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HEALTH DISTRICT

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DRAFT 1.0

ATTACHMENT to SNS plan

Grant County Strategic
National Stockpile
Management Plan
For H1N1 Influenza Drugs

~ May 2009 ~

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AUTHORITIES

1. RCW 70.05.070. The local Health Officer has authority to act to control and prevent the spread of any dangerous contagious or infectious disease that may occur in his/her jurisdiction.
2. RCW 43.20.050(4). All police officers, sheriffs, constables and all other officers and employees of the state or any county, city or township thereof, are authorized to enforce all rules adopted by the State Board of Health.
3. WAC 246-101-505. Local Health officers are to review and determine the appropriate action for instituting disease prevention and infection control, isolation, detention and quarantine measures necessary to prevent the spread of communicable disease, invoking the powers of the courts to enforce these measures when necessary.
4. WAC 246-101-425. Members of the general public shall cooperate with public health authorities in the investigation of cases and suspected cases, and cooperate with the implementation of infection control measures including isolation and quarantine.

INTRODUCTION

H1N1 Influenza A (“swine flu”) is a novel influenza virus that has significant potential for widespread contagion in humans
(see: <http://www.cdc.gov/h1n1flu/> and [Swine Flu Information - Washington St Dept of Health](#)).

To date H1N1 Influenza A isolates worldwide have shown in vitro sensitivity to oseltamivir and zanamivir. The FDA has issued Emergency Use Authorizations (EAU) for the use of those agents for H1N1 Influenza A treatment.

(see: http://www.cdc.gov/h1n1flu/eua/pdf/fda_letter_tamiflu.pdf and http://www.cdc.gov/h1n1flu/eua/pdf/fda_letter_relenza.pdf)

For further information see: <http://www.cdc.gov/h1n1flu/eua/>

The CDC Division of **Strategic National Stockpile** (DSNS) has been given the authority from HHS and CDC leadership to initiate shipment of materiel for the swine flu influenza outbreak. DSNS has been given permission to release 25 percent of states’ and Grant County allocation of SNS-held antiviral drugs*, personal protective equipment, and respiratory protection devices. Once this material leaves federal control, it becomes a state and/or local responsibility to maintain, store, secure, and deploy. If the materiel should go unused, states and local jurisdictions should be prepared for long term storage. At the time this document is being drafted, antivirals supplied by SNS *may only be used to treat H1N1 influenza A infections and related exposures*.

* approximately 2331 courses of oseltamivir and 658 courses of zanamivir

PROCEDURES

Custody of SNS supplies:

Once delivered to Grant County and receipted by designated representatives of the Grant County Health District (GCHD), custody of SNS supplies becomes the sole responsibility of GCHD.

Authority over SNS supplies:

GCHD will retain sole authority over all SNS supplies in Grant County in regards to their use even after release of those supplies to cooperating governmental and private agencies for distribution to the public. All distributions must be authorized by GCHD in writing. Distributions of SNS pharmaceuticals may only be made to agencies within Grant County capable of tracking, storing, accounting for, and dispensing to the public under the pharmacy and hospital laws, rules, and regulations of the State of Washington or those United States laws rules or regulations governing tribal reservations where Washington State law does not apply.

Receipt of Materials:

SNS materials will be delivered by agents of the Washington State Department of Health (DOH) to three designated sites in Grant County. Half will be delivered to the central previously identified storage site, one quarter to a designated cooperating south county site, and one quarter to a designated north county site. The pharmacists at those three locations are designated by GCHD to be agents working under the authority of GCHD (solely for the SNS supplies) to take receipt of the materials, perform receipt inventory, sign for receipt, and assure proper storage of materials. In case the pharmacist at any one of those designated locations is unable to act, alternates will be designated by the GCHD Administrator.

Storage of Materials:

The antivirals will be required to be maintained in a temperature range of 59 to 86 degrees and will need to be stored in accordance with Board of Pharmacy regulations which are summarized as follows: The antiviral storage site must:

- Be well lighted and ventilated;
- Have adequate space for operations and be a clean storage space;
- Have a secure entry with identified and limited access;
- Have secure walls and ceiling (acoustical tiles are not secure).

