next page should be utilized with inmates to obtain consent/declination for receipt of the influenza A (H1N1) 2009 vaccine.

U.S. DEPARTMENT OF JUSTICE

FEDERAL BUREAU OF PRISONS

INFORMATION ON VACCINATION (CONSENT/DECLINATION) FOR INFLUENZA A (H1N1) 2009 MONOVALENT INACTIVATED VACCINE

Influenza A (H1N1) 2009 Monvalent Vaccine (H1N1 Flu Shot)

The 2009 H1N1 influenza is caused by a new strain of influenza virus. It has spread to many countries. Like other flu viruses, H1N1 flu spreads from person to person through sneezing, coughing, and sometimes through touching objects contaminated with the virus. The H1N1 flu can cause: fever, sore throat, cough, headache, chills and muscle aches. Some people have reported diarrhea and vomiting. Most people feel better within a week or less. But some people get pneumonia or other serious illnesses. Some people have to be hospitalized and some die. The H1N1 flu is a new flu virus and is very different from seasonal flu viruses. Most people have little or no immunity to H1N1 flu (their bodies are not prepared to fight off the virus).

Persons should receive the influenza A (H1N1) 2009 monovalent vaccine according to following priorities depending upon the availability of vaccine:

Priority 1

- Pregnant women,
- Adults who live with or care for children younger than 6 months of age,
- Health care and emergency medical services personnel.

Priority 2

- All persons ages 18 to 24 years old,
- Persons ages 25 or older at high risk for influenza complications, including: pulmonary disorders including asthma; cardiovascular disorders (except hypertension); renal, hepatic (liver), and hematologic (blood) disorders (including sickle cell anemia); metabolic disorders including diabetes; immunosuppression/weakened immune system (e.g.,HIV or medication induced (cancer drugs);cognitive dysfunction (e.g., severe mental health disorder like schizophrenia); certain muscle or nerve disorders that lead to breathing/swallowing problems (e.g., seizure disorders or cerebral palsy).

Priority 3: All persons ages 25 to 64 years old.

Priority 4: All persons age 65 and above.

Persons who should not receive the influenza A (H1N1) 2009 monovalent vaccine:

- Those who have severe allergy to eggs,
- Those who have a hypersensitivity to any components of the vaccine,
- Have a history of Guillain-Barre Syndrome (GBS), a severe paralytic illness,
- Anyone with a current febrile illness or moderate or severe acute illness should wait until they recover before getting flu vaccine.
- Anyone who had flu-like illness confirmed by *real-time reverse transcriptase-polymerase chain reaction* (rRT-PCR) to be 2009 H1N1 virus earlier in 2009, should be considered *immune* and *should not* be given the influenza A (H1N1) 2009 vaccine.

When should I get influenza A (H1N1) 2009 vaccine?

You should get vaccinated as soon as the vaccine is available. Children under 9 years of age should get two doses, about a month apart; however, older children and adults need only one dose. The 2009 H1N1 influenza vaccine can be given at the same time as other vaccines, including the seasonal flu vaccine.

Can I get H1N1 flu infection even if I get the influenza A (H1N1) 2009 vaccine?

Yes. Influenza viruses change often, and they might not always be covered by the vaccine. The H1N1 vaccine is made just like seasonal flu vaccines. The vaccine is expected to be as safe and effective as seasonal flu vaccines. However, the H1N1 vaccine will not prevent "flu-like" illnesses caused by other viruses, nor prevent seasonal flu. The H1N1 flu vaccine is an inactivated (killed) vaccine given by injection into the muscle, like the seasonal flu shot.

Institution	**Identification**

What are the risks from influenza A (H1N1) 2009 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 from it. The viruses in the H1N1 vaccine are killed, so you cannot get flu from the vaccine. The risks from inactivated 2009 H1N1 vaccine are similar to those from seasonal inactivated flu vaccine:

- Mild problems: soreness, redness, or swelling where the shot was given, fever, or aches. If these problems occur, they will usually begin soon after the shot and last 1-2 days.
- Severe problems: Life-threatening allergic reactions are very rare. If they do occur, it is usually within a few minutes to a few hours after the shot.

Note: Depending on the manufacturer, each dose of *H1N1 flu vaccine* may contain trace amounts of the preservative thimerosol, a mercury derivative.

What if there is a moderate or severe reaction? What should I look for?
Any unusual condition, such as a high fever or behavior changes. Signs of a serious allergic reaction can include difficulty breathing, hoarseness or wheezing, hives, paleness, weakness, a fast heart beat or dizziness. If this happens, call for help right away. Tell your doctor what happened, the date and time it happened, and when the vaccination was given.

What if I am pregnant or breast feeding my infant?
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 the flu (pandemics of 1918-19 and 1957-58), deaths among pregnant women were associated with the flu. Pregnancy can change the immune system in the mother, as well as affect her cardiovascular system (heart and lung function). These changes may place pregnant women at increased risk for complications from the flu. Because the H1N1 flu shot is made from inactivated viruses (the viruses are killed), the risks are similar to those from seasonal flu vaccine. All pregnant women and breast feeding women can get inactivated influenza A (H1N1) 2009 vaccine.

