DEPARTMENT OF HEALTH & HUMAN SERVICES Centers for Medicare & Medicaid Services 7500 Security Boulevard, Mail Stop S2-12-25 Baltimore, Maryland 21244-1850



Center for Medicaid and State Operations/Survey and Certification Group

Ref: S&C-09-33

REVISED 4-28-2009

DATE: April 28, 2009

TO: State Survey Agency Directors

FROM: Director

Survey and Certification Group

SUBJECT: Survey and Certification Issues Related to Swine Flu Outbreak

****Memo revised to clarify 1135 Waiver Status****

Memorandum Summary

- <u>Situation</u>: Human cases of swine influenza A (H1N1) virus infection have been identified in several States in the United States, as well as internationally.
- <u>Emergency Declaration</u>: Charles Johnson, the Acting Secretary of the U.S. Department of Health and Human Services, as a consequence of confirmed cases of swine influenza A (swH1N1) in California, Texas, Kansas, and New York, declared that a public health emergency exists nationwide.
- <u>Authority</u>: In emergencies where certain conditions precedent have been met, the Secretary of the Department of Health and Human Services may invoke his or her waiver authority under Section 1135 of the Social Security Act and delegate to CMS the authority to waive or modify certain survey and certification requirements. At this time the Secretary has not invoked the 1135 authority. For this reason, we are reissuing this memo to clarify the statement of authority.

Human cases of swine influenza A (H1N1) virus infection have been identified in the United States as well as internationally. As of this date, there have been 40 confirmed cases of swine influenza A (swH1N1) in California, Texas, Kansas, New York, and Ohio. No deaths in the U.S. have been reported due to the illness. Additional cases of the virus have been confirmed in Mexico and Canada.

Swine flu is a respiratory disease of pigs caused by type A influenza that regularly causes outbreaks of influenza among pigs. Swine flu viruses do not normally infect humans; however, human infections with swine flu do occur, and cases of human-to-human spread of swine flu viruses have been documented.

The Acting Secretary of the U.S. Department of Health and Human Services (HHS) issued a nationwide public health emergency declaration in response to recent human infections with a newly discovered swine influenza A (swine flu) virus. The declaration, made under section 319 of the Public Health Service Act, will help HHS prepare for prevention and mitigation activities by enabling Food and Drug Administration (FDA) emergency use authorizations of drugs, devices, or medical tests under certain circumstances.

The Centers for Disease Control and Prevention (CDC) is working very closely with officials in States where human cases of swine influenza A (H1N1) have been identified, as well as with health officials in Mexico, Canada and the World Health Organization. This includes deploying staff domestically and internationally to provide guidance and technical support.

For more guidance on swine flu precautions, please see the following websites:

CDC Websites

- CDC Swine Flu Main Page: http://www.cdc.gov/swineflu/
- Interim Recommendations for Facemask and Respirator Use in Certain Community Settings Where Swine Influenza A (H1N1) Virus Transmission Has Been Detected: http://www.cdc.gov/swineflu/masks.htm
- Interim Guidance on Case Definitions to be Used For Investigations of Swine Influenza A (H1N1) Cases: http://www.cdc.gov/swineflu/casedef_swineflu.htm
- Risk of Swine Flu Associated with Travel to Affected Areas: http://wwwn.cdc.gov/travel/contentSwineFluTravel.aspx
- Checklist for long term care facilities: http://pandemicflu.gov/plan/pdf/longtermcare.pdf

HHS Websites:

- U.S. Department of Health and Human Services: http://www.hhs.gov/
- HHS Public Health Emergency declaration: www.hhs.gov/secretary/phe_swh1n1.html
- Pandemic Flu Website: http://www.pandemicflu.gov/

/s/ Thomas E. Hamilton

cc: Survey and Certification Regional Office Management