If the antivirals are *stored more than 30 days* (this excludes <30 days short term storage), the storage area must:

- Have continuous measurement of temperature and humidity and have records of the measurements;
- Have an alarm system, if not staffed 24/7;
- Have camera surveillance or a motion monitor for security;

Inventory Control:

SNS regulations require that the custodial jurisdiction must rack and document the inventory and, and retain records for two years. Inventory control and documentation will be the responsibility of the respective pharmacists acting under the authority of GCHD as long as the SNS materials are stored in hospital facilities which will last at least for the duration of the current federally designated H1N1 (swine variant) emergency. At the end of the emergency, if inventory remains, plans for long-term storage and inventory meeting the requirements above will be developed and executed.

Release of materials:

SNS pharmaceuticals are to be used solely for treatment of individuals with H1N1 infection or significant exposure to same. Any other use of SNS drug supplies is illegal and unauthorized under US federal law. Release of drugs from storage requires an appropriate signed

authorization by a pharmacist or designated GCHD public health nurse or physician legally able to take possession of prescription drugs. All entities other than GCHD to which release of materials is made must have signed one of the “Memorandum of Understanding Concerning Use of SNS Materials” listed in the appendices.

With appropriate documentation, SNS pharmaceuticals may be released to the following agencies for subsequent dispensing to end users: GCHD, Retail Pharmacies, and Hospitals.

Retail pharmacies may receive an initial allotment of up to thirty (30) courses of treatment with oseltamivir and 6 courses of zanamivir upon request to the GCHD, accompanied by a properly signed and countersigned MOU. GCHD will authorize the designated pharmacist to release the first allotment to the requesting pharmacy.

A retail pharmacy may request and receive subsequent allotments by submitting inventory records to GCHD indicating that supplies of oseltamivir are down to five (5) courses on premises and zanamivir to one course on premises.

Subsequent allotments will continue to be in these same quantities unless otherwise adjusted by the Grant County Health Officer or designee.

- Ephrata, Moses Lake and Quincy pharmacies supply requests will be filled from the Moses Lake site pharmacist only.
- Remaining pharmacy requests supplies will be filled via the north or south designated site based on the requestor’s location (north of I-90 or south of I-90).

Those inventory records and all receipts will be filed by date, by pharmacy, reconciled at intervals with inventories by the designated pharmacist, and kept by GCHD for no less than two years.

Hospitals do not possess, have custody of nor jurisdictional authority over SNS materials that may be stored on their premises. SNS materials must be properly released to the hospital from the designated pharmacy according to the process outlined above (requested through GCHD, then GCHD authorizes release by the designated pharmacy), before they can be dispensed. The designated pharmacist is designated to act for GCHD in releasing SNS pharmaceuticals to the hospital pharmacy.

It is recognized that in some instances the designated pharmacists will also be acting to receive the pharmaceuticals for the hospital. The following requirements apply to this type of release:

- All releases will be in reasonable quantities to cover current inventory needs to treat hospital inpatients and outpatients.
- All transfers from the SNS supply to hospital pharmacy supplies must be documented by written receipt and hospital inventory records.
- Those inventory records and all receipts will be filed by date, by pharmacy, reconciled from time to time with inventories by the designated pharmacist, and kept by GCHD for no less than two years.

Transportation and Physical Transfers:

Transportation of SNS materials is the responsibility of receiving entities, agencies, organizations, pharmacies and departments.

Inventory “Set-Asides”:

Government first responders: 60 treatment courses of oseltamivir are set aside from the total adult supply at Moses Lake SNS site, 30 treatment courses are set aside at both south and north SNS site for the treatment of first responders (EMS and Public Safety). These may be released only on order of the Grant County Health Officer or designee. The set asides will be reflected in the inventory records.

