

ISDH Long Term Care
Newsletter Issue # 09-33
November 6, 2009

In Today's Issue:
- H1N1 Update

H1N1 Update

Current Status

The past two months has seen a significant number of H1N1 influenza cases in Indiana. Emergency departments have reported a large number of cases and schools have reported a high number of absences. There have been some reports that the number of cases have decreased slightly over the past couple of weeks but H1N1 influenza activity is expected to continue in coming months.

States began receiving the injectable H1N1 vaccine in mid-October. Vaccine is being directed to local health departments for distribution. In most cases, local health departments are setting up clinics to administer the vaccine according to priorities established by the Centers for Disease Control and Prevention. There has been high demand for the vaccine with local health departments experiencing long lines at clinics.

While the initial deliveries of vaccine in October were rather small, the number of doses being received has now increased significantly. The ISDH expects a continued increase in vaccine availability throughout November and December.

H1N1 Vaccinations for Nursing Home Staff

Initial vaccination clinics have tended to focus on children and high risk individuals. Health care workers are a priority group for vaccination and, with increased availability of vaccine, local health departments have been making vaccine available for that group. The ISDH encourages health care workers to be vaccinated against the H1N1 virus.

The ISDH became aware of a situation that occurred at one clinic this week. A local health department held a vaccination clinic specifically for employees of nursing homes. Nursing homes had faxed names of employees to the local health department who were going to come to the clinic. Over 700 nursing home employees were expected to go to the clinic to receive the vaccination. Only 87 employees came to be vaccinated.

The vaccine is in very short supply and there is a large demand. The vaccine is being distributed by local Health Departments according to priorities. Health care providers may only get one opportunity to receive the vaccine. If a clinic is set up for health care workers and they do not show up, the vaccine will go to the next priority group. In that case health care workers will likely not have another opportunity until it becomes generally available to the public.

The State Department of Health has received several complaints from facilities about the lack of vaccine

for their workers. If these local clinics are not attended when scheduled, other local health departments may not schedule clinics for their health care workers. It is important that if a clinic is scheduled for workers in your county that you make a concerted effort to ensure that your staff attends the clinic.

It is important to contact your local Health Department for information on when and where vaccine may be available.

Skilled Nursing Facilities/Long-Term Care Open Door Forum

Updated November 4, 2009 - Information Discussion from the U.S. Department of Health & Human Services on H1N1 will be held on Tuesday, November 10, 2009 from 2pm-3pm ET.

The purpose of this third H1N1 call is to discuss the Secretary of Health and Human Services invoking her waiver authority under Section 1135 of the Social Security Act. Requests by providers to operate under the flexibilities afforded by the waiver should be sent to the CMS regional office. We will be taking live questions during this call. However, if you would like to submit a question prior to the call, please send your question to: Pandemic@cms.hhs.gov. Put "November 10, 2009 Call" in the subject line. We will have subject matter experts on hand to answer questions, and having your questions in advance ensure that we will have the right people available to respond.

All callers please dial: 1-800-837-1935 and use Conference ID 3H1N1. Dial in at least 20minutes prior to start of the call. The link to the SNF/Open Door site for the downloads:

http://www.cms.hhs.gov/OpenDoorForums/25_ODF_SNFLTC.asp.

Opening Remarks: Co-Chairs – Dr. Sally Phillips, Office of the Assistant Secretary for Preparedness and Response and Jean Sheil, CMS Pandemic Coordinator; Moderator – Susie Butler, CMS Office of External Affairs.

Helpful websites:

- www.flu.gov;
- www.cdc.gov/H1N1flu;
- <http://www.cms.hhs.gov/H1N1/Downloads/RequestingAWaiver101.pdf> --Information outlining the 1135 Waiver process;
- <http://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm100228.htm> -- information on antivirals;
- <http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM6539.pdf> -- CMS billing information;
- http://www.cms.hhs.gov/Emergency/Downloads/Medicare_FFS_Emergency_Qs_As_082609.pdf -- Information for Medicare Fee-for-Service Providers.

