

MEMORANDUM

TO: State Executives
AHCA/NCAL Leadership and Members

FROM: Janice Zalen, Sr. Director of Special Programs

SUBJECT: **H1N1 and Seasonal Influenza Update No. 27**

DATE: November 25, 2009

H1N1-Related 1135 Waivers

On October 23, President Obama declared that the 2009 H1N1 influenza pandemic constitutes a national emergency. This declaration allows the Secretary of Health & Human Services (HHS) to issue waivers under Section 1135 of the Social Security Act.

Unlike previous 1135 waivers that were limited to a few specific states, this emergency is proclaimed nationwide, but 1135 waivers are not actually needed nationwide. Hence, CMS is not relaxing regulations across the country, but instead developed a process to request an 1135 waiver for providers who need regulatory relief due to H1N1 influenza. According to CMS, by design, the waiver process is somewhat vague. There are no forms or checklists as each instance is anticipated to be case specific.

To request an 1135 waiver, a health care provider would submit an email that describes the facility and justification for requesting the waiver to the appropriate CMS regional office. CMS reviews and validates the 1135 waiver requests utilizing a cross-regional waiver validation team. As of November 10, CMS had granted 5 waivers (none to long term care). For more information including the email addresses of the regional offices, please go to <http://www.cms.hhs.gov/H1N1/Downloads/RequestingAWaiver101.pdf>. For additional information on 1135 waivers and other H1N1 issues, access the CMS H1N1 site at <http://www.cms.hhs.gov/H1N1/>.

Vaccine Declination Forms for Health Care Workers

The Immunization Action Coalition recently developed a one-page form, "Declination of H1N1 Influenza Vaccination" for use in health care settings for employees who decline vaccination. The form states reasons for vaccinating health care workers against H1N1 influenza and provides space for the employee's

signature if the employee declines vaccination, allowing the employer to document employee refusal.

To access "Declination of H1N1 Influenza Vaccination," go to: <http://www.immunize.org/catg.d/p4071.pdf>. To access the declination form for seasonal influenza vaccination, go to: <http://www.immunize.org/catg.d/p4068.pdf>.

Antiviral Medication

According to the CDC, it is not too late to begin antiviral treatment after 48 hours of the onset of flu symptoms. While antiviral treatment is most effective when begun within 48 hours of influenza illness onset, studies have shown that hospitalized patients still benefit when treatment is started with oseltamivir more than 48 hours after illness onset.

Because the government is concerned about the potential of a shortage of antiviral medication for adults, the Food and Drug Administration (FDA) issued Emergency Use Authorizations (EUA) that allow certain specific lots of Tamiflu capsules to be used beyond their expiration dates. It is important to understand that the EUA is very limited and facilities should not, at this time, purchase expired Tamiflu unless they are absolutely certain that it falls under the authorization. For additional information and a listing of the lot numbers that fall under the EUA, please access the FDA web site at www.fda.gov/newsevents/publichealthfocus/ucm154962.htm.

According to CDC recommendations, LTC facility residents are a priority for antiviral medication. To access the CDC recommendations and for additional information on antiviral medications to combat influenza, please see CDC's web site at <http://www.cdc.gov/h1n1flu/antiviral.htm>.

Importance of Pneumococcal Vaccine Stressed by CDC

CDC urges health care providers to make sure that patients with indications have received, or are provided, pneumococcal vaccine. The CDC notes that during the influenza pandemics of the 20th century, secondary bacterial pneumonia was a frequent cause of illness and death. With the current 2009 H1N1 influenza pandemic, and as with seasonal influenza, pneumococcal infections are once again being found among fatal cases in both children and adults.

To read the full text of the CDC letter to healthcare providers, go to: <http://www.cdc.gov/h1n1flu/vaccination/provider/lettertoprovider.htm>.