Health Care Workers: 120 treatment courses of oseltamivir are set aside from the total adult supply at the central SNS site and 30 treatment courses are set aside at the north county SNS storage site and 15 at the south county SNS storage site for the treatment of health care workers with direct patient contact. These may be released only on order of the Grant County Health Officer or designee. The set asides will be reflected in the inventory records.

The intent of set asides is to ensure treatment course availability for individuals who are at high risk of exposure to H1N1 influenza (swine variant) exposure in the line of duty. A secondary reason is to shorten the illness duration of critical personnel to expedite their return to work. Set asides are intended to be physically separated from the main store of SNS pharmaceuticals. They are not to be distributed until all other sources of oseltamivir in Grant County, public or private have been exhausted; and may only be used under direct written order of the Grant County Health Officer or designated Acting Grant County Health Officer.

Security:

Security of designated pharmacies is considered in general to be adequate to store SNS materials. In special circumstance of high security concerns the GCHD personnel or pharmacy personnel will notify and consult local law enforcement to secure storage or transport.

Designated Pharmacists:

The Grant County Health Officer designates specifically identified pharmacists / pharmacies.

SIGNATURES

Peggy, Grigg, RN, BSN
Administrator, Grant County Health District

Date

Alexander Brzezny, MD, MPH
Grant County Health Officer

Date

APPENDIX 1

Memorandum of Understanding concerning Storage, Use, and Management of Strategic National Stockpile Materials between _____ (Designated Pharmacy) and Grant County Health District (GCHD)

Dated: _____

_____ Pharmacy and GCHD understand that the SNS supplies released in the H1N1 influenza A emergency are subject to the following:

- The release is for the public good during a time of national emergency. Both the hospital and GCHD enter this agreement to promote the public's health and well being.
- GCHD holds custody of and sole authority over all SNS supplies in Grant County.
- The designated pharmacy agrees to store SNS pharmaceuticals in its pharmacy which complies with all requirements of law concerning hospital pharmacies and storage of prescription drugs in Washington State.
- The storage of SNS pharmaceuticals by the designated pharmacy will continue for the duration of the national emergency and for a reasonable time thereafter if inventory remains after the emergency ends.
- GCHD will expeditiously arrange for permanent storage of remaining inventory after the emergency ends.
- In addition to storage, the designated pharmacy will assign a pharmacist time and responsibility to act on behalf of GCHD as delineated in the *Grant County Strategic National Stockpile Plan for H1N1 Influenza A Drugs May 2009*.

Pharmaceuticals released from the SNS storage supply to the designated pharmacy will be:

- Discernibly separate from the SNS supply in the pharmacy.
- Released to the designated pharmacy at no cost.
- Released to the designated pharmacy in accordance with the *Grant County Strategic National Stockpile Plan for H1N1 Influenza A Drugs May 2009*.
- Maintained and used in accordance with Washington State law.
- Inventoried in such a fashion as to provide permanent inventory and utilization records back to GCHD.
- Appropriately prescribed, ordered and administered to the patients consistent with treatment guidelines for H1N1 Influenza A as provided by GCHD under the authority of the Grant County Health Officer.
- Provided to patients at no cost other than a small administration and handling fee as allowed under Washington State regulations and laws.
- Returned to GCHD on request of the Grant County Health Officer and at the end of the emergency.
- Prescribed and administered only for treatment of H1N1 influenza A documentable by medical record entries that confirm that that restriction has been complied with.

Signatures:

Designated Pharmacy Representative

Date

Grant County Health District

Date

APPENDIX 2

Memorandum of Understanding concerning Strategic National Stockpile (SNS) Pharmaceuticals between _____ Pharmacy and Grant County Health District (GCHD)

Dated: _____

_____ Pharmacy (the pharmacy) and Grant County Health District (GCHD) understand that the SNS supplies released in the H1N1 influenza A emergency are subject to the following:

- The release is for the public good during a time of national emergency. Both the pharmacy and GCHD enter this agreement to promote the public's health and well being.
- GCHD holds custody of and sole authority over all SNS supplies in Grant County.