Emergency Declaration and Section 1135 Waiver Authorization

Section 1135 of the Social Security Act [42 USC §1320b–5] permits the Secretary of the U.S. Department of Health and Human Services (HHS) to waive certain statutory and regulatory requirements for healthcare facilities in response to emergencies. However, two conditions must first be met for the Secretary to issue a section 1135 waiver: 1) the President must have declared an emergency or disaster under the Stafford Act or the National Emergencies Act, 2) the HHS Secretary must have declared a Public Health Emergency (PHE) under section 319 of the Public Health Service Act.

On October 23, 2009, President Obama signed a nationwide emergency declaration as a result of the 2009-H1N1 influenza pandemic, pursuant to the National Emergencies Act. On April 26, 2009, Acting Secretary Charles Johnson declared a public health emergency in response to the H1N1 virus, and Secretary Sebelius renewed that declaration on July 24, 2009, and again on October 1, 2009.

On October 27, 2009, Secretary Sebelius notified Congress of her intention to invoke the 1135 waiver authority effective 5:00 P.M. Eastern Standard Time on October 29, 2009, however, the effect will be retroactive to October 23, 2009. For this event, the "emergency area" is nationwide. The emergency period begins on October 23, 2009, and will last through the duration of the declared public health emergency for the 2009-H1N1 influenza pandemic.

The waiver invokes time-limited statutory authority under section 1135(b) of the Social Security Act (the Act) to permit CMS and its agents to waive or modify certain requirements, or modify certain deadlines and timetables for the performance of required activities. The normal requirements provide important protections for patients during normal day-to-day operations, but they may impede the ability of healthcare facilities to fully implement disaster operations plans that enable appropriate care during emergencies.

The time-limited statutory authority under section 1135(b) of the Act may be tailored to match the specific situational needs during each public health emergency event. This waiver provides flexibility to the extent necessary to ensure that sufficient health care items and services are available to meet the needs of the individuals enrolled in the Medicare, Medicaid, and Children's Health Insurance Program (CHIP), and to ensure that health care providers furnishing such items and services in good faith, but that are unable to comply with one or more of the usual requirements, may be reimbursed and exempted from sanctions that might otherwise apply, absent any determination of fraud or abuse.

As the 2009-H1N1 influenza emergency declaration is nationwide, the "emergency area" applies to all 50 States and U.S. territories. However, the waivers and modifications apply only to the extent that the provider in question has been affected by the H1N1 influenza (e.g., surge issues, staffing shortages, etc.). The Secretary has delegated to the CMS Administrator the determination in each case of the necessity for a waiver and the extent to which sufficient grounds exist for waiving such requirements with respect to a particular provider, or to a group or class of providers, or to a geographic area (other than for the Health Insurance Portability and Accountability Act [HIPAA] waivers permitted under section 1135).

Health care providers and suppliers should submit their requests to operate under the section 1135 waiver authority, or for other relief that may be possible, to the CMS Regional Office in their service area by email, and provide a copy of the request to their State Survey Agency (SA). Providers and suppliers will be required to submit justification for the necessity of the waiver. Federally certified/approved providers and suppliers must operate under normal rules and regulations unless they have sought and have been granted modifications under the 1135 waiver authority from specific requirements. The CMS Consortium email address for Indiana providers is: ROCHISC@cms.hhs.gov [(Midwest Consortium): Illinois, Indiana, Michigan, Minnesota, Ohio, Wisconsin, Iowa, Kansas, Missouri, Nebraska].

CMS will review and validate the 1135 waiver requests utilizing a cross-regional Waiver Validation Team. The cross-regional Waiver Validation Team will review the waiver requests, in consultation with the survey agencies, to ensure they are justified and supportable. Information to support the request should be clear and concise to ensure the Waiver Validation Team can quickly and efficiently validate the request. The waivers and modifications permitted under the section 1135 authority do not include waivers or modifications that are not actually needed at this time of a provider's request, but rather are anticipated for a later date.

CMS has released [Survey and Certification Letter 10-06-ALL](#) discussing the 1135 Waiver Authorization. The letter includes updated questions and answers.

Key Issues for Clinicians Concerning Antiviral Treatments for 2009 H1N1

CDC Health Advisory
November 6, 2009, 1:51 PM EST

Situation:

Although use of influenza antiviral drugs in the United States has increased during the 2009-2010 flu season, not all people recommended for antiviral treatment are getting treated. Listed below are important facts to consider when deciding whether a patient needs to be treated with antiviral medication.

