Antiviral Drug Guidance for Influenza A (2009-H1N1)

For Department of Energy (DOE) Site Medical Directors and the Site Contractor Workforce

September 2009

The following information is intended for DOE site medical directors and the contractor employees who will be serviced by the site medical directors. Separate guidance will be issued for Federal employees at Headquarters and at the site offices. Below is background information and guidance on antiviral drugs (prescription medicines) in the event of an influenza pandemic. Additional information can be found at the U.S. Department of Health and Human Service (HHS) website: **www.pandemicflu.gov/vaccine/antiviral_use.html**

Department of Health and Human Services recommendations

So far, most people who have contracted the new A 2009 H1N1 influenza virus have experienced influenza-like symptoms (such as sore throat, cough, runny nose, fever, malaise, headache, joint/muscle pain) and recovered without antiviral treatment. However, as of August 6, 2009, there have been 6,506 hospitalizations and 436 deaths in the United States reported to the Centers for Disease Control and Prevention that were attributed to the H1N1 virus. Antiviral drugs may reduce the symptoms and duration of illness, just as they do for seasonal influenza. They also may prevent transmission of infection and severe disease to those exposed to infected individuals.

There are two classes of antiviral drugs for influenza: inhibitors of neuraminidase, such as oseltamivir (Tamiflu®) and zanamivir (Relenza®); and adamantanes, such as amantadine and rimantadine. Tests on viruses obtained from patients in Mexico and the United States have indicated that current new H1N1 viruses are sensitive to neuraminidase inhibitors, but that the viruses are resistant to the other class, the adamantanes. Stockpiling amantadine and rimantadine has not been recommended because resistance to these agents among circulating Influenza A viruses is frequent, and among susceptible viruses, develops rapidly when they are used to treat influenza A virus infections. The World Health Organization and its partners are monitoring antiviral drug resistance to Tamiflu® based on three recently reported resistant isolates.

The guidance on antiviral use is based on the National pandemic response goals of slowing the spread of pandemic disease, reducing impacts on health, and minimizing societal and economic disruption. The Federal Government strongly encourages all

public and private sector employers, regardless of size, to plan for a pandemic, to protect the health of employees, and to assure continuity of operations.

Where antiviral drugs are available for treatment, clinicians should make decisions based on assessment of the potential benefits and risks from treatment. Antiviral treatment may reduce the duration of illness, complications, hospitalizations, death, and transmission of infection to others. The effectiveness of treatment is likely to be greatest when started shortly after the onset of symptoms, within 48 hours of illness onset, although a recent study of persons treated at hospital admission suggested that later treatment still may be effective in reducing mortality. Persons who are immunocompromised or immunosuppressed may also benefit from later treatment.

The Food and Drug Administration reported that "there have been post-marketing 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 Tamiflu®. Because these events were reported voluntarily during clinical practice, estimates of frequency cannot be made but they appear to be uncommon based on Tamiflu® usage data. These events were reported primarily among pediatric patients and often had an abrupt onset and rapid resolution. The contribution of Tamiflu® to these events has not been established. Patients with influenza should be closely monitored for signs of abnormal behavior. If neuropsychiatric symptoms occur, the risks and benefits of continuing treatment should be evaluated for each patient."

Workers in occupational settings with direct exposures to pandemic influenza patients and front-line emergency services (e.g. fire and emergency medical services personnel) will be at increased risk of acquiring infection. Prophylaxis for these individuals will reduce absenteeism due to illness and absenteeism due to fear of becoming infected while at work. Stockpiles by employers in the public and private sectors, in coordination with public health stockpiles, would extend protection more broadly than could be achieved through the public sector alone and improve the ability to achieve the National pandemic response goals of mitigating disease, suffering, and death, and minimizing impacts on the economy and functioning of society.

Antiviral drugs are being stockpiled by HHS as part of the Strategic National Stockpile, and by States. The current public sector stockpile target is 81 million drug regimens: 6 million regimens for containment and for slowing the entry of pandemic disease into the United States and 75 million regimens for treatment. HHS encourages governments, healthcare organizations, other employers, families, and individuals as appropriate, to purchase and stockpile sufficient antiviral drug supplies to support recommended antiviral drug use strategies.

Guidance for DOE sites

DOE site management, in conjunction with the Site Occupational Medical Director (SOMD), may elect to stockpile antiviral medications for their essential contractor employees. The terms of each contract will determine whether the cost of these

medications is an allowable expense under the contract. If a site has determined that it will dispense antivirals, specific site procedures should be developed for storing and dispensing antiviral medications. Individuals assigned Human Reliability Program (HRP) duties must report their illness or condition and the use of antiviral medications to the designated physician, the SOMD, or the HRP management official. *See* 10 C.F.R. § 712.12(h). The BEMT recommends that each site include this direction under the section for Pandemic Planning of their Continuity of Operations Plan (COOP).

Consideration should be given to the procurement and stockpiling of antiviral medications for sites designated as supporting DOE's Mission Essential Functions (MEFs) as defined by DOE Order 150.1, *Continuity Programs*. MEFs are defined as "the limited set of Department and Agency-level government functions that must be continued after a disruption of normal activities. MEFs provide vital services, exercise civil authority, maintain the safety of the general public, and sustain the industrial/economic base during disruption of normal operations." The Contractor Requirements Document (CRD) attached to this Order states that the contractor program must identify contractor/site-performed essential functions/activities that support departmental MEFs, as identified by the field element, and provide for planning to ensure the capability exists for performance of identified essential functions/activities. This should be enumerated in the section on Pandemic Planning in their COOP plan. Identifying MEFs and the employees who will perform them is the first step before informing these employees that they may be expected to continue operations in the event of a pandemic, as well as preparing them for the risks of performing such functions on-site.

For questions about this guidance, contact Bonnie S. Richter, M.P.H., Ph.D. by email at bonnie.richter@hq.doe.gov or by phone at 301 903-4501 or Michael Ardaiz, M.D., C.P.H., M.P.H. at Michael.ardaiz@hq.doe.gov or by phone at 301 903- 9910. Additional pandemic guidance and information regarding pandemic influenza planning can be found on http://www.hss.energy.gov/HealthSafety/pandemic.html