Pharmaceuticals released from the SNS storage supply to the pharmacy will be:

- Discernibly separate from any commercial pharmaceutical supplies in the pharmacy.
- Released to the pharmacy at no cost.
- Released to the pharmacy from the storage supply initially upon presentation of a signed and countersigned copy of this document
- Released in by procedures and in amounts delineated in the *Grant County Strategic National Stockpile Plan for H1N1 Influenza A Drugs May 2009*.
- Released subsequently by presentation of inventory and dispensing records as delineated in *Grant County Strategic National Stockpile Plan for H1N1 Influenza A Drugs May 2009*.
- Transported from storage sites at the pharmacy's expense by pharmacy personnel legally able to take receipt of prescription drugs under Washington State law.
- Inventoried in such a fashion as to provide permanent inventory and utilization records back to GCHD.
- Dispensed in accordance with Washington State Law for a legal prescription.
- Provided to patients at no cost other than a small administration and handling fee as allowed under Washington State regulations and laws.
- Returned to PCHHS on request of the Grant County Health Officer and at the end of the emergency.
- Dispensed only for treatment of H1N1 influenza documented by a prescription that confirms that federal restrictions have been complied with:
 - The prescription must state some variation of "for treatment..."
 - The prescription must state some variation of "...of H1N1" or "...of swine..."
 - The prescription *must* be filled within 48 hours (or two days) of the time that it was written.

It is understood that this agreement applies only to oseltamivir or zanamivir released from SNS supplies and does not apply to commercially obtained generic or brand name oseltamivir or zanamivir.

Signatures:

Designated Pharmacy Representative

Date

Grant County Health District

Date

APPENDIX 3

TREATMENT GUIDELINES

Interim Guidelines for Antiviral Drug Use for Influenza Infection Grant County Health District, 4 May 2009

These recommendations may be subject to change based on availability of medications, severity of disease and other important factors, including Washington Public Health Response Assessment Team (PHRAT) recommendations.

Treatment

Influenza should be considered in persons with acute febrile respiratory illness with cough or sore throat. **Treatment of hospitalized patients and outpatients at high risk for influenza complications should be prioritized.** Mild uncomplicated illness should not be treated.

Persons at high risk of complications from influenza who should be considered for antiviral therapy:

- Infants and children aged <5 years
- Persons with asthma or other chronic pulmonary diseases, such as cystic fibrosis in children or chronic obstructive pulmonary disease in adults
- Persons with hemodynamically significant cardiac disease
- Persons who have immunosuppressive disorders or are receiving immunosuppressive therapy
- HIV-infected persons
- Pregnant woman
- Persons with sickle cell anemia and other hemoglobinopathies
- Persons with diseases that require long-term aspirin therapy, such as rheumatoid arthritis or Kawasaki disease
- Persons with chronic renal dysfunction
- Persons with cancer
- Persons with chronic metabolic disease, such as diabetes mellitus
- Persons with neuromuscular disorders, seizure disorders, or cognitive dysfunction that may compromise the handling of respiratory secretions
- Adults aged >65 years
- Residents of any age of nursing homes or other long-term care institutions

Antiviral treatment should be initiated as soon as possible after the onset of symptoms. Evidence for benefits from treatment in studies of seasonal influenza is strongest when treatment is started within 48 hours of illness onset. However, some studies of treatment of seasonal influenza have indicated benefit, including reductions in mortality or duration of hospitalization even for patients whose treatment was started more than 48 hours after illness onset. Therefore, treatment for high-risk patients who are seen >48 hours after illness onset and are not improving is permitted.

Chemoprophylaxis

Routine prophylaxis with oseltamivir or zanamavir should be limited at this time to the following individuals who have contact with a confirmed or probable case:

1. Household close contacts of a confirmed or probable case who are at high-risk for complications of influenza (e.g., persons with certain chronic medical conditions, persons 65 or older, children younger than 5 years old, and pregnant women).
2. Health care workers who were not using appropriate personal protective equipment during close contact with an ill confirmed, probable, or suspect case of swine-origin influenza A (H1N1) virus infection during the case's infectious period.