It is critical to remember that it is not too late to treat, even if symptoms began more than 48 hours ago. Although antiviral treatment is most effective when begun within 48 hours of influenza illness onset, studies have shown that hospitalized patients still benefit when treatment with oseltamivir is started more than 48 hours after illness onset. Outpatients, particularly those with risk factors for severe illness who

are not improving, might also benefit from treatment initiated more than 48 hours after illness onset.

Recommendations for Clinicians:

Many 2009 H1N1 patients can benefit from antiviral treatment, and all hospitalized patients with suspected or confirmed 2009 H1N1 should receive antiviral treatment with a neuraminidase inhibitor -- either oseltamavir or zanamavir -- as early as possible after illness onset. Moderately ill patients, especially those with risk factors for severe illness, and those who appear to be getting worse, can also benefit from treatment with neuraminidase inhibitors. A full listing of risk factors for severe influenza is available at: <http://www.cdc.gov/h1n1flu/highrisk.htm>.

Although antiviral medications are recommended for treatment of 2009 H1N1 in patients with risk factors for severe disease, some people without risk factors may also benefit from antivirals. To date, 40% of children and 20% of adults hospitalized with complications of 2009 H1N1 did not have risk factors. Clinical judgment is always an essential part of treatment decisions.

When treatment of persons with suspected 2009 H1N1 influenza is indicated, it should be started empirically. If a decision is made to test for influenza, treatment should not be delayed while waiting for laboratory confirmation. The earlier antiviral treatment is given, the more effective it is for the patient. Also, rapid influenza tests often can give false negative results. If you suspect flu and feel antiviral treatment is warranted, treat even if the results of a rapid test are negative. Obtaining more accurate testing results can take more than one day, so treatment should not be delayed while waiting for these test results. For more information on influenza testing, please see: http://www.cdc.gov/h1n1flu/guidance/diagnostic_tests.htm.

Although commercially produced pediatric oseltamivir suspension is in short supply, there are ample supplies of children's oseltamivir capsules, which can be mixed with syrup at home. In addition, pharmacies can compound adult oseltamivir capsules into a suspension for treatment of ill infants and children. Additional information on compounding can be found at: <http://www.cdc.gov/H1N1flu/pharmacist/>.

For More Information

Updated Interim Recommendations for the Use of Antiviral Medications in the Treatment and Prevention of Influenza for the 2009-2010 Season: <http://www.cdc.gov/H1N1flu/recommendations.htm>

Questions & Answers:

Antiviral Drugs, 2009-2010 Flu Season: <http://www.cdc.gov/h1n1flu/antiviral.htm>

Influenza Diagnostic Testing: http://www.cdc.gov/h1n1flu/diagnostic_testing_clinicians_qa.htm

Updated Interim Recommendations for Obstetric Health Care Providers Related to Use of Antiviral Medications in the Treatment and Prevention of Influenza for the 2009-2010 Season: http://www.cdc.gov/H1N1flu/pregnancy/antiviral_messages.htm

Antiviral Drugs: Summary of Side Effects: <http://www.cdc.gov/flu/protect/antiviral/sideeffects.htm>

General information for the public on antiviral drugs is available in '2009 H1N1 and Seasonal Flu: What You Should Know About Flu Antiviral Drugs' at <http://www.cdc.gov/H1N1flu/antivirals/geninfo.htm> .

Downloadable brochures and informational flyers, including one on antiviral drugs, are available at <http://www.cdc.gov/h1n1flu/flyers.htm> .

For the FDA page on antiviral influenza drugs:

<http://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm100228.htm>

For additional information, you can also call CDC's toll-free hotline, 800-CDC-INFO (800-232-4636) TTY: (888) 232-6348, which is available 24 hours a day, every day.



That is all for today. Have a nice weekend.

Terry Whitson
Assistant Commissioner
Indiana State Department of Health

Toll-free H1N1 Flu Hotline: 1-877-826-0011

Flu Season is here. Here's what you can do:

- 1 CLEAN** your hands thoroughly and frequently.
- 2 COVER** your cough and sneeze.
- 3 CONTAIN** your germs by staying home if sick.