Health Questions: (check yes or no)

☐ Yes ☐ No Are you sick today?

☐ Yes ☐ No Did you have flu-like illness confirmed to be 2009 H1N1 virus earlier in the year?

☐ Yes ☐ No Do you have an allergy to eggs or to a component of the vaccine?

☐ Yes ☐ No Have you had a serious reaction to influenza vaccine in the past?

☐ Yes ☐ No Have you ever had Guillain-Barre syndrome (progressive paralysis)?

If you have any questions about H1N1 flu vaccination, please ask a health care provider.

****

CONSENT FOR VACCINATION

I,_____, have read the BOP information statement about the influenza A (H1N1) 2009 vaccination and have had the opportunity to ask questions about the benefits and risks receiving this vaccination.

I do want to receive the influenza A (H1N1) 2009 vaccination at this time.

_____ _____
Signature of the Recipient Date Signature of the Witness Date

****

DECLINATION FOR VACCINE

I do not want to receive the influenza A (H1N1) 2009 vaccination at this time.

_____ _____
Signature of the Recipient Date Signature of the Witness Date

Attachment 2.4 Employee Consent/Declination for Influenza a (H1N1) 2009 Monovalent Inactivated Vaccine

The form on the next page should be utilized with employees to obtain consent/declination for receipt of the influenza A (H1N1) 2009 monovalent inactivated vaccine.

U.S. DEPARTMENT OF JUSTICE
FEDERAL BUREAU OF PRISONS

EMPLOYEE CONSENT/DECLINATION FOR INFLUENZA A (H1N1) 2009 MONOVALENT INACTIVATED VACCINE

Depending upon the availability of vaccine, persons should receive the influenza A (H1N1) 2009 monovalent vaccine according to following priorities:

Priority 1
- Pregnant women,
- Adults who live with or care for children younger than 6 months of age,
- Health care and emergency medical services personnel.

Priority 2
- All persons ages 18 to 24 years old,
- Persons ages 25 or older at high risk for influenza complications, including: pulmonary disorders including asthma; cardiovascular disorders (except hypertension); renal, hepatic (liver), and hematologic (blood) disorders including sickle cell anemia; metabolic disorders including diabetes; immunosuppression/weakened immune system (e.g.,HIV or medication induced (cancer drugs);cognitive dysfunction (e.g., severe mental health disorder like schizophrenia); certain muscle or nerve disorders that lead to breathing/swallowing problems (e.g., seizure disorders or cerebral palsy).

Priority 3: All persons ages 25 to 64 years old.

Priority 4: All persons age 65 and above.

Health Questions: (check yes or no)

☐ Yes ☐ No Are you sick today?
☐ Yes ☐ No Did you have flu-like illness confirmed to be 2009 H1N1 virus earlier in the year?
☐ Yes ☐ No Do you have an allergy to eggs or to a component of the vaccine?
☐ Yes ☐ No Have you had a serious reaction to influenza vaccine in the past?
☐ Yes ☐ No Have you ever had Guillain-Barre syndrome (progressive paralysis)?

Consent / Declination

I have been provided with the facts about the inactivated influenza A (H1N1) vaccine (e.g., CDC VIS information), and I have read and understood them. I have been advised to notify my personal physician if I experience any adverse side effects thought to be related to the vaccine. I understand that the decision to be vaccinated is voluntary, and I agree to proceed with the H1N1 flu shot.

I certify to belong to the priority group being served as listed above and that the health information that I have provided is complete and accurate, to the best of my knowledge.

☐ **I do want the pandemic H1N1 vaccine.** ☐ **I do not want the flu vaccine at this time.**

_____ _____
Signature of the Recipient Date **Signature of the Witness Date**

****
***Disposition: (*staff use only*)** **Institution**_____

☐ **Referred for pandemic H1N1 flu vaccination:**

Date Given	Manufacturer	Lot #	Expiration Date	Site	Dose/Route

☐ **Deferred due to medical contraindication**

☐ **Refused vaccination**

_____
Clinician Signature & Stamp Date

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

Each regional HSA will purchase an initial stockpile of Tamiflu® and Relenza® per guidance from the BOP Medical Director. 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. 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.

/s/

RADM Newton E. Kendig, Director

Health Services Division

Attachment 2.6. Quarterly Pandemic Influenza Medication Certification

Region: _____ **Storage Facility: _____**

Date of Certification: _____ **Date of Last Certification: _____**

	Tamiflu Quantity	Tamiflu Expiration Date	Relenza Quantity	Relenza Expiration Date
Beginning balance				
Quantity received (+)				
Quantity distributed, detail below (–)				
Total on hand				

Antiviral Distributed

Institution	Date Sent	Quantity of Tamiflu Sent	Quantity of Relenza Sent

Antiviral Returned

I certify that the above quantities are correct and that all medication has been properly stored and secured, in accordance with manufacturer's recommendations and purchase agreement.

_____ _____ _____

Signature *Printed Name* *Title*

_____ _____ _____

Witness Signature *Printed Name* *Title*