Information from CDC on treatment of children under 1 year of age

Oseltamivir use for children < 1 year old was recently approved by the U.S. FDA under an Emergency Use Authorization (EUA), and dosing for these children is age-based. For dosing guidelines for children less than one year, please see: <http://www.cdc.gov/h1n1flu/childrentreatment.htm>

Children under one year of age are at high risk for complications from seasonal human influenza virus infections. The characteristics of human infections with swine-origin H1N1 viruses are still being studied, and it is not known whether infants are at higher risk for complications associated with swine-origin H1N1 infection compared to older children and adults. Limited safety data on the use of oseltamivir (or zanamivir) is available from children less than one year of age, and oseltamivir is not licensed for use in children less than 1 year of age. Available data come from use of oseltamivir for treatment of seasonal influenza. These data suggest that severe adverse events are rare, and the Infectious Diseases Society of America recently noted, with regard to use of oseltamivir in children younger than 1 year old with seasonal influenza, that "...limited retrospective data on the safety and efficacy of oseltamivir in this young age group have not demonstrated age-specific drug-attributable toxicities to date." (See IDSA guidelines for seasonal influenza.)

Because infants typically have high rates of morbidity and mortality from influenza, infants with swine-origin influenza A (H1N1) infections may benefit from treatment using oseltamivir.

Information from CDC on treatment of pregnant women

Oseltamivir and zanamivir are "Pregnancy Category C" medications, indicating that no clinical studies have been conducted to assess the safety of these medications for pregnant women. Because of the unknown effects of influenza antiviral drugs on pregnant women and their fetuses, oseltamivir or zanamivir should be used during pregnancy only if the potential benefit justifies the potential risk to the embryo or fetus; the manufacturers' package inserts should be consulted. However, no adverse effects have been reported among women who received oseltamivir or zanamivir during pregnancy or among infants born to women who have received oseltamivir or zanamivir. Pregnancy should not be considered a contraindication to oseltamivir or zanamivir use. Because of its systemic activity, oseltamivir is preferred for treatment of pregnant women. The drug of choice for prophylaxis is less clear. Zanamivir may be preferable because of its limited systemic absorption; however, respiratory complications that may be associated with zanamivir because of its inhaled route of administration need to be considered, especially in women at risk for respiratory problems.

For more information about antiviral drugs including dosing guidelines and please see the CDC antiviral web page <http://www.cdc.gov/h1n1flu/recommendations.htm> and the Infectious Diseases Society of America guidelines for seasonal influenza: <http://www.journals.uchicago.edu/doi/pdf/10.1086/598513>
Dosing guidelines for antiviral drugs (consult the manufacturer's package insert for complete information)

Agent, Group	Treatment (5 days)	Prophylaxis (10 days)
Oseltamivir		
Adults	75 mg PO bid	75 mg PO qday
Children	15 kg or less 15-23 kg 24-40 kg > 40 kg	30 mg PO qday 45 mg PO qday 60 mg PO qday 75 mg PO qday
Zanamivir		
Adults	Two 5mg inhalations (10mg) bid	Two 5mg inhalations qday
Children	Two 5mg inhalations (10mg) bid (age ≥ 7 years)	Two 5mg inhalations qday (age ≥ 5 years)

APPENDIX 4

**TREATMENT GUIDELINES (PENDING FINAL WASHINGTON PHRAT-
Public Health Response Assessment Team - RECOMMENDATIONS)**

SAMPLE PRESCRIPTION FORMAT

Name: _____

Address: _____

Date: _____

Rx: oseltamivir 75 mg
 disp: #10
 sig: One twice daily for five days to treat
 H1N1 influenza A (swine flu)

This prescription is not valid after two days

Signed By: _____

Copy to file